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Wearable Patches and Implantable Loop Recorders: The Impact of Continuous Rhythm Monitoring on Atrial Fibrillation Burden and Clinical Outcomes

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Abstract

The diagnosis and management of atrial fibrillation are being fundamentally transformed by the advent of continuous rhythm monitoring technologies, namely wearable patches and implantable loop recorders. This evolution necessitates a comprehensive review of how these tools are reshaping our understanding of the atrial fibrillation disease spectrum and influencing clinical outcomes. A clear overview of the evidence is required to guide their effective and cost-efficient integration into clinical practice. This review first defines the core technologies of wearable patches and implantable loop recorders, comparing their distinct applications and limitations. It then explores the critical paradigm shift from detecting isolated atrial fibrillation episodes to quantifying atrial fibrillation burden, detailing its role as a key biomarker for stroke risk and disease progression. We examine the profound diagnostic impact of continuous monitoring in unmasking the cause of cryptogenic stroke, syncope, and palpitations, and its utility in screening high-risk populations. The discussion further analyzes how atrial fibrillation burden guides anticoagulation therapy beyond the CHA2DS2-VASc score and serves as a superior metric for assessing the efficacy of rhythm control therapies. Finally, the review considers the economic implications and healthcare system requirements for implementing these long-term monitoring strategies. Future efforts must focus on refining evidence-based, burden-driven thresholds for initiating anticoagulation and other interventions. Research and policy development should also prioritize optimizing patient selection and ensuring the cost-effective deployment of these monitoring tools across diverse healthcare settings. As technology advances, the integration of continuous rhythm data with other biomarkers promises to usher in an era of truly personalized, precision medicine for atrial fibrillation management.

Keywords: Anticoagulation, Atrial fibrillation, Atrial fibrillation burden, Cryptogenic stroke, Implantable loop recorder, Rhythm monitoring, Stroke prevention, Wearable patch

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Introduction

The advent of wearable patches and implantable loop recorders has significantly advanced the landscape of continuous rhythm monitoring, particularly in the context of atrial fibrillation detection and management [1-6]. These technologies have been pivotal in elucidating the relationship between atrial fibrillation burden and clinical outcomes, offering insights into how sustained rhythm monitoring can influence patient prognosis.

Wearable patches, such as medical-grade continuous electrocardiogram devices, have emerged as practical tools for long-term rhythm surveillance [7-9]. According to recent research, these patches enable near-continuous monitoring, which is crucial for capturing intermittent or asymptomatic episodes of atrial fibrillation that might otherwise go undetected with traditional intermittent testing methods [10]. The ability to monitor over extended periods enhances the detection rate of subclinical atrial fibrillation, which is

often associated with increased stroke risk and adverse cardiovascular events. The use of wearable patches has been particularly emphasized in older populations, where the prevalence of undiagnosed atrial fibrillation is higher. Comparative studies have demonstrated that wearable continuous electrocardiogram patches outperform standard care in identifying atrial fibrillation episodes, thereby facilitating earlier intervention [11].

In addition to wearables, implantable loop recorders have been recognized for their capacity to provide long-term, high-fidelity rhythm data [12-15]. These devices are especially valuable in patients with cryptogenic stroke or transient ischemic attack, where undetected atrial fibrillation may be the underlying cause. The literature indicates that implantable loop recorders can monitor patients over months to years, significantly increasing the likelihood of atrial fibrillation detection compared to external monitors like Holter devices [16]. The LOOP study exemplifies this, showing that continuous monitoring with implantable loop recorders not only detects more atrial fibrillation



episodes but also correlates atrial fibrillation burden with clinical outcomes, including stroke risk [17].

The relationship between atrial fibrillation burden—defined as the total duration or frequency of atrial fibrillation episodes—and clinical outcomes has garnered considerable attention. Continuous rhythm monitoring has revealed that higher atrial fibrillation burden is associated with increased risk of stroke and other adverse events. This has led to the recognition of atrial fibrillation burden as a potential outcome predictor and therapeutic target. For instance, the LOOP trial demonstrated that patients with higher atrial fibrillation burden detected via implantable loop recorders had a correspondingly elevated risk of stroke, underscoring the importance of quantifying atrial fibrillation burden in clinical practice [17]. Such findings suggest that continuous monitoring not only aids in diagnosis but also provides prognostic information that can guide therapeutic decisions.

The clinical utility of these monitoring modalities extends to screening and secondary prevention. Wearable electrocardiogram patches have been employed in screening programs, particularly among older populations, to identify previously undiagnosed atrial fibrillation. The ability to detect subclinical atrial fibrillation through prolonged monitoring has implications for initiating anticoagulation therapy and reducing stroke incidence [11]. Similarly, implantable loop recorders have been used in patients with cryptogenic strokes, where their high sensitivity for atrial fibrillation detection has led to changes in management strategies, including the initiation of anticoagulation [18].

Despite these advantages, the use of implantable loop recorders is subject to considerations regarding medical necessity and cost-effectiveness. Policy guidelines, such as those from Aetna, specify that implantable loop recorders are not universally necessary for all indications, including residual atrial fibrillation burden monitoring, highlighting the importance of appropriate patient selection [19]. Moreover, the choice between wearable patches and implantable loop recorders depends on factors such as monitoring duration, patient compliance, and clinical context. For example, external monitors like Holter devices are limited by shorter monitoring periods, whereas implantable loop recorders provide continuous data over extended durations, which is critical for capturing infrequent atrial fibrillation episodes [16].

The integration of mobile health technologies and wearable devices into clinical practice reflects a broader trend toward remote and patient-centered monitoring. These technologies facilitate early detection, ongoing surveillance, and potentially improved clinical outcomes. The current state of the art emphasizes the importance of using medical-grade monitors, which are approved by regulatory bodies and prescribed by clinicians, to ensure data accuracy and clinical relevance [20]. As technology advances, the potential for wearable patches and implantable loop recorders to influence atrial fibrillation management and reduce associated morbidity continues to grow.

In summary, continuous rhythm monitoring through wearable patches and implantable loop recorders has transformed the approach to atrial fibrillation detection and management. These modalities enable comprehensive assessment of atrial fibrillation burden, which is increasingly recognized as a key predictor of adverse clinical outcomes. While wearable patches offer a practical solution for long-term monitoring in various settings, implantable loop recorders provide unparalleled sensitivity for detecting subclinical atrial fibrillation over extended periods. The integration of these technologies into

clinical pathways holds promise for improving patient outcomes by facilitating timely diagnosis, risk stratification, and targeted therapy. Future research and policy development should focus on optimizing patient selection and ensuring the cost-effective deployment of these monitoring tools to maximize their clinical benefits.

Defining the Tools: A Primer on Wearable Patches and Implantable Loop Recorders

Wearable electrocardiogram patches represent a significant evolution in external ambulatory monitoring. These compact, adhesive devices are designed for continuous, unobtrusive rhythm recording over extended periods, typically ranging from 7 to 14 days, with some models capable of monitoring for up to 30 days [21-23]. Technology centers on a single-use, water-resistant patch that is applied directly to the patient's chest, housing electrodes and a small recorder that captures a continuous single-lead electrocardiogram. Key features of these patches include their ease of application, often performed by the patient or in a clinical setting without specialized training, and their ability to operate without patient interaction, thereby maximizing compliance and capturing data during normal daily activities, including sleep and exercise [24-26]. Upon completion of the monitoring period, the patient mails the device back to a central facility for data analysis, where proprietary algorithms and clinician over-read generate a comprehensive report detailing arrhythmia burden, heart rate trends, and patient-activated symptoms.

In contrast, implantable loop recorders are miniaturized subcutaneous devices that provide long-term cardiac monitoring for years, not days [27, 28]. Approximately the size of a USB flash drive, these devices are inserted just beneath the skin in the left pectoral region during a brief, minimally invasive procedure performed under local anesthesia. The insertion is typically accomplished through a small incision of less than one centimeter and does not require sutures. The core technology of an implantable loop recorder continuously records a single-lead electrocardiogram into a circular buffer, which is permanently saved upon manual patient activation using a handheld trigger or automatically when the device's algorithm detects a predefined arrhythmia, such as atrial fibrillation, pause, or bradycardia. A critical feature of modern implantable loop recorders is their seamless integration with remote monitoring systems; data are transmitted wirelessly and automatically from the patient's home to a secure website for clinician review, enabling near real-time surveillance over a battery life that commonly extends to three years or more [29-33].

