

Original Article

Smartpatch long-term monitoring superior to 24-hour Holter for detecting idiopathic ventricular arrhythmia: a retrospective self-controlled study

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Abstract: Objective: To compare the diagnostic performance, patient comfort, and heart rate variability (HRV) assessment of a novel long-term Smartpatch monitor with those of a conventional 24-hour Holter monitor in patients with suspected idiopathic ventricular arrhythmia (IVA). Methods: This retrospective self-controlled study enrolled 164 patients who underwent simultaneous 24-hour Holter and 7- to 14-day Smartpatch monitoring. Detection rates of arrhythmia subtypes, premature ventricular contraction (PVC) burden, symptom-rhythm correlation, wearing comfort (assessed using 5-point Likert scale), HRV indices (SDNN, SDANN, RMSSD), and diagnostic accuracy were compared between different monitoring methods. Results: Compared with Holter monitoring, Smartpatch showed significantly higher detection rates for all arrhythmia subtypes (all $P < 0.05$). Among the 85 patients with negative Holter findings, Smartpatch provided an incremental diagnostic yield of 18.8% (16/85), resulting in changes in clinical management for 9 patients (5 receiving pharmacological therapy and 4 undergoing ablation). Smartpatch was associated with superior overall comfort scores (4.3 ± 0.5 vs 2.9 ± 0.9 , $P = 0.007$), a lower premature termination rate (1.2% vs 5.5%, $P = 0.035$), a higher proportion of valid recording data (98.5% vs 96.2%, $P < 0.001$), and a mean wear duration of 13.2 days. HRV indices were significantly higher with Smartpatch monitoring than with Holter monitoring ($P < 0.05$). Diagnostic sensitivity, specificity, and accuracy for IVA were 94.2%, 91.8%, and 93.1% with Smartpatch, respectively, compared with 78.5%, 85.4%, and 80.2% with Holter ($P < 0.001$, $P = 0.013$, $P < 0.001$, respectively). Conclusion: In patients with suspected IVA, long-term Smartpatch monitoring demonstrated higher arrhythmia detection rates, improved diagnostic accuracy, enhanced HRV assessment, and better patient comfort compared with 24-hour Holter monitoring. These findings support its use as a valuable tool for screening and diagnosis in patients with suspected IVA.

Keywords: Idiopathic ventricular arrhythmia, long-term dynamic electrocardiogram, Smartpatch, Holter monitoring, wearable devices

Introduction

Idiopathic ventricular arrhythmia (IVA) refers to premature ventricular contractions (PVCs) and nonsustained or sustained ventricular tachycardia occurring in patients without definite structural heart disease [1]. Although the prognosis is usually favorable, frequent IVA can cause symptoms such as palpitations, chest tightness, and fatigue. In severe cases, patients may experience syncope, transient loss of consciousness, and even tachycardia-induced cardiomyopathy, resulting in impaired

cardiac function and reduced long-term quality of life [2, 3]. Therefore, timely and accurate diagnosis and risk stratification of IVA are of great clinical importance.

Electrocardiography (ECG) remains the cornerstone of arrhythmia diagnosis. Conventional 12-lead ECG is easy to operate and can provide instantaneous electrocardiographic information. However, it's extremely short recording duration (typically only 10 seconds) substantially limits its diagnostic value in IVA patients characterized by long inter-episode intervals,

paroxysmal episodes, or asymptomatic events, resulting in a high risk of missed diagnosis [4]. The 24-hour Holter monitoring, which has been widely used since the 1980s, greatly extended the ECG recording duration and significantly improved arrhythmia detection rates [5]. However, for IVA patients with infrequent episodes, a 24-hour monitoring window remains insufficient, with reported positive detection rate ranging from only 16% to 40% [6, 7]. In addition, conventional Holter monitoring typically require multiple wires and a portable recorder, which significantly interferes with the patient's daily activities, sleep, and physical exercise. Additional limitations include skin irritation, electrode detachment, and signal artifacts caused by poor electrode contact, affecting patient comfort, compliance, and data quality [8].

In recent years, remote ECG monitoring technologies, especially long-term patch-based dynamic ECG monitoring systems, have provided a new solution to overcome these limitations [9]. These devices are wire-free, lightweight, and waterproof, allowing continuous monitoring for several days to weeks and improving the detection of sporadic and paroxysmal arrhythmia events [10, 11]. Smartpatch is a representative patch-based monitoring technology developed for long-term ECG assessment. A single device can provide continuous monitoring for up to 14 days and has demonstrated promising performance in the early detection and treatment of paroxysmal atrial fibrillation [12].

Subsequent studies have strengthened the evidence for patch-based long-term ECG monitoring. In patients with cryptogenic stroke, extended patch monitoring detected paroxysmal atrial fibrillation in 12%-16% of cases, representing a significantly higher detection rate than repeated 24-hour Holter monitoring [13]. Similarly, after atrial fibrillation ablation, continuous patch-based monitoring demonstrated superior sensitivity for detecting asymptomatic recurrence of atrial tachyarrhythmias compared with intermittent Holter monitoring, along with significantly better patient adherence [14]. Among patients undergoing evaluation for unexplained syncope or palpitations, wearable patch monitors have been shown to capture clinically significant arrhythmic events that are frequently missed by conventional short-term

recordings, thereby contributing to substantial changes in clinical management decisions [15].

Despite these promising findings across various arrhythmic populations, evidence regarding the use of Smartpatch in patients with suspected IVA remain extremely scarce. To date, no retrospective study has systematically compared Smartpatch with conventional 24-hour Holter monitoring in patients with IVA across multiple clinically relevant dimensions, including overall arrhythmia detection yield, identification of potentially high-risk ventricular arrhythmic events, heart rate variability (HRV) assessment, patient-reported comfort, and overall diagnostic accuracy. Given the sporadic and unpredictable nature of IVA episodes, prolonged monitoring may theoretically provide substantial diagnostic advantages; however, this hypothesis has not yet been rigorously validated in a self-controlled retrospective study.

