Clinical Summary

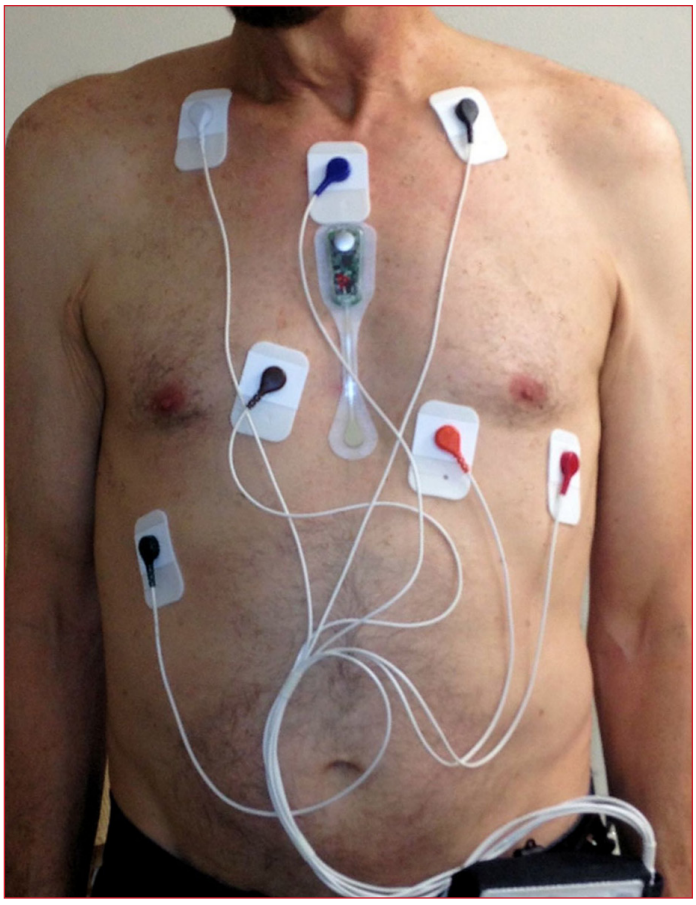
CAM vs. Holter Study

STUDY PURPOSE

To compare simultaneous recordings to determine diagnostic efficacy between an external patch system specifically designed to ensure better P-wave recordings and a standard Holter monitor

STUDY METHODS

- Prospective comparison of a single-channel patch monitor and a standard 3-lead Holter monitor:
  - **Carnation Ambulatory Monitor (CAM) (Bardy Diagnostics, Inc.)**
  - Standard DR180 Series 3-channel (leads V1, II, and V5) Holter monitor (NorthEast Monitoring, Inc.)
- 50 consecutive adult patients enrolled from a single center:
  - Both devices simultaneously applied and removed after 24 hours
  - Each patient served as their own control
- Holter and **CAM** reports were read in a blinded fashion by two electrophysiologists unaware of the findings in the other corresponding ECG recording
- All patients, technicians, and physicians completed a questionnaire on comfort, ease-of-use, and potential complications

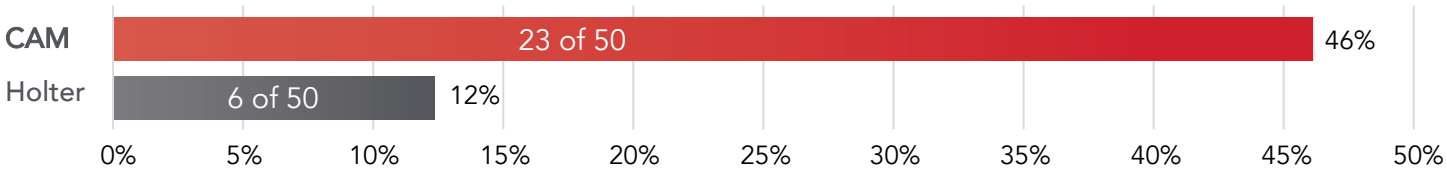


	OUTCOME MEASURES
Primary	• Impact on Clinical Decision-Making When Comparing Rhythm Findings
Secondary	• Patient Assessment - Device Preference - Comfort - Skin Irritation - Discreetness - Effect on Daily Activities - Effect on Sleeping • Clinician Assessment - Device Stability - Ease of Attachment

STUDY RESULTS

IMPACT ON CLINICAL DECISION-MAKING

The **CAM** Patch yielded clinically significant information that either altered patient management and/or prevented the need for intervention as indicated by the Holter.



Number of Patients with Clinically Significant Arrhythmia (n=50, p<0.001)

The **CAM** Patch identified arrhythmias missed or misidentified by the Holter in over a third of the patients. The Holter identified only a subset of clinically significant arrhythmias, all of which were also found using the **CAM** Patch.