The choice between a wearable patch and an implantable loop recorder is guided by the clinical question, required monitoring duration, and patient-specific factors [34]. Wearable patches are predominantly indicated for short- to medium-term monitoring, such as investigating unexplained syncope or palpitations, quantifying atrial fibrillation burden following an ablation procedure, or screening for subclinical atrial fibrillation in high-risk populations over a defined period [35, 36]. Their primary advantages include non-invasiveness, elimination of the need for a minor surgical procedure, and excellent short-term patient compliance as they require no daily maintenance. However, limitations include the finite wear duration, susceptibility to skin irritation or adhesion failure, and the potential to miss infrequent, paroxysmal arrhythmias that occur outside the monitoring window [37, 38].

Conversely, implantable loop recorders are indicated for long-term



monitoring when symptom-rhythm correlation is elusive or when detecting infrequent but clinically significant events [39]. This makes them the tool of choice for patients with cryptogenic stroke, recurrent unexplained syncope, or for the long-term management of arrhythmia syndromes. The paramount advantage of an implantable loop recorder is its longevity and continuous monitoring capability for up to several years, virtually guaranteeing the capture of intermittent arrhythmic events [40, 41]. Furthermore, their implantable nature eliminates issues related to patient adherence, skin reactions, and activity restrictions. The limitations, however, involve the minor procedural risks associated with insertion, such as infection, local reaction, or rare device migration, and a higher upfront device and implantation cost compared to a single-use wearable patch [42].

In summary, wearable patches offer a practical, high-compliance solution for focused diagnostic questions over weeks, while implantable loop recorders provide an unparalleled, long-term sentinel for capturing elusive arrhythmias over years. The integration of both tools into clinical practice allows for a stratified, patient-centric approach to continuous rhythm monitoring, ensuring the right technology is matched to the individual's diagnostic needs and risk profile.

From Episodes to Burden: Redefining the Atrial Fibrillation Disease Spectrum

The traditional paradigm of atrial fibrillation management has historically relied on the detection of discrete episodes, often prompted by symptomatic presentation. This approach categorized atrial fibrillation into broad, binary classifications such as paroxysmal (self-terminating) or persistent (sustained). However, this episodic model provided an incomplete and often misleading picture of the disease, as it was inherently limited by the snapshot-in-time nature of intermittent monitoring tools like Holters or occasional electrocardiograms [43-45]. The critical shift in our understanding, enabled by continuous rhythm monitoring, is the move from merely detecting if atrial fibrillation occurs to quantifying how much atrial fibrillation occurs—a metric known as atrial fibrillation burden. Atrial fibrillation burden is formally defined as the total amount of time a patient spends in atrial fibrillation during a specified monitoring period, expressed as a percentage. For example, a patient with an atrial fibrillation burden of 5% over 30 days has spent approximately 36 h in arrhythmia [46]. This quantitative measure moves beyond the simple presence or absence of an episode to provide a continuous, rather than categorical, assessment of disease activity. It captures the cumulative electrophysiological impact of atrial fibrillation on the atria, offering a more granular and dynamic view of an individual's arrhythmic state than the static classifications of the past.

Continuous monitoring technologies, particularly implantable loop recorders and long-term wearable patches, have been instrumental in revealing the true, often subclinical, pattern of atrial fibrillation. It is now evident that the clinical classifications of paroxysmal and persistent atrial fibrillation represent points on a fluid continuum, not distinct entities [47-50]. A patient clinically labeled as having paroxysmal atrial fibrillation may, through continuous monitoring, be found to have frequent, brief asymptomatic episodes that constitute a low burden, or conversely, may exhibit long, sustained runs of atrial fibrillation that go entirely unnoticed. This unmasking of the subclinical atrial fibrillation landscape has profound implications for diagnosis and management.

The patterns unveiled by continuous monitoring demonstrate that atrial fibrillation is a highly dynamic disease. An individual's

burden can fluctuate significantly over time, influenced by factors such as heart failure exacerbations, hypertension, sleep apnea, or post-operative states. This temporal variability means that a single 24 or 48 h Holter monitor provides a potentially unrepresentative sample, akin to judging a full-length film by a single frame [51, 52]. Long-term monitoring captures these fluctuations, providing a reliable 'average' of the disease's activity and its triggers over weeks, months, or years.

The clinical significance of atrial fibrillation burden extends far beyond mere quantification; it has emerged as a powerful, nuanced biomarker for both disease progression and thromboembolic risk [53-55]. Studies have consistently demonstrated a dose-response relationship between atrial fibrillation burden and the risk of ischemic stroke. The presence of any atrial fibrillation increases stroke risk, but the data increasingly suggest that a higher burden is associated with a correspondingly higher risk, independent of traditional risk scores like CHA₂DS₂-VASc [56-60]. This challenges the previous binary 'yes/no' approach to anticoagulation decision-making.

Furthermore, atrial fibrillation burden serves as a key indicator of the underlying atrial myopathy and the progressive electrical and structural remodeling that defines atrial fibrillation as a chronic disease [61, 62]. A high burden, even if asymptomatic, reflects a more advanced diseased substrate and is a strong predictor of future atrial fibrillation progression from paroxysmal to persistent forms. This makes burden a valuable prognostic tool, identifying patients who may benefit from more aggressive rhythm control therapy to halt or reverse this pathological progression [63].

The ability to measure burden also refines our approach to evaluating treatment efficacy, particularly after catheter ablation. The traditional success endpoint of 'freedom from any atrial fibrillation episode' is increasingly seen as impractical and potentially unrealistic [64, 65]. Instead, a clinically meaningful reduction in atrial fibrillation burden for instance, from 25% to 1% can be considered a significant therapeutic success, even if occasional brief episodes persist [66, 67]. This shift acknowledges the progressive nature of the disease and focuses on achieving meaningful patient-centered outcomes, such as improved quality of life and reduced stroke risk, rather than a rigid, absolute elimination of the arrhythmia.

The relationship between burden and symptoms is also notoriously poor. Many patients with a high atrial fibrillation burden experience no symptoms (so-called 'asymptomatic' or 'silent' atrial fibrillation), while others with a very low burden can be severely symptomatic [68, 69]. This dissociation underscores why symptom-driven monitoring is inadequate for comprehensive management. Quantifying burden objectively identifies the total arrhythmia exposure, ensuring that high-risk, asymptomatic patients are not overlooked while providing concrete data to correlate with symptoms in symptomatic patients [70, 71]. However, the integration of atrial fibrillation burden into clinical practice requires careful consideration. Universal consensus on specific burden thresholds that definitively trigger interventions, particularly anticoagulation, is still evolving. While any atrial fibrillation episode lasting more than a certain duration (e.g., 5 to 6 min) may confer increased risk, the exact burden level (e.g., 1% vs 5%) that should mandate a change in therapy is an area of active research and debate [72, 73]. This necessitates a patient-specific approach, where burden is interpreted in the context of the individual's overall stroke risk, symptom severity, and therapeutic goals.

In essence, the concept of atrial fibrillation burden, born from the capabilities of continuous monitoring, has fundamentally redefined the



atrial fibrillation disease spectrum. It has transformed our view from one of intermittent, symptomatic episodes to a model of a continuous, quantifiable disease process with variable clinical expression. This paradigm shift enables a more personalized and proactive management strategy. By focusing on burden, clinicians can better stratify stroke risk, more accurately assess the true severity of the atrial cardiomyopathy, and more meaningfully evaluate the success of therapeutic interventions [74-76]. This quantitative approach moves atrial fibrillation care from a reactive, episode-centric model to a proactive, burden-based strategy aimed at altering the long-term course of the disease and improving hard clinical outcomes.

The ongoing refinement of burden thresholds for clinical decision-making represents the next frontier in personalized atrial fibrillation care. As evidence from large outcomes trials continues to accumulate, atrial fibrillation burden is poised to become a central pillar in the risk stratification and treatment algorithms for millions of patients worldwide, solidifying its role as a critical biomarker in modern cardiology.

The Diagnostic Impact: Unmasking the Unknown

The advent of continuous rhythm monitoring has fundamentally altered the diagnostic landscape for a range of clinical presentations, moving from a paradigm of inference to 1 of evidence. In conditions like cryptogenic stroke, palpitations, and syncope, where the causative mechanism is often elusive and paroxysmal, traditional monitoring strategies have historically yielded disappointingly low diagnostic returns (Table 1). The limited duration of conventional Holter monitoring (24 to 48 h) means it captures only a brief window of a patient's cardiac rhythm, often missing infrequent but clinically critical events [77, 78]. Wearable patches and implantable loop recorders have dramatically improved this diagnostic yield by providing sustained surveillance that aligns with the sporadic nature of these conditions.