Therefore, this retrospective self-controlled study aimed to determine whether Smartpatch offers clinical advantages over 24-hour Holter monitoring in patients with suspected IVA. We hypothesized that Smartpatch would achieve a higher diagnostic yield, improved patient comfort, and enhanced HRV assessment. The novelty of this study lies in conducting a systematic direct comparison between Smartpatch and conventional Holter monitoring in patients with IVA within the domestic clinical setting. This study not only evaluated overall arrhythmia detection rates but also comprehensively assessed differences in the detection of potentially high-risk arrhythmia events, HRV parameters, patient wearing comfort, and overall diagnostic performance. The findings may provide evidence to support the optimization of clinical diagnostic strategies for IVA.

Subjects and methods

Patient selection

This was a retrospective, single-center, self-controlled study. A total of 164 patients who were admitted to The First People's Hospital of Hechi City for suspected IVA between January 2021 and December 2024 were consecutively included. All patients underwent both conventional 24-hour Holter monitoring and Smartpatch monitoring during the same hospitalization period.

Inclusion criteria: (1) age ≥ 18 years; (2) presence of suspected arrhythmic symptoms (e.g., palpitations, presyncope, syncope, chest tightness, or fatigue) within the previous month, or detection of frequent premature PVCs or non-sustained ventricular tachycardia on routine 12-lead electrocardiography during health examinations; (3) exclusion of structural heart disease based on echocardiography, coronary computed tomography angiography or invasive coronary angiography, and cardiac magnetic resonance imaging, thereby fulfilling the clinical definition of IVA; (4) completion of both 24-hour ambulatory Holter monitoring and 7-14-day Smartpatch patch-based electrocardiographic monitoring during the same hospital admission, with complete and interpretable recordings obtained from both devices; (5) availability of complete baseline data, symptom diaries, follow-up records, and comprehensive clinical diagnostic information from electronic medical records; (6) stable vital signs, alert mental status, and the ability to cooperate with device wearing and complete subjective comfort assessments; and (7) a minimum clinical follow-up duration of 3 months, with complete clinical outcome assessment data available.

Exclusion criteria: (1) pregnancy or lactation; (2) known allergy to electrodes, medical adhesives, or patch dressings, or the presence of severe dermatitis; (3) severe cognitive impairment or psychiatric disorders affecting the ability to complete symptom diaries or comfort questionnaire; (4) presence of cardiac implantable electronic devices, including permanent pacemakers, implantable cardioverter-defibrillators (ICDs), or cardiac resynchronization therapy (CRT) devices; (5) acute malignant arrhythmias requiring emergency electrical cardioversion or urgent radiofrequency catheter ablation; (6) structural heart disease, including end-stage heart failure, severe valvular disease, complex congenital heart disease, or hypertrophic cardiomyopathy; (7) advanced malignancy, severe hepatic or renal failure, or active autoimmune disease; (8) use of glucocorticoids or immunosuppressants within 7 days prior to assessment, which could potentially affect autonomic nervous function and HRV assessment; (9) concurrent participation in other controlled clinical trials involving wearable electrocardiographic devices; (10) missing $\geq 20\%$ of monitoring data, incomplete symptom diary records, or loss to 3-month clinical follow-

up; and (11) premature self-removal of the device during monitoring without obtaining a complete and valid 24-hour overlapping control recording.

This study was conducted in strict accordance with the principles of the Declaration of Helsinki. The study protocol was approved by the Medical Ethics Committee of the First People's Hospital of Hechi. Due to the retrospective nature of the study, the requirement for written informed consent was waived.

The inclusion and exclusion criteria were established according to the design requirements of retrospective studies comparing patch-based electrocardiography monitoring and Holter monitoring and were informed by eligibility criteria used in previous wearable ECG retrospective cohort studies [16, 17]. To minimize selection bias, standardized eligibility criteria were applied, including simultaneous evaluation with both monitoring devices, complete follow-up information, and exclusion of structural heart disease.

This study adopted a retrospective self-controlled design to reduce inter-individual confounding caused by variations in age, disease severity, autonomic nervous tone, and other baseline characteristics, thereby enabling a direct comparison of the performance of the two monitoring techniques. All patients underwent monitoring with both devices during the same hospitalization period. To ensure comparability between the two monitoring approaches, the complete 24-hour Holter recording period was used as the primary comparison window, and Smartpatch data corresponding to the overlapping 24-hour period were extracted for comparative analysis. By pairing recordings from both devices within each patient, this study minimized potential confounding factors. The patient screening and enrollment process is illustrated in **Figure 1**.

Data extraction

Conventional Holter monitoring was performed using the ECG-1352 12-lead dynamic ECG recorder (Hubei Meilin Biotechnology Co., Ltd., Hubei, China), with continuous recording for 24 hours. Patients were instructed to maintain detailed activity logs and symptom diaries during the monitoring period. After automated analysis by dedicated software, all recordings

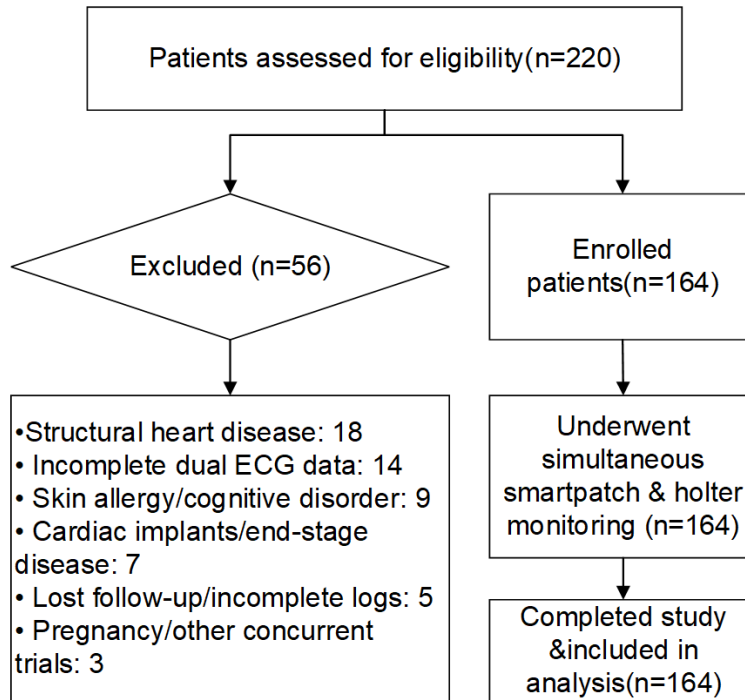


Figure 1. Patient enrollment flowchart.

were manually reviewed and corrected by experienced physicians with reference to the patients' activity and symptom diaries.