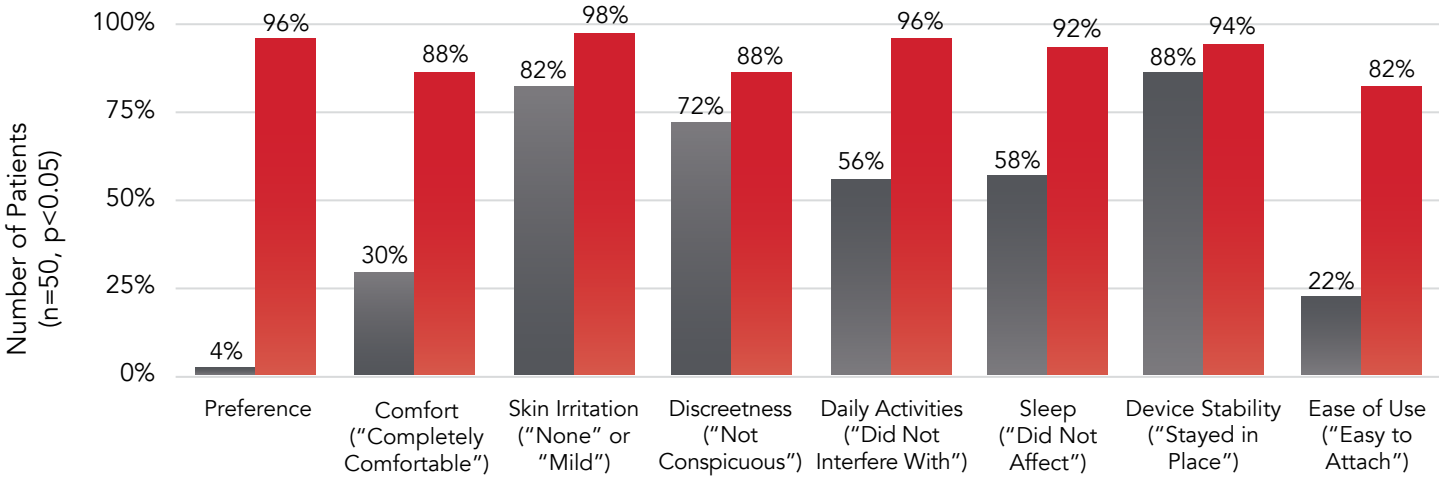
Missed by Holter (7 of 50 patients)	Misidentified by Holter (10 of 50 patients)	Identified by Both (6 of 50 patients)
• AFl, in addition to AF – Identified as AF only on Holter (3 patients) • NSVT • Sinus Arrest • AVB • CHB and Sinus Arrest*	• AT – Identified as AF on Holter (2 patients) • ST – Identified as AT on Holter • No AF – Identified as AF on Holter • AF – Identified as AT on Holter • ST – Identified as AT on Holter • No PVCs – Identified noise as frequent PVCs on Holter • 1:1 AT – Identified as ST on Holter • AT with no VT – Identified as AF with VT on Holter • AFl with CHB – Identified as AF with junctional escapes on Holter	• NSVT (2 patients) • Sinus Arrest • AF & AFl • AF • Wenckebach AVB

** 1 pt had 2 arrhythmias missed*

Abbreviations: AF, atrial fibrillation; AFl, atrial flutter; AT, atrial tachycardia; AVB, atrioventricular block; CHB, complete heart block; NSVT, nonsustained ventricular tachycardia; PVCs, premature ventricular contractions; ST, sinus tachycardia.

PATIENT & CLINICIAN ASSESSMENT

The **CAM** Patch outperformed the Holter monitor on all comparison metrics. The **CAM** Patch was significantly preferred by patients over the Holter monitor.



STUDY CONCLUSION

In a direct comparison on 50 consecutive patients, the single-channel **CAM** Patch monitor demonstrated to be comfortable, easy-to-use, and designed to reliably capture the P-wave as compared to the Holter monitor. As a result of the superior ECG clarity, it resulted in significantly improved rhythm diagnoses when compared to the standard 3-lead Holter.

The Carnation Ambulatory Monitor is designed to provide extended-duration cardiac monitoring for people who are suspected
of having cardiac arrhythmias. **Rx only.** For safe and proper use of the products mentioned herein, please refer to the Instructions for Use.

Source: Rho R, Vossler M, Blancher S, Poole JE. Comparison of two ambulatory patch ECG monitors: The benefit of the P-wave and signal clarity. American Heart Journal. 2018;203:109-117. doi:10.1016/j.ahj.2018.03.022.

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