Novel electrogram device with web-based service centre for ambulatory ECG monitoring

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ABSTRACT

Introduction: Arrhythmias are often intermittent, and a normal electrocardiogram (ECG) may not be diagnostic. The purpose of this study was to evaluate the usefulness of HeartWave500 (HW), a novel web-based ambulatory ECG monitoring device.

Methods: A total of 120 patients from the National Heart Centre, Singapore were prospectively randomised in a three to one ratio to either HW or a standard transtelephonic (TT) event recorder. HW records five leads and transmits to an internet server, while TT transmits audio data to a central station. Monitoring was conducted for two weeks. The diagnostic yield was calculated in two ways: the percentage of patients successfully diagnosed as a function of time, and the absolute number of new diagnoses per patient per week.

Results: 33 patients (14 male, 19 female; mean age 49.6 +/− 11.1 years) were randomised to TT. 87 patients (32 male, 55 female; mean age 43.7 +/− 12.2 years) were randomised to HW. At the end of two weeks, the percentage of patients diagnosed with any arrhythmia was similar for both groups (66.7 percent for TT versus 67.8 percent for HW). There was a trend toward significance for the number of diagnoses per patient per week for Week 2 between TT and HW (0.58 +/− 0.75 versus 0.34 +/− 0.55, p is 0.06). Transmitted ECGs were read earlier for HW (18 minutes vs. 1107 minutes, Mann-Whitney non-parametric test, p is less than 0.05). Transmitted recordings that were unreadable were also significantly lower for HW (8.0 percent vs. 17.6 percent, chi-square test, p is less than 0.05).

Conclusion: HW and TT have similar diagnostic yields. There is a trend toward a shorter monitoring time for HW. The ability of HW to record and transmit via the web, the earlier review of data and low unreadable data make HW an attractive alternative to TT.

Keywords: arrhythmia detection, HeartWave500, transtelephonic event recorder, web-based monitoring

INTRODUCTION

Cardiac arrhythmia is a potential cause of palpitations. Due to the paroxysmal nature of the symptoms, a conventional electrocardiogram (ECG) can be generated in only a third of patients. The demand for an ambulatory form of electrographic monitoring was recognised as early as the 1940s, when Dr Norman Jeff Holter developed a 34 kg backpack that could simultaneously record and transmit ECGs. The modern "Holter" monitor has shrunk dramatically and can record up to 1–2 days of continuous data. The specificity of the monitor is low however, with a reported diagnostic yield of only 33%–35%.[1-3] A transtelephonic (TT) electrographic monitor is capable of recording electrographic data and converting it to an audio signal. These signals are then transmitted by telephone to a central station. A TT device can monitor patients for a longer time, and the recordings have better correlations with patient symptoms. The reported diagnostic yield for TT is 55%–83%.[2-4]

With the rapid development of telemedicine worldwide, a web-based ambulatory monitoring device would be the next logical step. The aim of our study was to explore the usefulness of HeartWave500 (HW) (NextWave Biomedical, Singapore), a novel internet-based ambulatory ECG monitoring device. The HW (Fig. 1) was developed as a replacement for our current TT event recorders. It is no larger than a personal digital assistant, runs on AA batteries, and records using five leads. It is an event recorder that can record up to

Fig.1 HeartWave500 device

three events at any one time. The recorded ECGs are downloaded onto a computer with the use of a standard universal serial bus port. The images are then emailed as an attachment to a central mainframe computer. A computer-generated provisional diagnosis is available immediately. Should an abnormal rhythm be detected, a telephone short message service (SMS) is forwarded to a technician or physician. Patient information, baseline ECGs and the transmitted recordings can be accessed via the secure website. Symptoms can be reported and medical advice can be dispensed online, thus providing reassurance to patients.

METHODS

Patients were randomly assigned in a 3:1 ratio to either HW or a standard TT event recorder (RhythmCard, Intromedix Inc Central station: Cardiocomm GEMS II, CardioComm Solutions Inc, Victoria, BC, Canada). Informed written consent was obtained, and all the patients were counselled on the proper use of either the TT or HW device by our trained staff. One trial transmission was performed in the hospital under supervision in order to ensure proficiency with handling the devices. Helplines were made available to all patients throughout the two-week duration of monitoring. The patients were encouraged to maintain a diary of symptoms. Baseline characteristics for age, gender, race and drug therapy were recorded. History of hypertension, diabetes mellitus, hyperlipidaemia and smoking were noted. Symptoms of palpitations were defined as any feelings of abnormal heartbeat or rhythm experienced by the patient. Presyncope was defined as having symptoms of light-headedness or dizziness, while syncope was the complete loss of consciousness. The durations of all the three symptoms were documented (< 1 min, 1–5 min, 6–120 min or > 120 min).

