

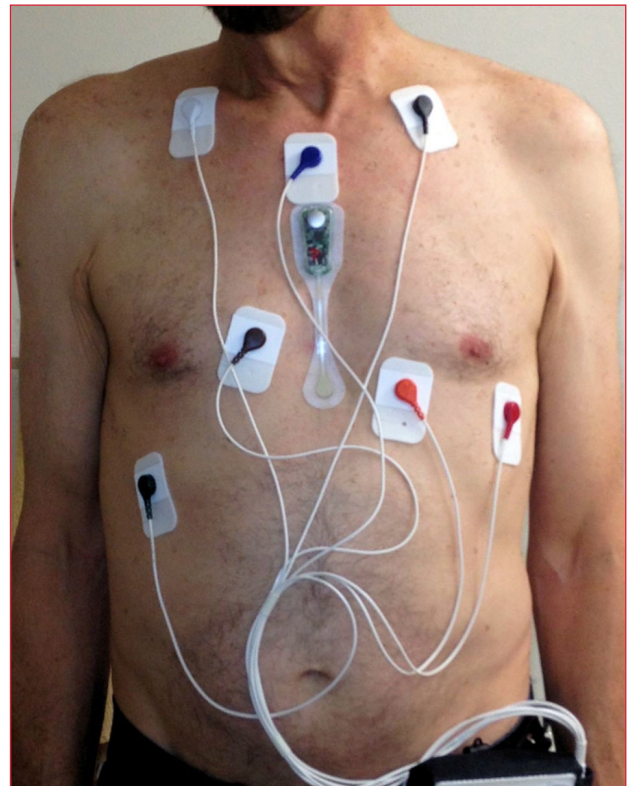
CAM vs. Holter Study

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 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

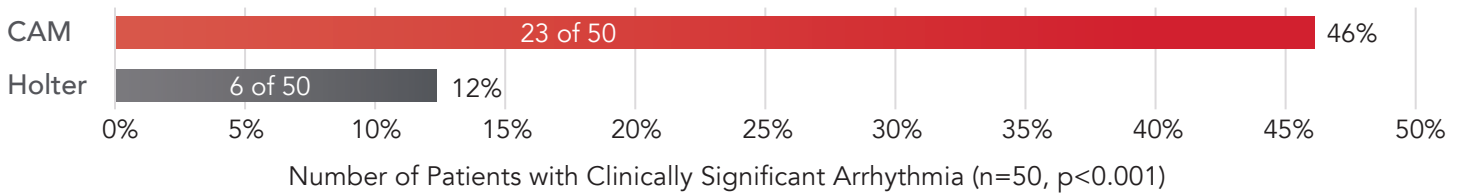


	OUTCOME MEASURES
Primary	<ul style="list-style-type: none">• Impact on Clinical Decision-Making When Comparing Rhythm Findings
Secondary	<ul style="list-style-type: none">• Patient Assessment<ul style="list-style-type: none">- Device Preference- Comfort- Skin Irritation- Discreetness- Effect on Daily Activities- Effect on Sleeping• Clinician Assessment<ul style="list-style-type: none">- Device Stability- Ease of Attachment

STUDY RESULTS

IMPACT ON CLINICAL DECISION-MAKING

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



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 on the CAM patch.

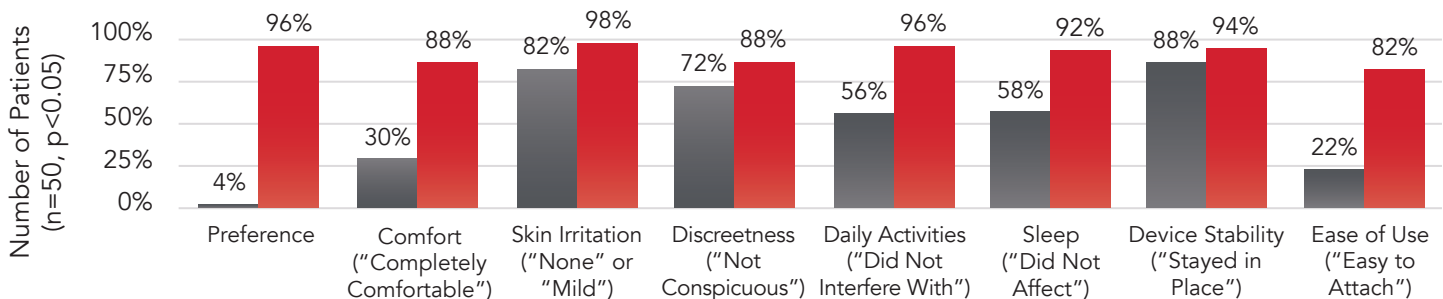
Missed by Holter (7 of 50 patients)	Misidentified by Holter (10 of 50 patients)	Identified by Both (6 of 50 patients)
<ul style="list-style-type: none"> • AFI, in addition to AF – Identified as AF only on Holter (3 patients) • NSVT • Sinus Arrest • AVB • CHB and Sinus Arrest* 	<ul style="list-style-type: none"> • 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 • AFI with CHB – Identified as AF with junctional escapes on Holter 	<ul style="list-style-type: none"> • NSVT (2 patients) • Sinus Arrest • AF & AFI • AF • Wenckebach AVB

* 1 pt had 2 arrhythmias missed

Abbreviations: AF, atrial fibrillation; AFI, 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 over the Holter monitor.



STUDY CONCLUSION



The single-channel CAM patch demonstrated to be comfortable, easy-to-use, and designed to reliably capture the P-wave. As a result of the superior ECG clarity, it resulted in significantly improved rhythm diagnoses and avoided inaccurate diagnoses made by the standard 3-lead Holter.

Source: Smith WM, Riddell F, Madon M, Gleva MJ. Comparison of diagnostic value using a small, single channel, P-wave centric sternal ECG monitoring patch with a standard 3-lead Holter system over 24 hours. *American Heart Journal*. 2017;185:67-73. doi:10.1016/j.ahj.2016.11.006