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

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

Holter monitors are a mainstay of clinical practice, but are cumbersome to access and wear and P-wave signal quality is frequently inadequate.

Methods This study compared the diagnostic efficacy of the P-wave centric electrocardiogram (ECG) patch (Carnation Ambulatory Monitor) to standard 3-channel (leads V1, II, and V5) Holter monitor (Northeast Monitoring, Maynard, MA). Patients were referred to a hospital Holter clinic for standard clinical indications. Each patient wore both devices simultaneously and served as their own control. Holter and Patch reports were read in a blinded fashion by experienced electrophysiologists unaware of the findings in the other corresponding ECG recording. All patients, technicians, and physicians completed a questionnaire on comfort and ease of use, and potential complications.

Results In all 50 patients, the P-wave centric patch recording system identified rhythms in 23 patients (46%) that altered management, compared to 6 Holter patients (12%), \( P < .001 \). The patch ECG intervals PR, QRS and QT correlated well with the Holter ECG intervals having correlation coefficients of 0.93, 0.86, and 0.94, respectively. Finally, 48 patients (96%) preferred wearing the patch monitor.

Conclusions A single-channel ambulatory patch ECG monitor, designed specifically to ensure that the P-wave component of the ECG be visible, resulted in a significantly improved rhythm diagnosis and avoided inaccurate diagnoses made by the standard 3-channel Holter monitor. (Am Heart J 2017;185:67-73.)

Since the advent of ambulatory electrocardiogram (ECG) recording in 1961 by Norman Holter, diagnosing cardiac rhythm disorders with Holter monitors has been a mainstay of clinical practice.\(^1\)\(^5\) Excluding the 12 lead ECG, the Holter monitor remains the most common tool for examining the heart rhythm. A Holter monitor traditionally records every heartbeat for 24 hours but requires wearing multiple electrodes and carrying a recording system that is usually worn on a belt or on a holster strap coupled to at least 3 cables attached to monitoring electrodes on the chest and abdomen. Such systems are relatively bulky and difficult to conceal at work or in public venues. Also, Holter electrodes often disconnect, especially during sleep when the patient may be unaware of electrode detachments and cannot be worn during showering. Similarly, exercising may result in electrode disconnection with perspiration and movement. Several patch monitors have been developed recently as alternatives to the Holter system.\(^6\)\(^9\) Patch monitors have, however, allowed for longer duration monitoring and, consequently, have matched or outperformed Holter yields, although the comparison, in this circumstance is merely one of compensating for lower diagnostic yield on a daily basis by increasing duration of recording.\(^10\)

The key to improving diagnostic yield, regardless of the specific duration of ECG monitoring, is the quality of the P-wave. Clarity of the P-wave, its morphology and its relationship and timing to the QRS is crucial for defining an arrhythmia's specific mechanism. Holters,
with multiple views of the cardiac signal and large inter-electrode spacing are more likely to capture the P-wave during an arrhythmia. Patch systems, on the other hand, with their single, short vector make the ECG’s P-wave signal detection relatively difficult, but they compensate partially by being easier to wear and adhering for longer periods.

In this study, we tested a new system whose design ensures both ease-of-use and visibility of the P-wave. We prospectively compared this new patch system with a standard Holter monitor over the limited period of 24 hours so as to not conflate ECG signal quality with duration of recording as regards diagnostic value.

### Methods

The purpose of this study was to compare the clinical value of an easier-to-use cardiac rhythm monitoring patch system, the Carnation Ambulatory Monitoring (CAM) System with a standard Holter recording. Following informed consent, approved by the regional Ethics Committee, 50 consecutive patients were enrolled from a population of individuals referred for rhythm monitoring for routine indications: syncope, near-syncope, palpitations, and/or the monitoring of known cardiac rhythm problems like atrial fibrillation. Each individual served as their own control and wore both systems simultaneously (Figure 1). Because of the location of use for the CAM system, patients were excluded from study participation if they had any skin rash or infection over the sternum or had a sternal incision within 3 months from the date of enrollment.