Smartpatch monitoring was conducted using the NS-SP-A-01 smart patch (Enshi Medical Technology (Shanghai) Co., Ltd., Shanghai, China). The device uses analog dual-lead ECG recording with a sampling frequency of 128 Hz and is equipped with internal memory capable of continuous recording for up to 14 days. The device has an IPX7 water-resistance rating. Patients were able to manually mark symptomatic events by pressing the device button. After completion of monitoring, all recordings were reviewed and analyzed by certified physicians using a cloud-based analysis system.

To ensure comparability between the two monitoring modalities, the complete 24-hour Holter recording period was defined as the primary reference time window. Corresponding Smartpatch data from the identical overlapping 24-hour period were extracted for analysis of all core parameters, including arrhythmia detection rates, PVC burden, HRV parameters, and symptom-rhythm correlation. This approach minimized potential bias introduced by differences in monitoring duration. Additional

arrhythmic events detected by Smartpatch beyond the overlapping 24-hour period and their impact on clinical management were analyzed as secondary outcomes.

Outcome measures

Primary outcomes: (1) Arrhythmia detection rate: The detection rates of the following arrhythmias by the two methods were compared: second-degree atrioventricular block, ventricular fibrillation events, nonsustained ventricular tachycardia, frequent premature ventricular contractions (> 1000 times/24 h), and supraventricular or ventricular tachycardia. All calculations were based on the overlapping 24-hour recordings obtained from simultaneous monitoring with both devices.

(2) Premature ventricular contraction burden: PVC burden was calculated as the percentage of PVCs among the total number of heartbeats recorded during the same 24-hour period. Holter-derived PVC burden values were directly provided by the analysis software, whereas Smartpatch-derived data were calculated as the mean 24-hour PVC burden generated by the cloud-based analysis system.

(3) Symptom-rhythm correlation: An symptom event was considered a valid correlation when the time point recorded in the patient diary or manually marked on the device (± 5 minutes) corresponded to an episode of tachyarrhythmia detected by the monitoring system during the recording period.

(4) Diagnostic performance: The final clinical diagnosis of IVA was determined through comprehensive clinical adjudication [18]. This adjudication process was performed by a panel of three senior cardiologists who were blinded to the device type. The final diagnosis was established based on a comprehensive assessment of clinical symptoms, ambulatory ECG findings from both monitoring systems, relevant electrophysiological examination results, and clinical follow-up outcomes over at least 3 months after multidisciplinary discussion.

Secondary outcome measures: (1) Comfort assessment: A self-designed questionnaire was used to evaluate patient comfort across five dimensions: interference with daily activities, impact on sleep, limitations of physical activity, skin reactions (such as erythema and pruritus), and subjective discomfort. Each dimension was assessed using a 5-point Likert scale (1 = very poor/severe interference, 5 = very good/no interference). The mean score for each dimension and the overall comfort score were calculated. Additionally, premature device removal or discontinuation of monitoring due to discomfort was recorded.

(2) HRV evaluation: HRV parameters were calculated based on all normal sinus RR intervals within the overlapping 24-hour recording period. Standard deviation of NN intervals (SDNN), standard deviation of the average NN intervals calculated over consecutive 5-minute windows (SDANN), and root mean square of successive differences (RMSSD) were compared between the two groups.

(3) Monitoring feasibility, data quality, and patient adherence: To comprehensively evaluate the feasibility, reliability, and patient acceptance of the two monitoring methods, the following supplementary indicators were collected:

Actual monitoring duration: the actual duration completed by each patient was recorded. For the Holter group, completion was defined as a continuous 24-hour recording; for the Smartpatch group, the total number of days from device application to planned removal or premature discontinuation was recorded.

Proportion of valid data: the proportion of valid ECG recording time relative to the total recording duration was calculated. Valid ECG signals were defined as segments without significant signal artifacts, including a signal-to-noise ratio > 20 dB, baseline drift < 0.5 mV, and absence of electrode dislodgement. Signal quality was initially assessed automatically by the system and subsequently independently reviewed and confirmed by two electrocardiographers blinded to monitoring modality.

Number of patient-activated symptom markers: for the Smartpatch group only, the total number of patient-activated event markers was

recorded, representing the number patients who manually pressed the device button to indicate suspected symptomatic episodes during monitoring.

Premature termination rate due to discomfort: The number and proportion of patients who, after having obtained valid 24-hour overlapping control recordings, failed to complete the planned Smartpatch monitoring period (7-14 days) due to skin allergy, significant discomfort, or device-related problems associated with wearing the device were counted.

(4) Incremental detection rate and clinical impact analysis: To evaluate the additional diagnostic value of Smartpatch compared with Holter monitoring, the incremental detection rate of Smartpatch was calculated. This index was defined as the proportion of patients with clinically significant arrhythmias detected by Smartpatch among patients with negative Holter findings.

For each predefined arrhythmia subtype (including non-sustained ventricular tachycardia and frequent premature ventricular contractions), the McNemar test was used to compare paired detection results between Smartpatch and Holter monitoring to determine whether differences in incremental detection were statistically significant. Incremental detection rate = (number of patients with negative Holter results and positive Smartpatch results/total number of patients with negative Holter results) × 100%.