Nowhere is this diagnostic impact more profound than in the evaluation of cryptogenic stroke an ischemic stroke with no identifiable cause after a standard workup. Undetected atrial fibrillation is a leading suspected etiology in these cases, and initiating anticoagulation is a key preventive strategy. Continuous monitoring has been pivotal in uncovering this 'unknown.' Major trials have demonstrated that implantable loop recorders increase the detection rate of atrial fibrillation in cryptogenic stroke patients by several-fold compared to conventional follow-up [79-81]. For instance, while routine care might detect atrial fibrillation in 1 to 3% of patients over 6 months, implantable loop recorders can identify atrial fibrillation in up to 30% of patients over the same period, directly influencing management by providing a rationale for anticoagulation to prevent recurrent strokes [82, 83].

Similarly, in the workup of unexplained palpitations and syncope,

long-term monitors provide a definitive symptom-rhythm correlation that was previously often unattainable. Patients with sporadic symptoms are frequently discharged from the emergency department with a nondiagnostic 12-lead electrocardiogram and a 24 h Holter that captures nothing of significance [84]. A wearable patch worn for 14 days, or an implantable loop recorder for months to years, vastly increases the probability of capturing an electrocardiogram during a symptomatic event [85]. This allows clinicians to distinguish between benign rhythms like sinus tachycardia and potentially dangerous arrhythmias like supraventricular tachycardia, pause-dependent bradycardia, or atrial fibrillation, thereby guiding targeted and effective therapy. Beyond investigating specific symptoms, continuous monitoring plays a crucial role in screening high-risk populations for subclinical atrial fibrillation. In older adults with comorbidities such as hypertension, diabetes, or heart failure, the prevalence of undiagnosed atrial fibrillation is substantial [86]. Proactive screening with wearable electrocardiogram patches in these cohorts has been shown to identify a significant number of cases that would have otherwise remained undetected until a potential stroke occurred. This is particularly relevant post-cardiac surgery, where the inflammatory and hemodynamic stress can trigger new-onset atrial fibrillation in up to a third of patients; extended monitoring with a patch during the recovery period is now a standard of care at many centers to ensure timely diagnosis and management.

The utility in the elderly population cannot be overstated. Age is the single most significant risk factor for atrial fibrillation, and arrhythmia is often entirely asymptomatic in this demographic. Community-based screening studies utilizing short-term intermittent electrocardiogram handheld devices or two-week patches have consistently found new atrial fibrillation in a meaningful percentage of asymptomatic, high-risk individuals over the age of 65 [87]. This proactive unmasking of the 'unknown' atrial fibrillation provides a critical opportunity for stroke prevention through the initiation of oral anticoagulation, fundamentally shifting the approach from secondary to primary prevention. However, this enhanced diagnostic sensitivity comes with a significant challenge: the detection of clinically irrelevant arrhythmias and the potential for false positives. The very algorithms designed to detect atrial fibrillation and other arrhythmias over vast amounts of data are not perfect [88, 89]. They can misinterpret other forms of supraventricular tachycardia, such as atrial tachycardia or frequent atrial ectopy, as atrial fibrillation. This can lead to 'over-diagnosis' and unnecessary patient anxiety, investigations, and even treatments if the automated findings are not meticulously verified by a trained clinician.

The issue of 'subclinical atrial fibrillation' itself presents a diagnostic and management gray zone. Continuous monitoring frequently detects very short-duration atrial fibrillation episodes (e.g., lasting only a few minutes). While it is now clear that any atrial fibrillation can increase stroke risk, the clinical significance and optimal management of

Table 1: Comparing diagnostic utility of continuous monitors across clinical scenarios.

Clinical scenario	Conventional monitoring yield	Impact of continuous monitoring	Key clinical action
Cryptogenic stroke	Low (1 to 3% over 6 months)	High (up to 30% over 6 to 12 months with implantable loop recorders); identifies atrial fibrillation as underlying etiology.	Initiation of oral anticoagulation for secondary stroke prevention.
Unexplained syncope	Low (short duration capture often misses infrequent events)	High (enables direct symptom-rhythm correlation); identifies bradyarrhythmias, pauses, or tachyarrhythmias.	Pacemaker implantation, medication adjustment, or ablation therapy.
Unexplained palpitations	Variable (dependent on symptom frequency)	High (increases probability of capturing electrocardiogram during symptoms); distinguishes benign from significant arrhythmias.	Patient reassurance, medication initiation, or referral for ablation.
Screening in high-risk populations (e.g., elderly, post-cardiac surgery)	Impractical with short-term monitors	Identifies previously undiagnosed, often asymptomatic, subclinical atrial fibrillation.	Initiation of anticoagulation for primary stroke prevention (shared decision-making).



very low-burden, brief subclinical atrial fibrillation are still areas of active research [90, 91]. Distinguishing between a short run of atrial fibrillation that warrants anticoagulation and a brief episode of atrial tachycardia that may not, is a critical interpretive task that falls to the physician reviewing the data. This underscores the indispensable role of clinician over-read. The raw output from a wearable patch or implantable loop recorder is a starting point, not an endpoint. The data must be interpreted by a cardiologist or cardiac electrophysiologist who can differentiate true atrial fibrillation from artifact or other supraventricular arrhythmias, contextualize the finding within the patient's overall clinical picture, and determine the appropriate clinical response [92, 93]. Technology is a powerful tool for generating data, but clinical judgment remains paramount for translating that data into wise patient care.

To mitigate the risk of false positives, modern devices and their associated software platforms are continually refining their algorithms. Machine learning techniques are being employed to improve the specificity of atrial fibrillation detection by better distinguishing it from other arrhythmia based on complex pattern recognition. Furthermore, the requirement for a certain episode duration (e.g., >5 to 6 min) to be considered clinically significant in some device programming helps filter out the very shortest, and potentially least consequential, episodes.

In summary, the diagnostic impact of continuous rhythm monitoring is transformative. It has unmasked a hidden world of subclinical and paroxysmal arrhythmias, providing answers for patients with cryptogenic stroke, syncope, and palpitations, and enabling proactive screening in high-risk populations. This has directly translated into improved clinical outcomes, particularly through stroke prevention. Yet, this powerful diagnostic capability demands a sophisticated and discerning approach from clinicians. The goal is not to find every possible arrhythmia, but to find the clinically relevant arrhythmias—those that impact prognosis, guide therapy, and ultimately improve patient care. Navigating this new landscape of abundant data, and distinguishing signals from noise, is the essential challenge and opportunity presented by these revolutionary technologies.

Guiding Anticoagulation Therapy: Beyond the CHA₂DS₂-VASc Score

The foundational principle for stroke prevention in atrial fibrillation has long been the CHA₂DS₂-VASc score, a clinical risk-stratification tool that effectively identifies patients who benefit from oral anticoagulation [94]. However, this paradigm was established in an era dominated by clinical atrial fibrillation—episodes that were either sustained or symptomatic enough to be captured on a routine electrocardiogram. The widespread adoption of continuous cardiac monitoring has uncovered a vast reservoir of subclinical, device-detected atrial fibrillation, challenged the simplicity of this approach and forced a critical re-evaluation of how and when to initiate anticoagulation [95].

Pivotal studies have been instrumental in elucidating the stroke risk associated with these previously undetectable arrhythmias. The asymptomatic atrial fibrillation and stroke evaluation in pacemaker patients study by Hohnloser et al. [96] was among the first to sound the alarm, demonstrating that in patients with cardiac pacemakers, subclinical atrial tachyarrhythmias (episodes >6 min) were associated with a significantly increased risk of ischemic stroke or systemic embolism. This established a direct link between brief, asymptomatic

atrial fibrillation and thromboembolic events, even in patients without a prior clinical atrial fibrillation diagnosis.

The cryptogenic stroke and underlying atrial fibrillation trial study by Sinha et al. [97] provided even more compelling evidence in a high-stakes population. In patients with cryptogenic stroke, the use of an implantable loop recorder dramatically increased the detection of atrial fibrillation compared to conventional monitoring. More importantly, the vast majority of these atrial fibrillation episodes were asymptomatic and of relatively short duration, yet their identification provided a clear etiology for the stroke. This evidence solidified the role of long-term monitoring in secondary stroke prevention and suggested that anticoagulating these patients upon atrial fibrillation detection could prevent recurrences.