The Holter uniformly used in this study was a state-of-the-art NorthEast Monitoring, DR 180 series 3-Channel Holter Recorder (Maynard, MA). All signals recorded on this device were analyzed using LX Analysis NEMON software, version 5.4F.

The new P-wave centric patch monitor, the CAM system is produced by Bardy Diagnostics (BDx), Charlotte, NC. The CAM system is optimized for both ease of use and for maximum P-wave clarity to improve arrhythmia diagnosis. It is shaped for application on the sternum, both from the perspective of comfort, especially for long-term wear by women, but more importantly, because of the sternal location’s proximity to the atria, and the evidence that myocardial currents flows through the mediastinum to the skin overlying the sternum.11-13 The length is 5.75 in and maximum width is 1.5 in with an hourglass shape narrowing to 0.375 in. The weight is 13 g with an inter-electrode distance 3.5 inches.

NEMON software, Research version of LX Analysis was used to receive the signals and process them. Outputs from LX Analysis was then formatted for ease of interpretation as shown in Figure 2. Both Holter and CAM recordings were read by independent readers from Digicardio, Inc, Mission Viejo, CA.

The primary endpoint of the trial was to compare the rhythm findings from each device that would provide a clinically important finding that could alter patient management, for example, the presence of previously undiagnosed atrial flutter in an atrial fibrillation patient considered for catheter ablation. Recordings were made with both systems only over a 24 hour period. Two blinded cardiac electrophysiologists cross-read each recording because reporting format differed between the two monitors, care was taken to prevent unintended bias in the comparisons. Consequently, each cardiac electrophysiologist independently reviewed the data in “scrambled” batches. One viewed the 50-patient batch of Holter data first, then the other viewed the 50-patient batch of patch data first. Readings were done separately. Patient identifiers were excluded upon review and the order of recordings was scrambled in both batches. Their identified arrhythmias were then entered into the database.

In addition to rhythm categorization, ECG parameters of PR, QRS, and QT intervals were correlated between the 2 systems. Patient comfort and ease of use was assessed as a preference: Holter, CAM, both, or neither. Skin irritation was also evaluated for both systems as none, mild, moderate or severe in the underlying skin according to a qualitative subjective assessment by the patient at the site of the monitoring electrodes. Subjects were queried as to whether they felt the monitors would be inconspicuous or not and whether or not activities of daily living were compromised, including the ability to sleep. Finally, the investigator assessed device stability at the end of the recording period and was asked his/her preference.

Descriptive statistics (mean, SD, range) were used to summarize quantitative variables. Diagnostic comparisons were compared using a standard $\chi^2$ test. Categorical data
obtained from the patient and investigator questionnaires were reported as a count (percentage) by category for each question.

No extra mural funding was used to support this work. Monitors were provided free of charge by Bardy Diagnostics. The authors are solely responsible for the design and conduct of this study, all study analysis, the drafting and editing of the manuscript, and its final contents.

Results

For the 50 patients studied, 33 (66%) were male. The mean age was 54.8 ± 17.8. Multiple indications for Holter monitoring were sometimes present. Syncope was the indication in 10 (20%), near-syncope in 8 (16%), palpitations in 14 (28%), management of known arrhythmias in 17 (34%), and unlabeled in 1 (2%).

PR, QRS, and QT interval correlations are shown in Figure 3. The correlation coefficients between Holter and CAM measurements were 0.93, 0.86, and 0.94, respectively.

The CAM patch recording system yielded clinically significant information that either altered patient management and/or prevented the need for intervention as indicated by the Holter (eg, noise misidentified as ventricular ectopy) in 23 of 50 patients (46%) with 3 of the 23 patients having 2 significant findings found on the CAM. The Holter recordings identified only 6 of 50 patients (12%) with significant findings. Moreover, all 6 Holter monitor recordings with clinically significant arrhythmias were also found on the Carnation monitor. Table lists the 23 pertinent events identified by the CAM.