Furthermore, clinically significant arrhythmias detected only by Smartpatch (i.e., missed by Holter) were further reviewed to determine whether these findings resulted in changes in clinical management. A change in clinical management was defined as the initiation of new therapeutic interventions or modification of existing treatment strategies based on Smartpatch findings, including initiation or adjustment of anti-arrhythmic drug therapy and recommendation or performance of radiofrequency catheter ablation.

Statistical analysis

Statistical analyses were performed using SPSS 21.0 software. Continuous variables were expressed as mean ± standard deviation (SD), and intergroup comparisons were made

Table 1. Baseline clinical data of included patients (N = 164)

Characteristics	Values/number of cases (%)
Demographic data	
Age (years, $\bar{x} \pm s$)	57.82 $\pm$ 3.62
Male [n (%)]	95 (57.93%)
BMI (kg/m ² , $\bar{x} \pm s$)	23.55 $\pm$ 1.56
Clinical data	
LVEF (%), $\bar{x} \pm s$)	54 $\pm$ 12
History of arrhythmia (years, $\bar{x} \pm s$)	3.30 $\pm$ 2.23
Previous AAD types ($\bar{x} \pm s$)	1.3 $\pm$ 0.7
History of ablation [n (%)]	32 (19.51%)
Clinical manifestations [n (%)]	
Asymptomatic (found during physical examination)	20 (12.20%)
Palpitations, shortness of breath, decreased exercise tolerance	132 (80.49%)
Syncope or pre-syncope symptoms	12 (7.32%)
Type of arrhythmias [n (%)]	
Frequent premature ventricular contractions	126 (76.83%)
Nonsustained ventricular tachycardia	28 (17.07%)
Sustained ventricular tachycardia	6 (3.66%)

Note: AAD: Anti-arrhythmic drug; BMI: body mass index; LVEF: left ventricular ejection fraction.

using paired *t*-tests. Categorical variables were presented as numbers (percentages), and intergroup comparisons were made using paired McNemar tests.

For diagnostic performance evaluation, sensitivity and specificity were compared between Smartpatch and Holter monitoring using the paired McNemar test. Diagnostic accuracy was also compared using paired categorical analysis based on matched diagnostic outcomes. The 95% confidence intervals (CIs) for positive predictive value (PPV) and negative predictive value (NPV) were calculated using the Wilson score method, without formal hypothesis testing. For analyses involving multiple comparisons, *P*-values were adjusted using the Benjamini-Hochberg procedure to control the false discovery rate.

To identify independent predictors associated with incremental detection of clinically significant arrhythmias by Smartpatch in patients with negative Holter findings, multivariate logistic regression analysis was performed. The dependent variable was the detection of clinically significant arrhythmias by Smartpatch (yes = 1, no = 0). Candidate independent variables were selected based on clinical relevance

and previous literature, including factors potentially associated with arrhythmia detection: age (continuous variable), sex (male = 1, female = 0), BMI (continuous variable), left ventricular ejection fraction (LVEF; continuous variable), symptom type (with “other” as the reference category, dummy variables were created for palpitations and syncope), history of prior ablation (yes = 1, no = 0), and number of antiarrhythmic drug classes used (continuous variable). A backward stepwise regression method (removal criterion *P* > 0.10) was used to identify independent predictors. Model calibration and goodness-of-fit were assessed using the Hosmer-Lemeshow test. A two-sided *P*-value < 0.05 was considered statistically significant.

Results

Baseline characteristics

A total of 164 patients were finally included, including 95 males (57.93%) and 69 females (42.07%). The mean age was 57.82 $\pm$ 3.62 years, and the mean BMI was 23.55 $\pm$ 1.56 kg/m². The mean LVEF was (54 $\pm$ 12%). All patients had received antiarrhythmic drug therapy before assessment, with a mean number of 1.3 $\pm$ 0.7 antiarrhythmic drugs per patient.