Further refining our understanding, studies like predicting determinants of atrial fibrillation by Diederichsen et al. [98] have investigated the use of implantable loop recorders to predict the future onset of clinical atrial fibrillation in high-risk patients. This proactive identification of at-risk individuals underscores the continuum of the disease and positions device-detected atrial fibrillation as a critical, intervening variable between clinical risk factors (captured by CHA₂DS₂-VASc) and the overt outcome of stroke. The collective evidence from these and other trials confirms that device-detected atrial fibrillation is not merely an electrical curiosity but a bona fide biomarker of elevated stroke risk. This new evidence, however, has created a profound clinical dilemma: while a 30 min episode of asymptomatic atrial fibrillation detected by an implantable loop recorder undoubtedly increases stroke risk, does it confer the same level of risk as permanent, clinical atrial fibrillation? And consequently, does it warrant the same commitment to lifelong oral anticoagulation with its associated bleeding risks? The central question is one of thresholds: What combination of atrial fibrillation burden (duration) and patient-specific CHA₂DS₂-VASc score should trigger a conversation about anticoagulation.

Current guideline recommendations reflect a cautious, evolving stance on this complex issue. Major societal guidelines from organizations like the American Heart Association and European Society of cardiology now acknowledge the stroke risk associated with device-detected atrial fibrillation [99, 100]. They generally recommend that for patients with a CHA₂DS₂-VASc score of 2 or higher in men (3 or higher in women), the detection of an atrial fibrillation episode lasting longer than 24 h should lead to oral anticoagulation initiation. For episodes shorter than 24 h, the decision is less clear-cut, and guidelines encourage a shared decision-making process that weighs the burden of atrial fibrillation, the patient's stroke risk profile, and their bleeding risk. The 24 h threshold is somewhat arbitrary, derived largely from older studies and the practical limitations of past monitoring technologies. The contemporary view, informed by continuous monitoring data, suggests that stroke risk increases in a graded fashion with atrial fibrillation burden, with no clear, safe 'zero-risk' threshold. This has fueled the concept of a potential burden-based anticoagulation strategy. The hypothesis is that there may be a burden level perhaps 5 to 6 min to initiate risk, and a higher level like 1 to 5% to strongly mandate therapy where the net clinical benefit of oral anticoagulation tips favorably [101].

This concept was directly tested in the non-vitamin K antagonist oral anticoagulants in patients with heart rate episodes - atrial fibrillation network 6 and apixaban for the reduction of thrombo-embolism in patients with subclinical atrial fibrillation trials, which randomized patients with device-detected atrial fibrillation and additional stroke



risk factors to receive anticoagulation or placebo/aspirin [102]. Both studies demonstrated that anticoagulation with a non-vitamin K antagonist oral anticoagulant reduced the risk of stroke in this population. However, this benefit came with a concomitant increase in the risk of major bleeding. Crucially, the absolute risk reduction for strokes was modest, underscoring that the risk profile for subclinical, device-detected atrial fibrillation is different from that of clinical atrial fibrillation [103]. The practical takeaway from these landmark trials is that the decision to anticoagulate for device-detected atrial fibrillation must be highly personalized. For a patient with a high CHA₂DS₂-VASc score and a device-detected atrial fibrillation burden of several hours, the evidence now strongly supports oral anticoagulation initiation. For a patient with a lower score and only brief, rare episodes, the risk of bleeding may outweigh the potential benefit. The duration of the longest single episode, the total atrial fibrillation burden, and the patient's values and preferences all must be integrated into the final decision [104].

Looking forward, the future of anticoagulation in atrial fibrillation is likely to move beyond a binary application of the CHA₂DS₂-VASc score towards a dynamic, multi-parametric model. This model would integrate the continuous variable of atrial fibrillation burden from monitoring devices with clinical risk factors, biomarkers of atrial cardiomyopathy (e.g., cardiac magnetic resonance imaging findings, B-type natriuretic peptide levels), and potentially even genetic data to generate a more precise, individualized estimate of stroke risk.

In summary, continuous rhythm monitoring has successfully pushed anticoagulation strategy beyond the confines of the CHA₂DS₂-VASc score. It has proven that subclinical atrial fibrillation is a significant contributor to stroke and provided a therapeutic target for a previously untreatable cause, as in cryptogenic stroke. The work now lies in refining our response. The challenge for clinicians is no longer just if to anticoagulate, but when. By thoughtfully applying the latest evidence and guidelines, and engaging in shared decision-making, clinicians can harness the power of continuous monitoring to deliver more precise, effective, and personalized stroke prevention, ushering in a new era where therapy is guided not just by clinical risk factors, but by the direct, quantifiable electrical activity of the heart.

Assessing Treatment Efficacy: A New Metric for Success

The primary goal of rhythm control therapy in atrial fibrillation—whether with antiarrhythmic drugs or catheter ablation—has traditionally been the complete absence of any recurrent atrial fibrillation episode. This binary ‘success or failure’ endpoint, often assessed through sporadic, symptom-driven monitoring, is increasingly recognized as both unrealistic and clinically incomplete (Table 2).

The advent of continuous rhythm monitoring has fundamentally transformed this paradigm, introducing atrial fibrillation burden as a superior, quantitative, and patient-centered metric for evaluating treatment efficacy.

Continuous monitoring provides an objective and comprehensive dataset against which the impact of any rhythm control intervention can be measured. Prior to a procedure like catheter ablation or the initiation of a new antiarrhythmic drug, a baseline atrial fibrillation burden is established using a wearable patch or implantable loop recorder [105]. This pre-treatment burden serves as a crucial benchmark. Following the intervention, the same patient is monitored continuously over the long term, allowing for a direct, before-and-after comparison of the total time spent in atrial fibrillation, rather than just the presence or absence of discrete episodes. This quantitative approach reveals a spectrum of outcomes that the old binary model obscured. For instance, a therapy may not achieve complete freedom from atrial fibrillation, but it might reduce a patient's burden from 50% to 2% [106]. From a patient's perspective, this represents a dramatic clinical improvement, potentially translating to the resolution of debilitating symptoms and an improved quality of life. Conversely, a patient deemed a ‘success’ by the old standard because they lack clinical episodes might still have a significant, asymptomatic burden that confers ongoing stroke risk and indicates an unstable atrial substrate.

Defining what constitutes a ‘successful’ reduction in atrial fibrillation burden is therefore nuanced and must be individualized. Clinically, success is often defined as a ≥75% relative reduction in atrial fibrillation burden from baseline or an absolute burden reduced to below a certain threshold, such as 1% or 0.5% [107]. This acknowledges that the therapeutic goal is not necessarily perfection, but rather a meaningful attenuation of the disease's impact. For a patient with a pre-ablation burden of 40%, achieving a post-procedure burden of 1% is a 97.5% reduction—a unequivocal success, even if brief, asymptomatic episodes persist [108]. The data from continuous monitoring allows for highly personalized therapy titration. In the management of antiarrhythmic drugs, for example, if a patient on one drug achieves only a modest burden reduction, the clinician has objective evidence to consider switching to a different, potentially more effective agent. The timing and dosage of medications can be adjusted based on the precise patterns of atrial fibrillation recurrence captured by the monitor, moving away from a trial-and-error approach to a data-driven optimization process [109].

Furthermore, this strategy enables the early identification of treatment failure. With traditional follow-up, a patient might only present months or years after an ablation with a recurrence of sustained, symptomatic atrial fibrillation. With continuous

Table 2: The evolution of success metrics in rhythm control therapy.