Examples of the differences in findings between the two recording methods for the exact same arrhythmia simultaneously documented in the same patient are shown in Figure 4. All images are untouched and represent precisely the ECG seen by the managing cardiologist, except for the added arrows and annotations. Such arrows and annotations are highlighted in the figure legends to facilitate explanation of a particular rhythm finding.

For the endpoint of patient comfort, 48 of 50 patients (96%) preferred wearing the patch monitor compared to the 3-lead standard Holter. At the time of Holter removal, 15 patients (30%) reported that they felt the Holter was completely comfortable to wear. On the other hand, 44 (88%) of those wearing the CAM felt that it was completely comfortable to wear.

Skin irritation was either “none” or “mild” in 49 patients (98%) using the CAM patch and none experienced severe skin irritation. In comparison, “none” or “mild” skin irritation occurred in 41 patients (82%) using the Holter electrodes, but 3 Holter patients (6%) reported “severe” skin irritation.

Concealment of the fact of wearing a medical device during activities of daily living is important for many people. Because each patient was simultaneously wearing both devices, patient assessment of the acceptability of each device is inevitably subject to possible interaction. Nevertheless, some degree of comparison is possible. Fourteen patients considered the Holter was conspicuous (28%) but only 6 patients felt this was the case with the CAM patch (12%). One patient failed to provide a response. Activities of daily living were compromised by wearing the Holter in 22 patients.
over the 24 hour period the recording was made compared to 2 with the CAM patch. Sleep was considered to be affected in 21 patients (42%) by the Holter but only 4 (8%) by the CAM patch. All comparisons yield a $P < .05$ in favor of the CAM.

Device stability was also assessed by the investigator. The Holter system stayed in place for 24 hours as initially attached in 44 (88%) and became unattached in 5 (10%) with no assessment in 1 (2%). For the CAM, the system stayed in place in 47 (94%), unattached in 1 (2%) with no assessment in 2 (4%). When asked which system the patients preferred, only 3 (6%) preferred the Holter while 43 (86%) preferred the CAM patch; four (8%) gave no response, $P$-value $<.05$ in each case.

The subjects felt that the Holter did not ‘interfere with routine activities of daily living’ 56% of the time and did not affect the subject’s ability to sleep 58% of the time. The CAM patch was deemed by the subjects to not ‘interfere with routine activities of daily living’ 96% of the time and did not affect sleep 92% of the time, $P < .05$.

Technicians reported that they found the Holter device ‘easy to attach to the patient’ only 22% of the time compared to their use of the CAM patch which they deemed ‘easy to attach to the patient’ 82% of the time, $P < .05$.

**Discussion**

This study demonstrated both superior diagnostics per 24 hours and superior comfort and ease of use of the Carnation Ambulatory Monitor P-wave centric patch compared to a state-of-the-art, traditional Holter recorder. The reason for improved diagnostic yield has to do with the design of the patch system to focus on P-wave fidelity as critical to arrhythmia diagnosis. The reason for improved comfort and ease of use has to do with the device’s small size, its light weight, location of use, and female friendly shape. The sternal location enhances P-wave recording as the right atrium is beneath the sternum, and is an easily identified, unambiguous location for patch application. Moreover, in females, and in some men, the sternum is free of hair and merely requires removal of skin oils for proper patch application. Importantly, for women, the narrow, hourglass design of the patch, makes it more comfortable for wear in the inter-mammary space.

Despite minor improvements, Holter monitors have remained essentially unchanged from both the physician and the patient perspective for nearly 45 years. They require wearing multiple electrodes and carrying a recording system that is usually worn on a belt or on a holster strap. Although current generation Holters are smaller, they remain relatively bulky and difficult to conceal. Further, the use of wires to connect electrodes to a device increases complexity and the likelihood of a disconnection during activity. Standard Holters also can disconnect during sleep and must be removed during showering. For these reasons, and for the historically limited diagnostic yield of Holters, efforts have grown to develop a patch electrode to replace the Holter monitor.