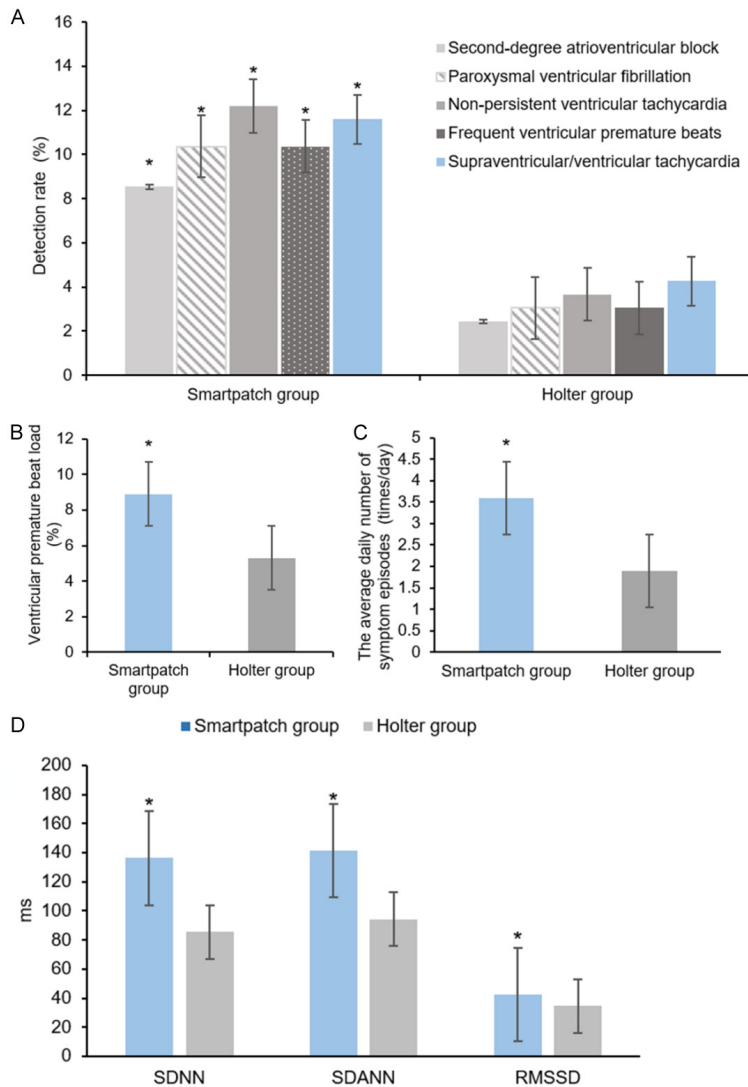


Figure 2. Comparison of key parameters monitored between Smartpatch group and Holter group. A. Contrast of arrhythmia detection rates. B. Comparison of premature ventricular contraction burden. C. Comparison of average daily symptomatic episodes. D. Contrast of HRV indices. Note: HRV: heart rate variability; SDNN: standard deviation of NN intervals; SDANN: standard deviation of the average NN intervals; RMSSD: root mean square of successive differences; *, Relative to the Holter group, $P < 0.05$.

With 32 patients (19.51%) who had a history of unsuccessful radiofrequency catheter ablation at other institutions or arrhythmia recurrence (**Table 1**).

Arrhythmia detection rates

As shown in **Figure 2A**, Smartpatch monitoring demonstrated significantly higher detection rates for all predefined arrhythmia types compared with Holter monitoring (all $P < 0.05$). Smartpatch demonstrated improved detection capability for second-degree atrioventricular

block (8.54% vs. 2.44%), paroxysmal ventricular fibrillation (10.37% vs. 3.05%), nonsustained ventricular tachycardia (12.20% vs. 3.66%), frequent premature ventricular contraction (10.37% vs. 3.05%), and supraventricular/ventricular tachycardia (11.59% vs. 4.27%) ($P < 0.05$).

Premature ventricular contraction burden and symptom-rhythm correlation

The 24-hour PVC burden was noticeably higher with Smartpatch monitoring than with Holter monitoring [$(8.9 \pm 4.6\%)$ vs. $(5.3 \pm 3.14\%)$, $P = 0.012$] (**Figure 2B**). The average number of symptomatic events recorded per day was also noticeably higher during Smartpatch monitoring compared with Holter monitoring [(3.6 ± 2.7) events/day vs. (1.9 ± 1.3) events/day, $P = 0.023$] ($P < 0.05$) (**Figure 2C**).

Patient tolerability, comfort, and compliance

In the multidimensional comfort assessment, Smartpatch monitoring showed significantly higher scores than Holter monitoring across all five dimensions (including interference with daily activities, impact on sleep, restriction of physical activity, skin reactions, and subjective discomfort)

and overall comfort score (all $P < 0.05$; **Table 2**). Differences were particularly pronounced in the dimensions of interference with daily activities (4.6 ± 0.5 vs. 3.1 ± 0.8) and sleep disturbance (4.4 ± 0.6 vs. 2.8 ± 1.1). The rate of premature monitoring termination due to discomfort was significantly lower with Smartpatch than with Holter monitoring [1.2% (2/164) vs. 5.5% (9/164), $P = 0.032$].

The improved tolerability was accompanied by better monitoring completion. As shown in **Table 3**, the actual average effective duration

Table 2. Comparison of multidimensional comfort scores between Smartpatch and Holter monitoring

Assessment dimension	Smartpatch	Holter	Pairing difference (Smartpatch - Holter) $\bar{d} \pm S_d$ (95% CI)	<i>t</i>	<i>P</i> -value
Interference with daily activities	4.6 $\pm$ 0.5	3.1 $\pm$ 0.8	1.5 $\pm$ 0.9 (1.3-1.7)	21.28	0.012
Impact on sleep	4.4 $\pm$ 0.6	2.8 $\pm$ 1.1	1.6 $\pm$ 1.2 (1.4-1.8)	17.12	0.004
Exercise limitation	4.3 $\pm$ 0.7	2.5 $\pm$ 1.2	1.8 $\pm$ 1.3 (1.6-2.0)	17.45	0.012
Skin reaction	4.2 $\pm$ 0.8	3.0 $\pm$ 1.0	1.2 $\pm$ 1.0 (1.0-1.4)	15.43	0.005
Subjective discomfort	4.3 $\pm$ 0.6	3.2 $\pm$ 1.1	1.1 $\pm$ 1.2 (0.9-1.3)	11.54	0.006
Overall comfort score (mean)	4.3 $\pm$ 0.5	2.9 $\pm$ 0.9	1.4 $\pm$ 0.9 (1.2-1.6)	19.83	0.007
Monitoring discontinuation rate [n (%)]	2 (1.2%)	9 (5.5%)	-	-	0.035

Note: A 5-point Likert scale was used (1 = Very Poor, 5 = Very Good). The comfort score was evaluated using a paired *t*-test, and all *P*-values were corrected using the Benjamini-Hochberg method.