Aspect	Traditional episode-based paradigm	Modern burden-based paradigm	Clinical implications of the shift
Primary endpoint	Binary: Freedom from any atrial fibrillation episode	Continuous: Percentage reduction in atrial fibrillation burden (e.g., ≥75% reduction or absolute burden <1%).	Acknowledge that reducing disease impact is a success, even without complete elimination.
Definition of success	Rigid and often unrealistic; classifies patients as ‘success’ or ‘failure’	Nuanced and patient-centered; defines success as a clinically meaningful improvement.	Prevents misclassification of asymptomatic patients and better correlates with quality of life.
Monitoring methodology	Sporadic (e.g., symptom-based, periodic Holter); prone to missing asymptomatic recurrences	Continuous (e.g., implantable loop recorder, repeated patches); provides a complete, objective dataset.	Enables accurate comparison between before-and-after and captures asymptomatic burden.
Therapy titration	Trial-and-error; based on symptom recurrence	Data-driven; drug choice/dosage or need for repeat ablation is guided by burden trends.	Allows for personalized, proactive management adjustments before clinical failure occurs.
Identification of failure	Late; often only upon return of sustained, symptomatic atrial fibrillation	Early; detects gradual, asymptomatic increase in burden during remote monitoring.	Enables timely intervention (e.g., medication change, repeat ablation) to regain rhythm control.
Application in clinical trials	Uses ‘freedom from atrial fibrillation’ as a primary endpoint	Increasingly uses ‘percent reduction in atrial fibrillation burden’ as a primary endpoint.	Generates more realistic and clinically applicable evidence for new therapies and technologies.



monitoring, a gradual, asymptomatic creep in atrial fibrillation burden can be detected remotely and early, sometimes even before the patient becomes symptomatic [110]. This early warning allows the clinician to intervene proactively—by adjusting medication, scheduling a follow-up ablation, or reinforcing risk factor management—rather than waiting for a catastrophic clinical failure. This is particularly critical in the post-ablation ‘blanking period,’ the first 3 months after the procedure during which early recurrences are common and may not predict long-term failure. Continuous monitoring provides an unparalleled view into this volatile period, distinguishing between transient, inflammatory-induced arrhythmias that will resolve and a persistent, high burden that signals a true failure of the lesion sets, guiding early re-intervention strategies [111].

The shift to burden-based assessment also refines clinical trial endpoints. Modern studies of ablation technologies and antiarrhythmic drugs are increasingly using percentage reduction in atrial fibrillation burden as a primary efficacy measure, recognizing it as a more sensitive and clinically relevant indicator of a treatment’s effect than the rigid endpoint of freedom from any episode. This evolution in trial design is generating more realistic and applicable evidence for practicing clinicians.

In summary, the integration of continuous monitoring into the management of rhythm control therapies has redefined success from a binary state to a continuous spectrum of improvement. Atrial fibrillation burden serves as an objective, powerful, and individualized yardstick, capturing the true clinical benefit of an intervention in a way that episodic monitoring cannot. By providing a clear, data-driven narrative of a therapy’s performance, continuous monitoring empowers clinicians to personalize treatment plans, titrate therapies with precision, and identify failures early. This not only optimizes patient outcomes and quality of life but also represents a more sophisticated and rational approach to the long-term management of a chronic, progressive condition like atrial fibrillation.

Clinical Trials

Wearable patches and implantable loop recorders are pivotal in the continuous rhythm monitoring of atrial fibrillation, offering distinct advantages and challenges in clinical studies. ILRs are often considered the gold standard due to their high sensitivity and long-term monitoring capabilities, while wearable patches provide a non-invasive alternative with promising accuracy. Both technologies are instrumental in detecting atrial fibrillation, guiding management strategies, and improving patient outcomes.

The post-embolic rhythm detection with implantable vs external monitoring (PER DIEM) trial investigated the effectiveness of implantable loop recorders compared to external loop recorders for detecting atrial fibrillation in patients who had experienced ischemic stroke [112]. The study’s results highlighted significant differences in atrial fibrillation detection rates between the two monitoring strategies over a 12-month period. The study included 300 randomized patients, with a median age of 64.1 years (interquartile range (IQR) 56.1 to 73.7 years). Women constituted 40.3% of the participants. A significant portion, 66.3%, had a stroke of undetermined etiology, and the median CHA₂DS₂-VASC score was 4 (IQR 3 to 5). A high percentage of participants completed cardiac monitoring for 24 h or longer (91.0%) and both the assigned monitoring and 12-month follow-up visit (86.3%). The baseline characteristics of the two device groups were similar. The primary outcome, defined as the development of definite atrial fibrillation or highly probable atrial fibrillation lasting

at least 2 min within 12 months of randomization, was observed in a significantly higher proportion of patients in the implantable loop recorders group compared to the external loop recorders group. Specifically, 15.3% (23/150) of patients in the implantable loop recorder group had atrial fibrillation detected, vs 4.7% (7/150) in the external loop recorders group. This translated into a between-group difference of 10.7% (95% confidence interval (CI) 4.0% to 17.3%) and a risk ratio of 3.29 (95% CI 1.45 to 7.42; $p = 0.003$). The absolute increase suggests that approximately one additional patient was diagnosed with atrial fibrillation for every 10 patients monitored with an implantable loop recorder instead of an external loop recorder. While atrial fibrillation detection rates were not significantly different during the first 30 days of monitoring, new atrial fibrillation diagnoses continued to accumulate in the implantable loop recorder group beyond 30 days, unlike the external loop recorders group. From 30 days to 12 months, the implantable loop recorders group had significantly more atrial fibrillation diagnoses (10.7%) compared to the external loop recorders group (1.3%). A per-protocol analysis, including 259 patients, also showed a significantly higher rate of new atrial fibrillation with the implantable loop recorder (18.3%) compared to the external loop recorders (5.3%), with a risk ratio of 3.46 (95% CI 1.54 to 7.80; $p = 0.002$). Out of the eight prespecified secondary outcomes, six did not show statistically significant differences between the two groups. Five patients (3.3%) in the implantable loop recorder group experienced recurrent ischemic stroke, compared to eight patients (5.3%) in the external loop recorders group. The between-group difference was -2.0% (95% CI -6.6% to 2.6%). One patient (0.7%) in each group had intracerebral hemorrhage, resulting in a 0% between-group difference. Three patients (2.0%) in each group died, showing a 0% between-group difference. One patient (0.7%) in the implantable loop recorder group had a device-related serious adverse event, while none in the external loop recorders group did. This event involved skin erosion over the device, requiring removal. The combined end point of death along with atrial fibrillation detection within 12 months occurred in 17.3% of the implantable loop recorder group versus 6.7% of the external loop recorders group, with a significant adjusted hazard ratio (HR) of 2.64 (95% CI 1.27 to 5.49; $p = 0.009$). Older age (Relative risk (RR) 1.03 per year; $p = 0.002$) and the device group (RR 3.28; $p = 0.004$) were the only significant features associated with atrial fibrillation detection. There were significant differences in patient-reported satisfaction with the monitoring strategy in 12 months ($p < 0.001$), with 42.9% of implantable loop recorder patients reporting high satisfaction. In summary, the PER DIEM trial demonstrated that implantable loop recorders significantly increase the detection of atrial fibrillation over 12 months in ischemic stroke patients without prior atrial fibrillation, compared to prolonged external loop monitoring for 30 days. While implantable loop recorders were superior for atrial fibrillation detection, most secondary clinical outcomes did not show significant differences between the two monitoring strategies.

A post-hoc analysis of the LOOP study by Spona et al. [113] identified a distinct circadian pattern in the occurrence of atrial fibrillation episodes among high-risk individuals without known arrhythmia by continuous electrocardiogram monitoring using implantable loop recorder. A total of 41,713 atrial fibrillation episodes were identified across 430 participants. The median duration of these atrial fibrillation episodes was 18 min, with an IQR of 8 to 64 min. The median number of atrial fibrillation episodes per participant was 21, ranging from 4 to 82. The median atrial fibrillation burden, calculated as the percentage of time from debut to end of monitoring, was 0.17%, with a range of 0.04% to 0.83%. Sunday was the most frequent day



for atrial fibrillation onset, accounting for 15.3% of episodes. Friday was the least frequent day for atrial fibrillation onset, with 13.6% of episodes. Atrial fibrillation occurred slightly more often during spring (26%) compared to other seasons. The median time of atrial fibrillation onset was 09:57:15 AM, with an IQR from 05:15:30 AM to 03:33:00 PM. The most frequent time of onset was 09:00 AM (when rounded to the nearest hour), which was twice as likely as onset at 09:00 PM. A significant proportion, 22%, of all atrial fibrillation episodes occurred between 08:00 and 11:00 AM. This indicates that atrial fibrillation onset predominantly occurred in the morning. 25,329 (61%) of episodes occurred between midnight and noon. Nocturnal episodes, defined as those with onset between 10:00 PM and 07:00 AM, were observed in 368 (86%) of atrial fibrillation participants. These nocturnal episodes constituted a median of 40% of all episodes and 37% (with an IQR of 14% to 63%) of each participant's episode. Nocturnal episodes had a median duration of 28 min (10 to 104 min), which was longer compared to daytime episodes, which had a median duration of 14 min (8 to 44 min). The averaged heart rate during atrial fibrillation was 81 beats per minute (BPM), with an IQR of 71 to 96 BPM. Tachycardic episodes: 330 (77%) participants experienced atrial fibrillation episodes with heart rates equal to or above 100 BPM. These faster episodes lasted longer, with a median duration of 50 min (15 to 201 min), compared to slower episodes (below 100 BPM) which had a median duration of 30 min (21 to 85 min). In summary, the study revealed a clear circadian rhythm for screening-detected atrial fibrillation, with a morning peak in onset and nocturnal episodes being common, longer-lasting, and accounting for a substantial portion of all atrial fibrillation events. These findings suggest potential implications for the timing of atrial fibrillation screening strategies.