Patch replacements of Holters have been led by the work of iRhythm Technologies, who for the past 6 years,
The authors have sought to simplify the dermal ECG recording process with its Zio and Zio-XT patch recording systems. They have demonstrated both increased ease of use and improved diagnostics, the latter, however, by increasing recording time for many more days (up to 14) than a standard Holter. No patch system, however, has been able to match a Holter on a per-24 hour-basis for diagnostic yield for two reasons. First, Holters provide multiple views of the cardiac signal and, as such, are more likely to capture the P-wave during an arrhythmia. Second, the short vector of most patch systems makes ECG signal detection relatively difficult in comparison to the large interelectrode spacing that a Holter wire system allows. Thus, the most commonly used patch system heretofore has underperformed a Holter on a per-day basis.10

To circumvent the traditional problems inherent in signal to noise limitations of short-patch vectors, the CAM employs a new patch system circuit design to lower the noise floor together with advanced compression signal processing to ensure P-wave recording. The QRS signal, with its higher frequency domain and much larger signal amplitude is usually relatively easy to capture from almost any electrode pair on the thorax. By using the sternal location, both the P-wave and the R-wave are more easily identified and thereby facilitate rhythm analysis.

Older generations of electrocardiographers understood the seminal value of accurate p wave identification—“cherchez le p’. Our examples shown in Figure 4 emphasize the clinical value conferred by such a strategy. In Figure 4G, being confident the p wave morphology during the pause is clearly different to the sinus beats removes any uncertainty about possible AV block and the need for pacing. In Figure 4C minor atrial bigemini is distinguished from possible second degree AV block. In Figure 4D, the clear demonstration of atrioventricular dissociation confirms the broadcomplex tachycardia is ventricular in origin.

In addition to improved p wave clarity, the CAM provides medium field and far field views which contribute additional diagnostic information. In Figure 4A the far field view clearly shows the presence of atrial flutter as a separate consistent cycle length above the scatter plot of atrial fibrillation. Again, in Figure 4F, the two different cycle lengths of the two alternating junctional escape foci are seen as nearly flat isoelectric lines on the RR interval plot. These are but two examples of the insights gained from multiple perspectives on a particular rhythm disorder.

There are some limitations to our study. Firstly, we undertook our comparison using only one Holter system. However, we regard the Holter selected as a superior recording device and one which is commonly employed globally. We also acknowledge that true blinding is not possible when comparing a 1-lead to a 3-lead system. However, as described in the Methods, we endeavored to compensate for the “visibility” of the ECG recording system by employing scrambled batch reads.

Although this study was undertaken only in adults, we believe the CAM monitoring system will also be valuable for monitoring arrhythmias in children, where movement artifact frequently degrades the quality of Holter recordings.

**Conclusion**

This study demonstrates that the CAM system, a small, comfortable and easy to use patch recording system designed to reliably capture the P-wave, can be used to more accurately identify rhythm disorders compared to a standard Holter monitor.

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<table>
<thead>
<tr>
<th>Table. A total of the 23 clinically pertinent events identified by the CAM compared to 6 by the Holter including arrhythmias misdiagnosed on the Holter but shown to be inaccurate on the CAM</th>
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<tbody>
<tr>
<td>1 had NSVT (#1)</td>
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<tr>
<td>3 had Atrial flutter, in addition to AF. Holter only identified AF (#4, 16, 37)</td>
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<tr>
<td>1 had sinus arrest (#7)</td>
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<tr>
<td>1 had AV block (#8)</td>
</tr>
<tr>
<td>2 had AT, and not AF as in Holter (#11, 12)</td>
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<tr>
<td>1 had ST rather than AT as in Holter (#19)</td>
</tr>
<tr>
<td>1 had no AF seen in the CAM which was misidentified as AF in the Holter (#20)</td>
</tr>
<tr>
<td>1 had AF on the CAM but misidentified as AT on the Holter (#21)</td>
</tr>
<tr>
<td>1 had CHB and sinus arrest, not seen with Holter (#22)</td>
</tr>
<tr>
<td>1 had ST falsely called AT on the Holter (#26)</td>
</tr>
<tr>
<td>1 had noise identified as frequent PVCs on Holter, which didn’t exist (#27)</td>
</tr>
<tr>
<td>1 had clear 1:1 AT, not ST, on the CAM (#34)</td>
</tr>
<tr>
<td>1 had AT, rather than AF as was misidentified on the Holter, and no VT was present as misidentified on the Holter (#41)</td>
</tr>
<tr>
<td>1 had AF and junctional escapes were misidentified on the Holter that were actually AF with CHB on the CAM (#46)</td>
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**Identified by both monitors similarly:**