Table 3. Comparison of monitoring data completeness and patient compliance

Evaluation indicators	Smartpatch (n = 164)	Holter (n = 164)	Statistic	<i>P</i> value
Monitoring duration and compliance				
Planned monitoring duration	14 days	24 hours	-	-
Actual days of monitoring completed ($\bar{x} \pm s$)	13.2 $\pm$ 1.5 days	1.0 $\pm$ 0.1 day	-	-
Extended monitoring completion rate [n (%)]	160 (97.6)	164 (100.0)	-	-
Number of active symptom markers for patients ($\bar{x} \pm s$)	4.1 $\pm$ 3.2 times	Not applicable	-	-
Data quality				
Effective data ratio ($\bar{x} \pm s$, %) (95% CI)	98.5 $\pm$ 2.1 (98.2-98.8)	96.2 $\pm$ 4.8 (95.5-96.9)	T = 6.12	0.001
Tolerance and safety				
Early termination of monitoring due to discomfort [n (%)]	2 (1.2)	9 (5.5)	-	0.035*
Due to skin allergies [n]	1	7	-	-
Due to other discomforts [n]	1	2	-	-

Note: "Extended monitoring completion rate" refers to the proportion of patients who completed monitoring for more than 24 hours; for the Smartpatch group, it was defined as wearing the device for ≥ 7 days. The comparison of the proportion of valid data was performed using the paired *t*-test, with a mean difference of 2.3% (95% CI: 1.6%-3.0%). The premature termination rate was compared using the paired McNemar test (discordant pairs: 1 case terminated in Smartpatch only, 8 cases terminated in Holter only; two-sided exact *P* = 0.035). Not applicable: Holter is a passive recording device and does not have a patient-activated marking function. CI, confidence interval.

of Smartpatch monitoring was 13.2 $\pm$ 1.5 days (close to the planned 14 days), while Holter monitoring was completed per protocol for 24 hours (1.0 day). All patients using Smartpatch successfully utilized the symptom event-marking function, with an average of 4.1 $\pm$ 3.2 manually activated event markers per patient.

Regarding data quality, based on predefined criteria for valid ECG signals (no significant noise, baseline drift, or electrode detachment, with consistency between automated assessment and manual review), the proportion of valid data was slightly higher with Smartpatch

monitoring than with Holter monitoring (98.5 $\pm$ 2.1% vs. 96.2 $\pm$ 4.8%, *P* < 0.001; **Table 3**).

HRV

As shown in **Figure 2D**, HRV analysis demonstrated significantly higher SDNN, SDANN, and RMSSD values with Smartpatch monitoring compared with Holter monitoring (*P* < 0.05).

Diagnostic performance

Using the final clinical diagnosis as the gold standard, paired diagnostic performance analyses were performed. Smartpatch demonstrat-

Table 4. Comparison of diagnostic efficacy between Smartpatch and Holter monitoring (N = 164)

Diagnostic efficacy indicators	Smartpatch		Holter		Statistical value	P value
	Numerical value (%, 95% CI)	n/N	Numerical value (%, 95% CI)	n/N		
Sensitivity	94.2 (89.7-97.1)	96/102	78.5 (72.1-84.0)	80/102	$\chi^2 = 12.07$	< 0.001
Specificity	91.8 (86.4-95.5)	57/62	85.4 (79.0-90.3)	53/62	$\chi^2 = 6.23$	0.013
Accuracy	93.1 (89.5-95.7)	153/164	80.2 (74.4-85.1)	133/164	T = 8.94	< 0.001
Positive predictive value	92.5 (87.9-95.6)	96/101*	83.1 (77.4-87.7)	80/89*	-	-
Negative predictive value	93.8 (89.6-96.5)	57/63*	81.6 (75.8-86.3)	53/75*	-	-

Note: Sensitivity and specificity were compared using a paired McNemar test, accuracy was compared using a paired t-test, and P-values were corrected using the Benjamini-Hochberg method. Positive predictive value (PPV = TP/(TP+FP)) and negative predictive value (NPV = TN/(FN+TN)) were calculated using the Wilson scoring method with 95% confidence intervals without hypothesis testing. *The denominators for PPV and NPV were TP+FP and TN+FN, respectively, based on the diagnostic 2x2 table, and therefore do not equal the total sample size (N=164). The gold standard is a comprehensive clinical diagnosis based on symptoms, complete electrocardiogram data, electrophysiological examination, and a 3-month follow-up. CI: confidence interval; TP: True positive; FP: False positive; FN: False negative; TN: True negative.

Table 5. Incremental detection rate of Smartpatch (Based on Holter's own testing report)

Types of arrhythmias	Holter negative cases (A)	Only Smartpatch detected cases (B)	Incremental detection rate (B/A, %)	P value
Second-degree atrioventricular block	82	3	3.7	0.083
Non-sustained ventricular tachycardia	80	5	6.3	0.025
Frequent ventricular premature beats	75	4	5.3	0.046
Paroxysmal ventricular fibrillation	84	1	1.2	0.317
Supraventricular/ventricular tachycardia	78	3	3.8	0.083
Total de duplication	85	16	18.8	0.001

Note: Incremental detection rate = (Number of patients with positive findings only by Smartpatch/Number of patients with negative Holter results) × 100%. The denominator varies for each type of arrhythmia, as the number of Holter-negative patients differs. IVA: idiopathic ventricular arrhythmia; CI: confidence interval; PVC: premature ventricular contraction.

ed significantly improved diagnostic performance for IVA compared with Holter monitoring (all $P < 0.05$; **Table 4**). Specifically, compared with Holter monitoring, Smartpatch showed higher sensitivity (94.2% vs. 78.5%), specificity (91.8% vs. 85.4%), diagnostic accuracy (93.1% vs. 80.2%), PPV (92.5% vs. 83.1%), and NPV (93.8% vs. 81.6%) for IVA detection (all $P < 0.05$).

Incremental detection rate and impact on clinical management

Smartpatch monitoring demonstrated additional diagnostic value beyond conventional Holter monitoring (**Table 5**). The denominators for each arrhythmia subtype (i.e., the number of patients with negative Holter findings) were derived exclusively from the original Holter reports rather than from the clinical diagnosis presented in **Table 1**. Consequently, these values do not directly correspond mathematically with the prevalence rates shown in **Table 1**.

Specifically, **Table 1** represents the final clinical diagnosis integrating all available information, including Smartpatch findings and 3-month follow-up outcomes, whereas **Table 5** specifically quantifies the additional arrhythmia detection capability of Smartpatch among patients with negative Holter results.

Among patients with arrhythmias not detected by Holter monitoring, Smartpatch successfully identified additional clinically significant arrhythmic events in a proportion of patients. The incremental detection rates were statistically significant for most predefined arrhythmia categories ($P < 0.05$), except for second-degree atrioventricular block and paroxysmal ventricular fibrillation events, which did not reach statistical significance.