A study by Frausing et al. [114] (NCT02726698) reported to examine brady- and tachyarrhythmias using continuous rhythm monitoring in patients with paroxysmal self-terminating atrial fibrillation (Figure 1). Nearly half (45%) of the patients in the study experienced either bradyarrhythmia or tachyarrhythmia episodes during continuous rhythm monitoring, which spanned over 1272 patient-years. Specifically, 106 patients (27%) experienced rapid atrial fibrillation or atrial flutter, while 47 patients (12%) had pauses of ≥ 5 seconds or bradycardias of ≤ 30 BPM. A smaller group of 22 patients

(6%) experienced both types of episodes. A total of 69 patients (18%) experienced one or more bradyarrhythmia episodes. Of the 428 bradyarrhythmia episodes observed, 318 (74%) were pauses lasting ≥ 5 s. These episodes were generally short-lasting, with a median duration of 0.5 min. Timing: 47% of bradyarrhythmia episodes occurred during the night (between 9 PM and 6 AM). Exclusively nocturnal episodes were observed in 13 (19%) of patients with bradyarrhythmia. Associated Factors: Bradyarrhythmias were often observed during v or at the termination of atrial fibrillation or atrial flutter. Patients experiencing bradyarrhythmias were generally older, had more comorbidities, and were more frequently on rate control therapy compared to those with tachyarrhythmias. Multivariable analysis identified several factors significantly associated with higher rates of bradyarrhythmia episodes: age >70 years (HR 2.3, 95% CI 1.4 to 3.9), a longer PR interval (HR 1.9, 95% CI 1.1 to 3.1), and a CHA₂DS₂-VASc score ≥ 2 (HR 2.2, 95% CI 1.1 to 4.5). Conversely, treatment with verapamil or diltiazem was associated with lower bradyarrhythmia rates (HR 0.4, 95% CI 0.2 to 1.0). Patients with bradyarrhythmias showed a significantly larger left atrial volume index and lower left atrial reservoir and contractile function compared to patients without episodes. Tachyarrhythmia episodes occurred in 128 patients (33%), with 106 patients experiencing only tachyarrhythmia. The median number of episodes per person was 4 (IQR 1 to 11). Most were rapid atrial fibrillation with a median rate of 207 BPM (IQR 194 to 222), and 95% occurred during the daytime. Only age ≥ 70 years was associated with a significantly lower tachyarrhythmia risk (HR 0.4, 95% CI 0.2 to 0.7). No sustained ventricular tachycardias were observed in the study. Patients who experienced both brady- and tachyarrhythmias (n = 22) had higher episode burdens. These patients generally mirrored those with bradyarrhythmia, being older and having more comorbidities than those with tachyarrhythmia. Progression to persistent or permanent atrial fibrillation was observed in 54 (14%) of patients. More patients with brady- or tachyarrhythmia episodes experienced progression (21%) compared to those without episodes (9%). Syncope and heart failure hospitalizations were rare, with four hospitalizations for heart failure and three for syncope, none of which were directly related to an implantable loop recorder detected episode. The most common causes for hospitalization were atrial fibrillation related symptoms and planned cardioversion.

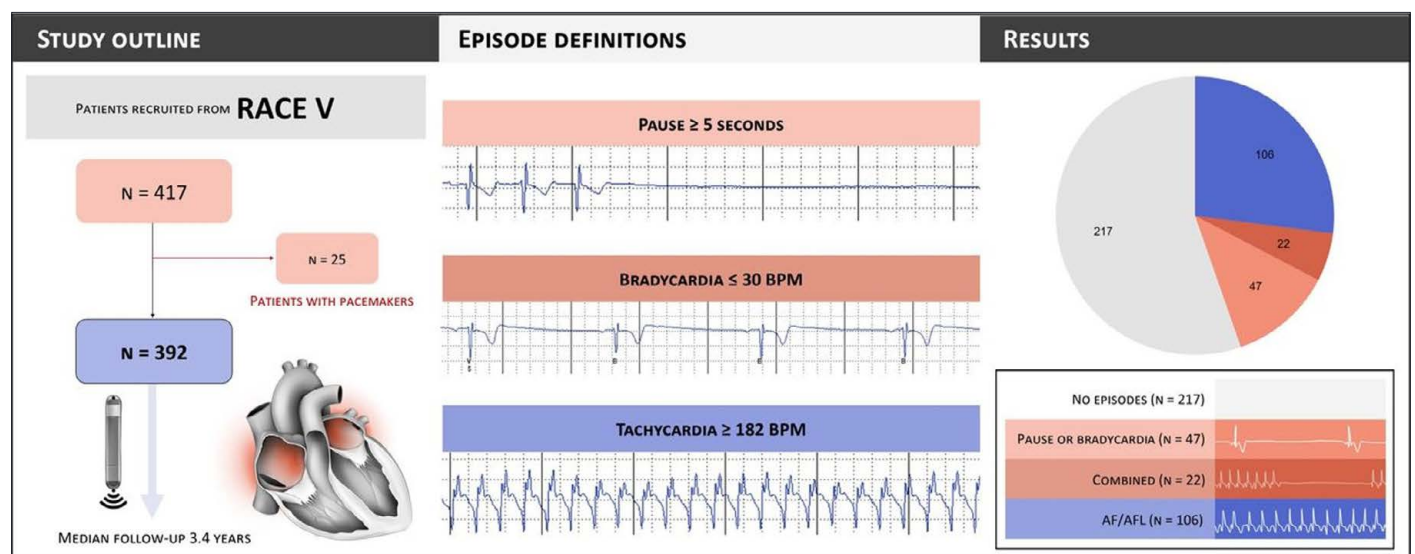


Figure 1: Summary of the study's design and key results, referencing conditions like atrial fibrillation and atrial flutter, as well as heart rate. The study is part of the RACE V project, which investigates how blood clotting, electrical changes in the heart, and vascular health contribute to atrial fibrillation [114].



The thorough evaluation by online rhythm evaluation, extended Holter monitoring and implantable cardiac monitor of patients with cryptogenic stroke to detect atrial fibrillation study by Bettin et al. [115] (NCT02641678) investigated the use of implantable loop recorders in patients with cryptogenic stroke to detect occult atrial fibrillation and other incidental electrocardiographic findings. The study also evaluated the optimal duration of monitoring and the reasons for implantable loop recorder explantation. The study was a prospective, monocentric trial involving 173 patients with cryptogenic stroke who received an implantable loop recorder between November 2010 and December 2014. All patients underwent standard protocols for stroke cause detection before implantable loop recorders implantation. The mean follow-up period for patients was 24.8 ± 11.5 months. Atrial tachyarrhythmias were detected in 33 patients (19.1%). The diagnosis of atrial fibrillation was made after a mean of 10.7 ± 11.4 months. The time to first atrial fibrillation detection ranged widely, from 0.2 to 39.8 months. Specifically, atrial fibrillation was detected in 17.5% of patients during the first 1.5 years of monitoring. Beyond atrial fibrillation, 15 patients (8.7%) had other incidental findings stored in the implantable loop recorders memory. Short episodes of sinus arrest at night, which did not necessitate a permanent pacemaker, were observed in 8 patients (4.6%). Five patients (2.9%) required DDD-pacemaker implantation due to sinus arrest or symptomatic bradyarrhythmias, occurring after a median monitoring period of 23.1 ± 7.4 months. Other findings included atrial flutter and an AV-nodal re-entry tachycardia, each in one patient, both of whom underwent successful catheter ablation. As of the study's reporting, implantable loop recorders had been explanted in 111 patients. A significant number, 71 implantable loop recorders, were explanted before the battery reached its end-of-service status. The primary reason for implantable loop recorder explantation was patient preference (51%). Other reasons included battery depletion (24%) and diagnosis of atrial fibrillation (15%). Patient acceptance of continued electrocardiogram monitoring until battery depletion was poor, with 64% of the 111 explanted implantable loop recorders removed

before battery end-of-life. The study highlights a significant number of clinically relevant electrocardiogram findings during extended monitoring. Given these findings, the authors recommend extending implantable loop recorder monitoring until the end of battery life.