The diagnoses were divided into either benign

cardiac rhythms (normal sinus rhythm, sinus arrhythmia, sinus tachycardia [heart rate > 100/min], premature ventricular contractions, low atrial rhythm, wandering atrial pacemaker, occasional atrial premature beats and normal paced rhythm), or clinically significant cardiac rhythms (ventricular tachycardia, sinus bradycardia [< 50/min], complete or high-grade heart block, ventricular flutter/fibrillation, supraventricular tachycardia [SVT], atrial flutter, atrial fibrillation [AF] and junctional tachycardia). For the HW device, a computer-generated diagnosis was also available. These include normal sinus rhythm, sinus arrhythmia, sinus tachycardia, premature ventricular contractions, ventricular tachycardia, sinus bradycardia, second-degree heart block and ventricular flutter/fibrillation.

For the purpose of this study, initial transmission of a particular rhythm was considered as a diagnostic event, while further transmission of the same rhythm was not considered as a new diagnosis. Transmissions of a different arrhythmia were considered to represent additional diagnoses. The diagnostic yield for both the TT and HW devices were calculated in two ways: the percentage of patients successfully diagnosed as a function of time; and the absolute number of new diagnoses per patient per week. For the first outcome, the cumulative percentage of patients with one, two or three diagnoses as a function of time was calculated. For the second outcome, the absolute number of new diagnoses made in a given week was divided by the number of patients who continue to wear either the TT or HW device.

The data was analysed using the Stata program (Stata, College Station, TX, USA). A comparison between the continuous variables was performed using the Student's *t*-test or the Mann-Whitney non-parametric test. For categorical variables, a comparison was made using the Pearson chi-square test. The cumulative percentage of patients with any diagnosis as a function of time was estimated using the Kaplan-Meier technique. For the second outcome (number of diagnoses/patient/week), a comparison was made between the two devices using the Student's *t*-test.

RESULTS

The baseline characteristics of both the TT and HW groups of patients are shown in Table I. 33 patients were randomised to the TT group. Their mean age was 49.6 ± 11.1 (range 23–73) years, with 14 (42%) male and 19 (58%) female. All 33 patients had palpitations (seven [21%] patients < 1 min, 12 [36%] patients 1–5 min, nine

Table I. Baseline characteristics.

Characteristic	No. (%)	
	Transtelephonic (n = 33)	HeartWave500 (n = 87)
Gender		
Male	14 (42%)	32 (37%)
Female	19 (58%)	55 (63%)
Race		
Chinese	27 (82%)	70 (80%)
Malay	1 (3%)	5 (7%)
Indian	3 (9%)	9 (10%)
Others	2 (6%)	3 (3%)
Symptoms		
Palpitations	33 (100%)	83 (95%)
Presyncope	10 (30%)	24 (24%)
Syncope	2 (6%)	3 (3%)
Anti-arrhythmic drugs	5 (15%)	15 (17%)
Hypertension	1 (3%)	12 (14%)
Smoking	5 (15%)	5 (6%)
Hyperlipidaemia	9 (27%)	10 (11%)
Diabetes mellitus	1 (3%)	3 (3%)

[27%] patients 6 min–1 hr, five [15%] patients > 1 hr in duration). Ten patients had presyncope (four patients < 1 min, three patients 1–5 min, two patients 6 min–1 hr and one patient > 1 hr in duration). Two patients had syncope. One patient had a previous history of non-sustained ventricular tachycardia and another had mitral valve prolapse. Four patients were on anti-arrhythmic drugs, two were on Vaughan Williams class II drugs, atenolol (Beacons Pharmaceuticals, Singapore) and propanolol (Astra Zeneca UK Ltd, London, UK), one was on Vaughan Williams class IV drugs, diltiazem (Beacons Pharmaceuticals, Singapore) and one on Vaughan Williams class I drugs, disopyramide (Pfizer Inc, New York, NY, USA)