For instance, the overall detection rate of paroxysmal ventricular fibrillation events by Smartpatch was 10.37% (17/164). Among these cases, Holter monitoring detected 16

Table 6. Multivariate logistic regression analysis of factors affecting Smartpatch increment detection in Holter negative patients

Variable	β	SE	Wald χ^2	P value	OR (95% CI)
Age (every 10 years increase)	0.18	0.22	0.67	0.413	1.20 (0.78-1.85)
Male (vs Female)	0.32	0.41	0.61	0.435	1.38 (0.62-3.08)
BMI (kg/m ²)	0.05	0.10	0.25	0.617	1.05 (0.86-1.28)
LVEF (every 5% decrease)	0.12	0.15	0.64	0.424	1.13 (0.84-1.52)
Symptom types			2.15	0.341	
Palpitation	0.54	0.48	1.27	0.260	1.71 (0.67-4.38)
Syncope	-0.23	0.61	0.14	0.706	0.79 (0.24-2.62)
Other (reference)	-	-	-	-	1.00
Previous ablation history (with vs without)	0.68	0.53	1.65	0.199	1.97 (0.70-5.56)
Types of antiarrhythmic drugs	-0.08	0.29	0.08	0.783	0.92 (0.52-1.63)

Note: A total of 85 patients with negative Holter results were included in the analysis, of whom 16 (18.8%) had clinically significant arrhythmias incrementally detected by Smartpatch. The Hosmer-Lemeshow test yielded a *P* value of 0.672, indicating good model fit. No variable was found to be an independent predictor of incremental detection (all *P* > 0.05), suggesting that the incremental diagnostic value of Smartpatch is consistent across clinical subgroups and is not significantly influenced by the above factors. B: regression coefficient; SE: standard error; Wald χ^2 : Wald chi-square statistic; OR: odds ratio; CI: confidence interval; BMI: body mass index; LVEF: left ventricular ejection fraction; AAD: anti-arrhythmic drug; IVA: idiopathic ventricular arrhythmia.

cases, and Smartpatch identified one additional case. This finding was consistent with **Table 5**, in which one additional case was detected among 84 patients with negative Holter findings.

For non-sustained ventricular tachycardia, among 80 patients with negative Holter findings, Smartpatch newly detected 5 cases, yielding an incremental detection rate of 6.3% (5/80). After removing overlapping cases among different arrhythmia categories, 16 patients were identified as having clinically significant arrhythmias detected exclusively by Smartpatch. Among these 16 patients, 9 (5.5% of the total study patients) had their clinical management strategy changed, including initiation of antiarrhythmic medication (*n* = 5) and radiofrequency catheter ablation (*n* = 4).

Multivariable regression analysis

To identify potential predictors associated with incremental arrhythmia detection by Smartpatch, multivariate logistic regression analysis was performed among patients with negative Holter results (*n* = 85). The dependent variable was additional detection of clinically significant arrhythmias by Smartpatch (yes/no). Candidate predictors included age, sex, BMI, LVEF, symptom type (palpitations/syncope/others), history of previous ablation, and number of baseline antiarrhythmic medication classes.

The results (**Table 6**) showed that none of the included variables were independently associated with incremental detection by Smartpatch (all *P* > 0.05).

Discussion

This study directly compared the clinical utility of the novel Smartpatch monitoring system with conventional Holter monitoring in patients with suspected IVA. Our findings demonstrated that, compared with 24-hour Holter monitoring, Smartpatch provided higher arrhythmia detection capability, improved patient comfort, enhanced HRV assessment, and better diagnostic performance. Importantly, Smartpatch provided incremental diagnostic value that directly altered clinical decision-making in a subset of patients.

These findings are highly consistent with the findings from the study by Kim *et al.* [19], in which patch-based ECG monitoring achieved superior detection performance compared with conventional Holter monitoring for paroxysmal atrial fibrillation and ventricular arrhythmias. Our study extends previous findings by evaluating the clinical advantages of Smartpatch monitoring in an IVA population, thereby providing additional evidence for its potential role in arrhythmia evaluation. Compared with the approximately 5%-10% premature termination rates reported by Dzikowicz *et al.* [20], the pre-

mature termination rate (1.2%) observed with Smartpatch in our study was relatively low. This difference may be related to the optimized adhesive materials, lightweight patch design, and IPX7 waterproof capability, which may significantly reduce skin irritation and minimize interference with daily activities. Furthermore, compared with the 12-lead ECG database reported by Zheng *et al.* [21], although Smartpatch uses a dual-lead recording configuration, it demonstrated higher sensitivity and better patient compliance in the IVA screening scenario, suggesting that monitoring tools should be flexibly selected according to different clinical settings.

Previous studies have demonstrated that prolonged ECG monitoring can increase arrhythmia detection rate by approximately 16%-40% [22]. In the present study, Smartpatch achieved relatively high detection rates for clinically important ventricular arrhythmic events, including non-sustained ventricular tachycardia (12.20%) and paroxysmal atrial fibrillation (10.37%), which may be attributable to its prolonged continuous recording capability and improved ability to capture intermittent arrhythmic episodes [23]. Mechanistically, this benefit is essentially associated with expansion of the observation window, thereby increasing the probability of identifying infrequent events that may be missed during short-term recordings [24].