- NSVT (#10)
- Sinus arrest (#28)
- AF and AFl, and marked bradycardia (#30)
- NSVT (#31)
- CHB, Wenckebach AVB in presence of muscular dystrophy (#38)

**Abbreviations:** AF, Atrial fibrillation; AFl, atrial flutter; AT, atrial tachycardia; AV, atrioventricular block; CAM, Carnation Ambulatory Monitor; CHB, complete heart block; NSVT, non-sustained ventricular tachycardia; PVCs, Premature Ventricular Contractions; ST, sinus tachycardia.
Robert Edwards and Dr. Jeanne E. Poole, and review of the paper for technical accuracy by Gust Bardy.

References


The top panel shows the ECG from the P-wave centric sternal patch. The bottom panel shows the rhythm recorded with the standard 3 lead Holter monitor. Both panels are duplicated exactly as presented to the managing physicians. Some lettering, however, is added to these images to aid in rhythm explanation. A, In the top tracing, there is evidence of transient atrial flutter affecting the specifics of the ablation procedure. The RR plot also shows a transient 2:1 atrial flutter episode after a prolonged period of atrial fibrillation at the arrow. The atrial flutter lasts for about 2 minutes (AFL at arrow) before returning to atrial fibrillation in a slightly form. The bottom Holter tracing is consistent with atrial flutter but easily overlooked as atrial fibrillation. B, In the top tracing there is clear sino-atrial exit block with junctional escape beats. The RR interval plot is consistent with frequent sino-atrial exit block. The specific cause of the pauses in the bottom Holter tracing event is unclear. C, In the top tracing and in both the 25 mm/sec and 5 mm/sec recordings, the second P-wave (P1) is premature, indicating that this second P-wave (P2) is ectopic. The RR plot also shows a pattern of dense atrial bigeminy. In the bottom Holter tracing, the rhythm could be misinterpreted as Wenckebach block. D, Top tracing shows retrograde VA conduction on beats 2, 3 and 4 of the wide complex tachycardia episode but no retrograde P-wave on the first beat in the series, confirming that it is VT. The RR plot also is consistent with frequent ventricular ectopy. The bottom tracing shows a wide complex 4 beat run, likely VT, but not definitively so. E, The top tracing shows onset of rapid, accelerating atrial tachycardia with subsequent aberration. The red arrows show the first 5 ectopic atrial beats. The bottom Holter tracing was read as ventricular tachycardia. This patient was treated for prior, documented atrial tachycardia with the patient continuing to have palpitations. F, The top tracing shows atrial flutter with two different alternating junctional escape rhythms during complete heart block. The RR interval plot confirms two, flat isoelectric lines reflecting the two different junctional escape rhythms. The bottom Holter tracing shows atrial flutter with unclear conduction, possibly appearing as slow antegrade conduction. G, Top tracing shows a run of atrial tachycardia with block. The P-wave morphology of the atrial tachycardia (P2) is clearly different than that of the sinus beats (P1). The pause in AV conduction is at least influenced by the burst of premature beats and, unlike the bottom Holter tracings, where the P-wave is not distinctly different than the sinus P-wave and there is a strong indication that there is a problem with AV conduction.