87 patients were randomised to the HW group. Their mean age was 43.7 ± 12.2 (range 21–56) years, with 32 (37%) male and 55 (63%) female. 83 (95%) patients had symptoms of palpitations at presentation (20 [24%] patients < 1 min, 21 [25%] patients 1–5 min, 31 [37%] patients 6 min–1 hr, 11 [13%] patients > 1 hr in duration). 24 patients had presyncope (eight patients each for < 1 min and 6 min–1 hr, seven patients for 1–6 min, one patient for > 1 hr in duration). Three patients had previous syncopal episodes. 21 patients had a history of arrhythmia or structural heart disease. Six had a history of AF. Of these, one patient had a previous AF ablation, while another had a previous surgical Maze procedure. Three patients had previous documented SVT. Two patients had previous atrial ectopics documented, while another two had ventricular ectopics. One patient had both atrial and ventricular ectopics

and one was known to have arrhythmogenic right ventricular cardiomyopathy. One patient had a history of non-sustained ventricular tachycardia. Three patients had previous permanent pacemaker implantation, and one patient had a ventricular septal defect repair procedure performed as a child. Two patients were on only Vaughan Williams class I drugs, flecainide (iNova Pharmaceuticals Pty Ltd, Thornleigh, NSW, Australia) and propafenone (Abbott Laboratories, Abbott Park, IL, USA), seven patients were on class II drugs alone (four on atenolol, three on propanolol) while two patients were on both flecainide and bisoprolol [Merck Serono, Geneva, Switzerland]. Four patients were on Class III drugs (two on sotalol [Pharmaforte Pte Ltd, Singapore], and two on amiodarone [Sanofi-Avents, Paris, France]). There was no statistically significant difference in the baseline characteristics for age, gender, race, symptoms and duration at presentation, as well as history of hypertension, diabetes mellitus and smoking status between the two groups.

For TT, a total of 108 transmissions were made by 33 patients over the two weeks of monitoring. Of these, 19 (18%) were unreadable. The median time from ECG transmission to being read by a technician was 1,107 (range 2–19,581) minutes. Normal sinus rhythm was diagnosed in 16 patients, sinus arrhythmia in 12, sinus tachycardia in eight, premature ventricular contractions in four, atrial premature beats in two, and sinus bradycardia, supraventricular tachycardia and atrial fibrillation in one patient each. For HW, the 87 patients in this group had 609 attempts at recordings and a corresponding 609 attempted transmissions (from patient diaries). 493 (81%) attempts at recording were successful, and of these successful recordings, 445 (90%) were transmitted. However, the central station received only 424 transmissions; the remaining 21 transmissions were unsuccessful. The median time from ECG transmission to being read by a technician was 18 (range 0–3,511) minutes. Of the 424 successful transmissions, 19 (4%) were unreadable recordings. Normal sinus rhythm was diagnosed in 63 patients, sinus arrhythmia in 18, sinus tachycardia in nine, premature ventricular contractions in ten, atrial premature beats in three, sinus bradycardia in one, AF in two (2%) and normal paced rhythm in three (3%) patients. A comparison between the physician diagnosis and computer-generated diagnosis was also made. Of the 424 transmissions, a consistent diagnosis was made by both the reporting physician and the computer-generated report in 313 (74%) cases.

The percentage of patients successfully diagnosed

as a function of time was calculated for both devices. The TT device yielded 0.55 ± 0.71 diagnoses/patient/week in Week 1 and 0.58 ± 0.75 diagnoses/patient/week in Week 2. For HW, 0.62 ± 0.77 diagnoses/patient/week were made in Week 1 and 0.34 ± 0.55 diagnoses/patient/week in Week 2. There was a trend toward significance for Week 2 between TT and HW (p = 0.066) but not for Week 1 (p = 0.6253). The cumulative percentage of patients with one, two or three diagnoses as a function of time was also calculated. At the end of two weeks, 66.7% of patients in TT vs. 67.8% of those in the HW group had one or more diagnoses made (Fig. 2).

Fig. 2 Kaplan-Meier curves showing the cumulative diagnostic yield of transtelephonic and HeatWave500 device for patients with one, two or three diagnoses as a function of duration of monitoring.