Additionally, Smartpatch demonstrated significantly better scores than Holter monitoring across all five comfort dimensions, including interference with daily activities, sleep disturbance, exercise restriction, skin reactions, and subjective discomfort. The overall comfort score was also significantly higher with Smartpatch (4.3 ± 0.5 vs. 2.9 ± 0.9). Improved tolerability may contribute to better monitoring completion and higher-quality data acquisition. In this study, Smartpatch enabled patients to complete an average monitoring duration of 13.2 days, yielding a high proportion of valid data (98.5%). Moreover, the improved data quality associated with Smartpatch may partly explain its superior diagnostic performance. Stable electrode adhesion, reduced motion interference, and continuous signal acquisition may decrease signal loss and improve arrhythmia identification accuracy. Compared with

previously reported single-lead patches or loop recorders [25], the wireless, waterproof, patch-based design of Smartpatch reduces limitations associated with multiple leads and bulky recorders. Chua *et al.* [26] reported that the 14-day ECG patch was well tolerated and enabled longer continuous monitoring than 24-hour Holter, thereby improving clinical diagnostic accuracy for paroxysmal arrhythmias. Our findings are consistent with these observations. This explains why the comfort advantage not only improves subjective experience but also ensures prolonged high-quality signal acquisition, reducing motion artifacts and signal loss caused by electrode dislodgement, thereby minimizing false-negative results at the source and safeguarding a high detection rate [27, 28].

We observed that SDNN, SDANN, and RMSSD values were significantly higher with Smartpatch monitoring than with Holter monitoring. These observations are consistent with previous findings reported by Gabriels *et al.* [29] and Schaarup *et al.* [30], who demonstrated improved HRV assessment with long-term patch-based ECG monitoring. Although HRV analysis in this study was performed using the overlapping 24-hour recording data, the higher HRV values observed with Smartpatch may be partly attributed to its superior signal stability, continuous data acquisition capability, and reduced signal loss caused by electrode displacement or motion artifacts. These advantages may allow more accurate identification of normal sinus RR intervals and reduce measurement variability during HRV calculation.

SDNN and SDANN primarily reflect overall cardiac autonomic modulation, whereas RMSSD serves as a sensitive indicator of short-term parasympathetic activity. The higher values of these parameters obtained with Smartpatch monitoring suggest that improved recording quality may enhance the reliability of autonomic function assessment [31-34]. Clinically, reduced HRV has been associated with increased risks of arrhythmic events and adverse cardiovascular outcomes. Therefore, more reliable HRV measurements provided by long-term patch-based monitoring may offer additional information for risk stratification and follow-up management in patients with IVA. However, the prognostic significance of HRV differences

between monitoring modalities requires further validation in prospective studies.

In addition, Smartpatch demonstrated an incremental detection rate of 18.8% (16/85) among patients with negative Holter findings. Among these patients, 9 (5.5% of the total cohort) subsequently experienced changes in clinical management, including initiation of antiarrhythmic drug therapy ($n = 5$) and radiofrequency catheter ablation ($n = 4$). These findings highlight the potential clinical relevance of prolonged monitoring by providing additional diagnostic information beyond conventional short-term recordings. Among the patients undergoing radiofrequency ablation, two had non-sustained ventricular tachycardia episodes detected by Smartpatch but missed by Holter monitoring. These additional recordings provided valuable information for electrophysiological evaluation and treatment planning.

The incremental yield observed in our IVA cohort was comparable to the 10%-25% incremental diagnostic yield reported by Edouard et al., who used 14-day patch monitoring in patients with syncope or palpitations [35]. The relatively moderate detection rate may be related to differences in patient populations, as patients with IVA generally exhibit less frequent and more unpredictable arrhythmic episodes compared with broader symptomatic arrhythmia cohorts.

In terms of diagnostic performance, Smartpatch achieved a sensitivity of 94.2% and a specificity of 91.8%, both of which were significantly higher than those of Holter and comparable with previously reported patch-based (sensitivity range, 85%-95%) [36]. This advantage may result from the combination of prolonged monitoring duration and stable signal acquisition, which increases the likelihood of capturing intermittent arrhythmic events while reducing signal artifacts associated with motion and electrode displacement [37]. The high positive predictive value of 92.5% and negative predictive value of 93.8% suggest that Smartpatch may provide reliable diagnostic information for both confirmation and exclusion of clinically relevant arrhythmias.

A key finding of this study was that Smartpatch identified clinically significant arrhythmias missed by Holter in 5.5% of patients, lead-

ing to changes in clinical management in 9 cases (5 receiving antiarrhythmic drug therapy and 4 undergoing radiofrequency catheter ablation). These findings further support the substantial impact of long-term patch-based monitoring in improving diagnostic pathways and guiding treatment decisions in real-world clinical settings.

Nevertheless, several limitations of this study should be acknowledged. First, although the self-controlled design minimized the influence of inter-individual differences, patients were aware that they were wearing both devices, and their behaviors and subjective perceptions may have been influenced by the Hawthorne effect (i.e., behavioral changes resulting from awareness of study participation). This effect may have influenced the subjective comfort assessments of both monitoring modalities. Second, although 3-month clinical follow-up information was incorporated into the final clinical adjudication process, longer-term prognostic endpoints, including 5-year cardiovascular events or mortality, are required to further evaluate the long-term clinical value of extended ECG monitoring in patients with ventricular arrhythmias. Third, the absence of cost-effectiveness analysis represents an important limitation. Although Smartpatch offers superior diagnostic performance, its higher device-related costs, requirement for cloud-based analysis platform, and potential increase in physician interpretation workload may influence its clinical implementation, particularly in healthcare systems with limited resources. Fourth, this study was conducted at a single center in the Guangxi region, which may be subject to specific genetic backgrounds and environmental factors, and the generalizability of the results needs to be validated in multicenter, multi-regional populations. Further prospective multicenter studies with longer follow-up are required to confirm its long-term clinical benefits and cost-effectiveness.

Conclusion

This study demonstrated that, in patients with suspected IVA, long-term dynamic ECG monitoring using Smartpatch provides higher arrhythmia detection rate, improved diagnostic performance, enhanced HRV assessment, and better patient comfort compared with conven-

tional 24-hour Holter monitoring. Smartpatch may represent a promising non-invasive monitoring approach for improving arrhythmia detection and clinical decision-making in patients with suspected IVA.

Disclosure of conflict of interest

None.

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