The mhealth screening to prevent strokes (mSTOPS) trial study by Steinhubl et al. [116] (NCT02506244) investigated the effectiveness of a home-based wearable continuous electrocardiogram monitoring patch in detecting undiagnosed atrial fibrillation and its associated clinical consequences (Figure 2). The study revealed several significant outcomes regarding atrial fibrillation diagnosis rates, initiation of anticoagulants, and healthcare resource utilization. Individuals randomized to immediate monitoring with a self-applied wearable electrocardiogram patch showed a significantly higher rate of new atrial fibrillation diagnosis after 4 months compared to those in the delayed monitoring group. Specifically, 3.9% (53/1366) of the immediate group were diagnosed with new atrial fibrillation, versus 0.9% (12/1293) in the delayed group, representing an absolute difference of 3.0%. This difference was also observed in the per-protocol analysis, with 5.1% (46/906) in the immediate group versus 0.6% (5/832) in the delayed group, an absolute difference of 4.5%. Over a 1-year follow-up period, the actively monitored group had a higher incidence of newly diagnosed atrial fibrillation. There were 109 monitored individuals (6.7 per 100 person-years) compared to 81 unmonitored individuals (2.6 per 100 person-years), showing a difference of 4.1. In the actively monitored cohort, 65 individuals were initially found to have atrial fibrillation via the electrocardiogram patch, with 43 detected on the first patch and 22 on the second. Additionally, 44 individuals received a clinical diagnosis of atrial fibrillation either before or after monitoring was completed without atrial fibrillation findings during monitoring. Active monitoring was linked to a higher rate of anticoagulant initiation (5.7 vs 3.7 per 100 person-years; difference, 2.0). This was also true specifically for atrial fibrillation related anticoagulant initiation (2.4 vs 1.3 per 100 person-years; difference, 1.1). Monitored

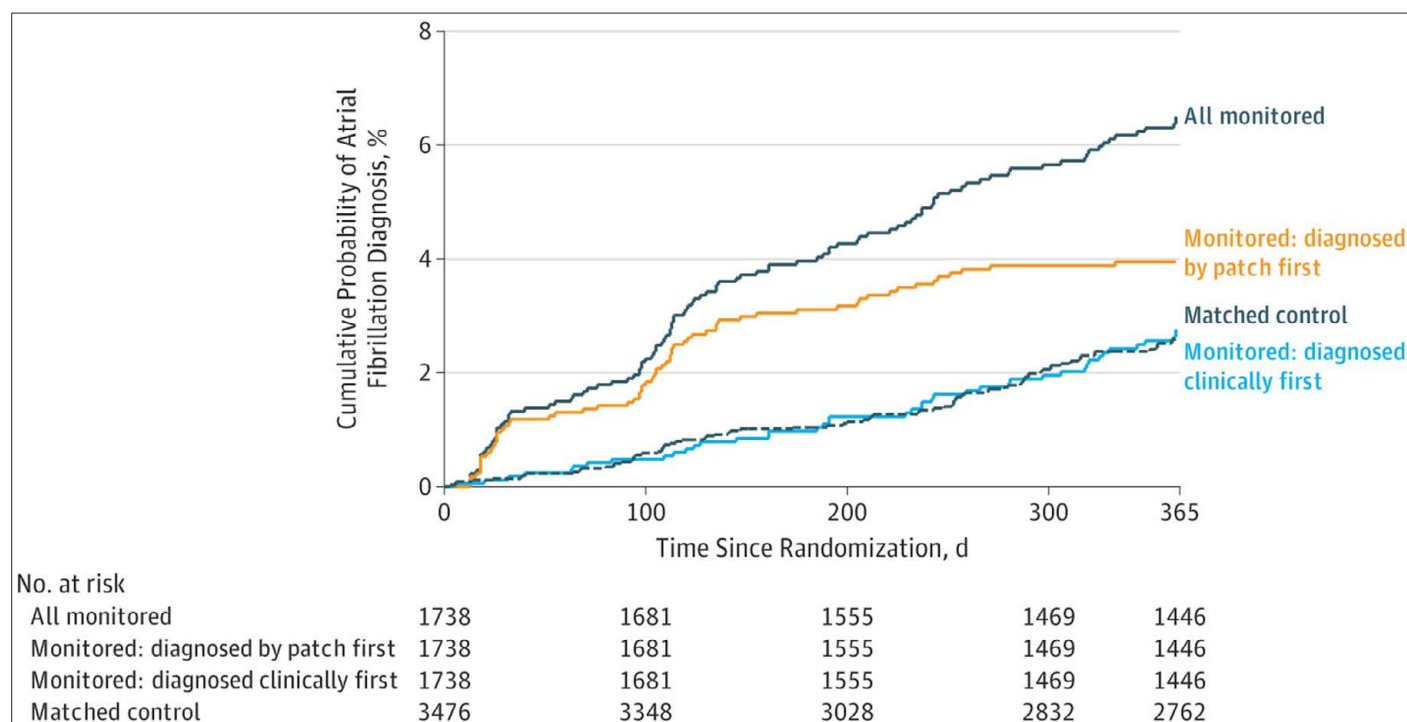


Figure 2: Cumulative rate of first diagnosis of atrial fibrillation in the actively monitored and observational cohorts [116].



individuals experienced increased outpatient cardiology visits (33.5 vs 26.0 per 100 person-years; difference, 7.5) and primary care visits (83.5 vs 82.6 per 100 person-years; difference, 0.9). Active monitoring was also associated with an increase in the initiation of antiarrhythmic medication and ablation or cardioversion procedures. Furthermore, pacemaker or defibrillator placements were higher in the monitored cohort. There was no significant difference in atrial fibrillation related emergency department visits and hospitalizations between monitored and unmonitored groups (1.3 vs 1.4 per 100 person-years; difference, 0.1). The mean wear time for the electrocardiogram patch was 11.7 days (SD 4.1), with 97.8% analyzable electrocardiogram data. The median total monitoring time was 593.3 h per participant. The median burden of atrial fibrillation (percentage of monitored time in atrial fibrillation) was 0.9%. Most individuals diagnosed with atrial fibrillation by electrocardiogram patch had a relatively low burden of paroxysmal atrial fibrillation, with only a small percentage (3/65 (4.6%)) having persistent atrial fibrillation. Only 17.4% of participants (12 out of 69) who had atrial fibrillation while wearing a patch recalled experiencing symptoms potentially associated with atrial fibrillation, and most symptoms were mild. In conclusion, the mSTOPS trial demonstrated that using a home-based wearable electrocardiogram sensor patch for immediate monitoring significantly increases the detection rate of undiagnosed atrial fibrillation in high-risk individuals. This proactive monitoring also leads to a higher initiation of anticoagulants and increased healthcare resource utilization, particularly for cardiology visits, without a significant increase in atrial fibrillation related emergency department visits or hospitalizations. The findings suggest that early detection of atrial fibrillation, even asymptomatic forms, can influence clinical management and resource use, although further research is needed on the long-term clinical implications of these findings.

A study by Kwun et al. [117] (NCT04857268) investigated if the AT-patch, a wearable monitor, could effectively detect new-onset atrial fibrillation in high-risk patients, as identified by a high CHA₂DS₂-VASc score (Figure 3). The AT-Patch device detected new-onset atrial

fibrillation in 3.4% (11 out of 320) of the high-risk patients enrolled in the study, as confirmed by two independent cardiologists. A previous history of heart failure was significantly more prevalent in the group of patients where atrial fibrillation was detected (36.4%, or 4 out of 11 patients) compared to the non-atrial fibrillation group (5.2%, or 16 out of 309 patients), with a statistically significant difference ($p = 0.003$). When a CHA₂DS₂-VASc score of ≥ 4 was combined with a previous history of heart failure, the detection rate for atrial fibrillation significantly increased to 24.4%. Comparison of the recorded electrocardiogram data showed that supraventricular ectopic rhythms were significantly more frequent in the new-onset atrial fibrillation group (3.4%) than in the non-atrial fibrillation group (0.4%; $p = 0.001$). Similarly, ventricular ectopic rhythms were also significantly more frequent in the new-onset atrial fibrillation group (5.2%) compared to the non-atrial fibrillation group (1.2%; $p < 0.001$). In summary, the study found that the AT-patch detected a moderate number of new-onset atrial fibrillations in high-risk patients. A notable finding was the strong association between previous heart failure and atrial fibrillation detection, especially when combined with a high CHA₂DS₂-VASc score. Additionally, both supraventricular and ventricular ectopic rhythms were significantly more common in patients who developed new-onset atrial fibrillation.