DISCUSSION

Compared to a standard Holter, the superiority of patient-activated TT devices in terms of efficacy and cost-effectiveness is well proven. Studies have shown that a monitoring duration of two weeks is the most cost-effective. In a study by Reiffel et al, it was found that 87% of patients would have an initial transmission corresponding to palpitations in the first two weeks.[5] Only an additional 9% yield would be achieved if monitoring was extended to four weeks. This was the basis for the two-week monitoring period utilised in this study.

Two outcomes were used to compare the effectiveness of HW. The cumulative percentage of patients with one, two or three diagnoses as a function of time was similar between TT and HW (66.7% vs. 67.8%). However, at the end of Week 2, there was a trend toward significance for the second outcome of the number of diagnoses/patient/week in favour of HW (0.58 ± 0.75 vs. 0.34 ± 0.55, p = 0.066). This suggests that a monitoring duration of two weeks may not be necessary for HW (with only an additional 0.34 ± 0.55 diagnoses/patient made in Week 2). There are several possible explanations for this outcome. First, there is feedback on the recorded data via a liquid crystal display (LCD screen on HW), thus allowing patients to re-record, should the signals be sub-optimal. For TT, the converted audio signals have to contend with inherent noise levels on fixed telephone lines (our current TT devices do not support data transmission via the global system for mobile communications). Consequently, up to 18% of transmitted data from TT is unreadable compared to 4% for HW. Better quality data in multiple channels in HW means that fewer transmissions are required before a diagnosis is made, thereby cutting down on the monitoring time. Also, transmissions are read on the next working day for TT. Unlike the HW server, there is no SMS service in TT when an abnormal rhythm is detected. On a weekend,
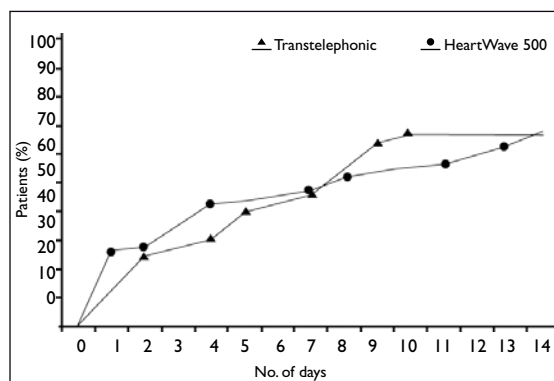
this often means that transmitted data is read only on the following Monday. This would account for the median time of transmission to review of 1,107 minutes in TT, compared to 18 minutes for HW. Early diagnosis of significant arrhythmias may be potentially significant, as earlier detection of AF, for example, could have suggested the need for anticoagulation therapy. There is also added reassurance for the HW user, as there is immediate feedback.

The potential application of HW in clinical practice is substantial. The recent Catheter Ablation for the Cure of Atrial Fibrillaton Study used a TT ECG recorder for patients one month after ablation.[6] Routine daily 30-second recordings were conducted for three months. This study showed a substantial number of asymptomatic AF recurrences, which was consistent with another study by Senatore et al, where up to 50% of AF recurrences were asymptomatic.[7] A device like HW that can transmit consistently, for prolonged periods of time and in multiple leads would be superior in detecting AF in this setting. HW can also be used in patients with chronic heart disease who work out in public gymnasiums. In a study by Kouidi et al, TT was used as a monitoring tool for this subset of high-risk patients and was shown to be safe and efficacious.[8] A device like HW that gives immediate feedback on a large LCD screen, a readily available computer-generated diagnosis and immediate SMS warning system would be superior to TT. In our study, only three patients in the HW group had a permanent pacemaker implanted. Although a normal paced rhythm was detected for all three patients, the usefulness of HW in this setting remains to be examined.

However, there are practical drawbacks to the HW. It records five leads, which would take considerable time and effort to put on. Furthermore, due to its

multiple functions, the current model uses more energy. In the two-week monitoring period, patients often had to change batteries at least once, thus increasing the cost. The use of the internet as a transmitting medium also has its drawbacks, especially if patients are not computer savvy. The current computer-generated report software only has 74% consistency with a physician-read diagnosis.

In conclusion, HW is an exciting new device that offers a glimpse of what future cardiac monitors would look like. It incorporates an essential and everyday medium in our lives: the internet. With advancing wireless and battery technology, many of its drawbacks are not insurmountable. In fact, the next generation of HW devices is already on the drawing board.

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