Economic and Healthcare System Considerations

The integration of long-term continuous monitoring into standard care necessitates a rigorous analysis of its economic impact and implications for healthcare systems. While the upfront costs of devices like implantable loop recorders and multi-week wearable patches are significant, a comprehensive cost-effectiveness analysis must weigh these initial investments against the potential for substantial long-term savings, primarily through the prevention of major adverse cardiovascular events [118]. Studies, particularly in the cryptogenic stroke population, have demonstrated that implantable loop recorder guided management can be cost-effective [119]. This is because the cost of a single preventable stroke—encompassing acute

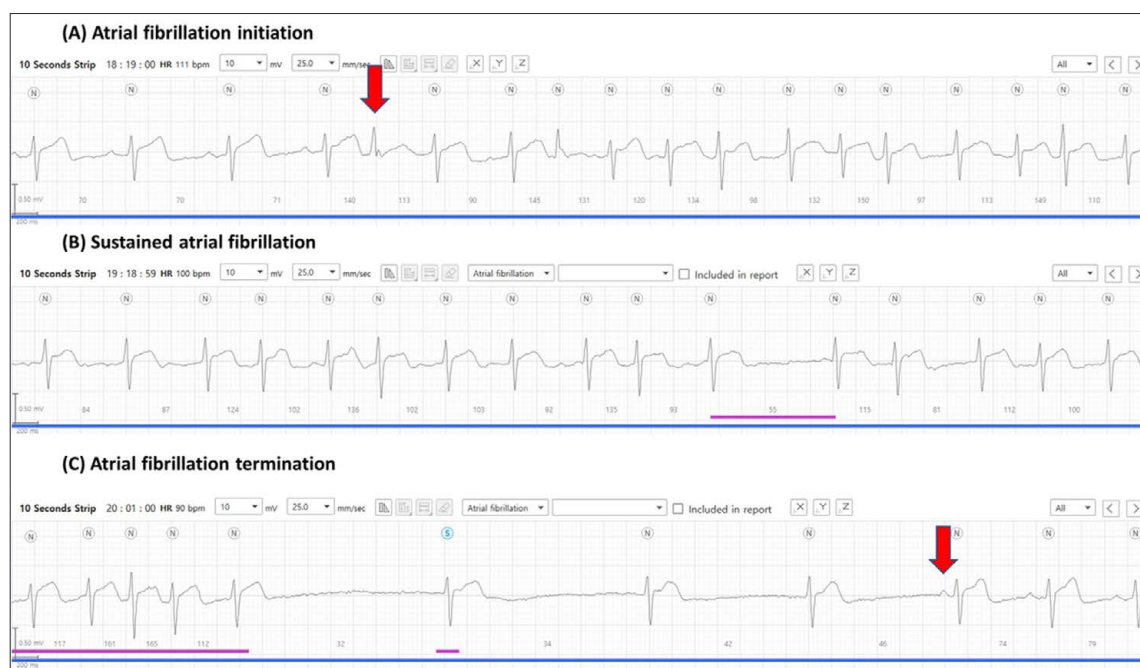


Figure 3: The AT-Patch recorded three stages of atrial fibrillation: (A) how it starts with a premature beat, (B) how it continues, and (C) how it stops, marked by the return of a P wave [117].



hospitalization, rehabilitation, and long-term disability care—far exceeds the cost of the monitoring device and its associated follow-up, especially when it leads to targeted anticoagulation that prevents a recurrent event. Beyond stroke prevention, these monitoring strategies influence broader healthcare utilization in complex ways. On one hand, the proactive identification of arrhythmias like atrial fibrillation in high-risk populations has the potential to reduce the incidence of undiagnosed strokes and heart failure exacerbations, thereby decreasing costly emergency department visits and hospital admissions [120]. This represents a shift from reactive, high-acuity care to proactive, preventative management. Effective monitoring can also reduce the ‘diagnostic odyssey’ for patients with unexplained syncope or palpitations, potentially avoiding repeated, low-yield testing and providing a definitive diagnosis more efficiently.

On the other hand, the high sensitivity of these technologies can inadvertently increase healthcare utilization. The detection of subclinical arrhythmias, particularly those of uncertain significance, often triggers a cascade of downstream activities: additional specialist consultations (e.g., with electrophysiologists), further diagnostic testing (e.g., echocardiograms, stress tests), and sometimes the initiation of treatments that themselves require monitoring [121]. This ‘domino effect’ can increase short-term costs and place additional demand on clinical resources, highlighting the need for careful patient selection and clear clinical protocols to avoid unnecessary interventions. A critical challenge for healthcare systems is the infrastructure required to manage the large volumes of data generated by continuous and remote monitoring. A single clinic implanting hundreds of implantable loop recorders annually creates a continuous stream of remote transmissions, each requiring timely clinician review [122]. Managing this workflow demands robust digital platforms, dedicated ancillary staff for initial data triage, and clear protocols for prioritizing alerts (e.g., atrial fibrillation vs asystole) to ensure that critical findings are acted upon promptly while minimizing alert fatigue for clinicians.

The economic model for reimbursing this remote data management remains a point of evolution. While the device itself may be covered, the ongoing work of interpreting daily transmissions, managing the digital platform, and responding to patient concerns requires sustainable billing codes and reimbursement structures [123]. Without adequate financial support for this operational backbone, the clinical benefits of remote monitoring may be undermined by unsustainable administrative burdens on healthcare practices, potentially limiting patient access to these technologies. Furthermore, the cost-effectiveness equation varies significantly by clinical context. Monitoring for secondary stroke prevention in a 70-year-old with hypertension presents a very different proposition than screening a low-risk, asymptomatic 50-year-old [124]. Therefore, the economic viability of these tools is intimately tied to appropriate patient selection, guided by evidence-based criteria that target populations most likely to experience a net clinical and economic benefit.

In summary, while long-term monitoring strategies represent a significant advancement, their adoption must be coupled with a clear-eyed view of their systemic impact. They offer the potential for long-term cost savings through preventative care but require upfront investment and the development of new clinical workflows. The future of sustainable implementation hinges on optimizing patient selection, establishing efficient data management infrastructures, and ensuring that reimbursement models align with the value provided by continuous, remote patient management.

Conclusion

The integration of wearable patches and implantable loop recorders into clinical practice has irrevocably shifted the paradigm of atrial fibrillation management from a reactive, episode-based model to a proactive, burden-centric strategy. By providing continuous, long-term rhythm data, these technologies have unmasked the true spectrum of the disease, enabling earlier diagnosis, more accurate risk stratification, and a nuanced assessment of treatment efficacy. The quantification of atrial fibrillation burden, in particular, has emerged as a critical biomarker, linking subclinical arrhythmia to tangible clinical outcomes and refining decisions regarding anticoagulation and rhythm control. As the evidence base solidifies, the ongoing challenge lies in seamlessly incorporating these data streams into routine care pathways to improve patient outcomes.

Looking ahead, the future of continuous rhythm monitoring is poised for further transformation. The next frontier will be the development of precise, burden-based thresholds to guide anticoagulation and other interventions, moving beyond arbitrary duration cut-offs to personalized risk calculators that integrate atrial fibrillation burden with clinical factors, biomarkers, and genetic data. Concurrently, the integration of artificial intelligence and machine learning will be crucial for managing the vast dataflow, enhancing diagnostic accuracy, and predicting individual patient trajectories. For these advancements to reach their full potential, future efforts must also focus on health policy innovation, establishing sustainable reimbursement models and robust clinical infrastructure to ensure the equitable and cost-effective deployment of these powerful tools, ultimately paving the way for a new era of precision cardiology.

Acknowledgements

None.

Conflict of Interest

None.

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