

COMPARISON OF QUALITY OF AMBULATORY ELECTROCARDIOGRAMS OBTAINED USING NOVEL WIRELESS 'ANDROID APP' BASED WEBCARDIO SYSTEM AND CONVENTIONAL HOLTER

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ABSTRACT

BACKGROUND

Ambulatory electrocardiogram (AECG) is done when cardiac arrhythmia is suspected. The conventional method of AECG recording uses 24 hour Holter. WebCardio using WiPatch is a new AECG system which can record for 72 hours. Since it is new and the WiPatch is placed in the left upper part of chest, the quality of the ECG especially that of P wave needs to be evaluated.

METHODS

The study compared the quality of AECG of wireless Android App based WebCardio system with the AECG of conventional Holter by simultaneously connecting both for 24 hours in patients having indication for AECG. The study was done in the department of cardiology, Medical College, Thrissur. The quality of P and QRS were compared at specific time periods of AECG, in the events and arrhythmias picked by AECG system and by scanning the entire AECG page by page. Periods of artefacts and no recording were evaluated. System generated events, maximum heart rate, minimum heart rate and longest RR interval were compared in both recordings.

RESULTS

141 patients had simultaneous recordings by both systems of AECG. Overall quality of AECG was better with the WebCardio compared to Holter (138 Vs 125, $p=0.001$). Quality of P wave was better in the WebCardio than Holter (135 Vs 122, $p=0.002$) whereas quality of QRS was similar. The occurrence of artefacts lasting for more than 30 seconds was more in Holter compared to WebCardio (40 Vs 26, $p=0.065$), and no-recording lasting for more than 30 seconds were similar in the Holter and WebCardio (11 vs. 13). The maximum heart rate, minimum heart rate and longest RR interval were correctly identified in higher number of cases by WebCardio than the Holter (136 vs. 131, 139 vs. 138, 137 vs. 133 respectively), though statistically not different.

CONCLUSIONS

The study showed that the overall quality of 24 hour AECG recording was better in the WebCardio compared to Holter. This difference was due to the better quality of P in the WebCardio. Ambulatory ECG with WebCardio systems is a good alternative to conventional Holter.

KEYWORDS

Holter, WebCardio, Arrhythmia, Ambulatory ECG, Patch

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BACKGROUND

Ambulatory electrocardiogram (AECG) is done in conditions like syncope, palpitation or stroke to look for arrhythmias. There are different types of AECG devices which can record AECG for less than 1 minute, as done in event recorders, or for longer periods as in implantable loop recorders.^{1,2} Conventional wired Holter which records for 24 hours is the commonest type of AECG recording in the clinical practice,

though longer periods of recording can be helpful in many clinical situations. The conventional Holter uses a device with wires strapped onto the body so that some persons who undergo the test find it bulky and uncomfortable to wear during daily activities. Patches with embedded electrodes and capability to transmit ECG data wirelessly are now available. Experience with patch based AECG recording is limited as it is a relatively new concept. In a study conducted by Barrett PM et al, using the Zio patch, with ability to record for 14 days, patients found the patch comfortable to wear with lesser interference in activities of daily living. The Zio patch was better acceptable to both the patients and physicians than the conventional Holter.³

WebCardio system is a new AECG device available in India and is provided by Gadgeon. It consists of LifeSignals Inc's WiPatch, a mobile phone with WebCardio App, and the remote server where the data is stored and analysed. The WiPatch is a small light weight, disposable, coin cell operated patch which can be worn at the left upper part of the chest.

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After applying to the patient's body, the WiPatch is paired with an android based mobile phone with internet connectivity and having the WebCardio patient App (available for download in 'Google play store') installed in it. Once paired, WiPatch continuously and wirelessly transmits two channels of ECG signals to the mobile for 72 hours if not disconnected earlier. WiPatch is to be within the wireless range of the mobile phone for transmitting the data. Occasional movement out of range is not a problem as the WiPatch has an on-board memory for storing ECG signal for four hours, and the data will be transferred as and when the patch and the mobile come in range, within that period. The data from the mobile phone is transmitted to cloud (remote server) through internet, and is stored there permanently. As the WebCardio is a new device with limited clinical data there is a need to assess the quality of AECG obtained with it. In arrhythmia analysis, proper identification of the P and QRS are very important. Since the WiPatch is placed in the left upper part of chest and not directly above the heart, the quality of P and QRS needs evaluation. Presence of artefacts and baseline fluctuation can also interfere with the identification of P wave. Considering the obvious ease of using the patch based AECG, if the quality of AECG is good, WebCardio system will be a very useful clinical tool.

We wanted to compare the quality of AECG obtained by 'Android App' Based WebCardio system using WiPatch with the AECG obtained by conventional Holter by simultaneously connecting both systems in patients having clinical indications for AECG evaluation.

METHODS

The study was conducted in the department of cardiology of Government Medical College Hospital, Thrissur, Kerala with approval from institutional ethics committee. All patients had clinical indication for AECG monitoring as decided by the physician. Those who consented for simultaneous evaluation with Holter and WebCardio were included. Those with implanted devices like pacemakers were excluded. AECG of patients who had simultaneous recording with conventional 24 hour Holter and WebCardio system were evaluated. In patients who had 72 hours of recording with WebCardio, the first 24 hours period having simultaneous recording with Holter was considered for comparison.

The conventional Holter recording was done by either a 3 channel or a 12 channel recorder (Hanix- DL- 820 /Hanix 820-DL pro) strapped to the body. The wires of the recorder were connected to soft gel adhesive electrodes placed on the chest using the Mason Likar system after preparation of chest. The recorder was strapped to the body and the wires and electrodes secured with tapes to minimize the movement and chance of lead disconnection. The AECG data for 24 hours was recorded using a flash memory card and was later transferred to the computer and analysed using specific software, ECG lab Holter 12 plus. The quality of AECG and the events were evaluated by the investigating cardiologists.

All patients had simultaneous recordings with WebCardio system also. The WiPatch was placed in the left

upper part of the chest after skin preparation and paired with the mobile device. Relevant details were entered at the start of the procedure using the WebCardio App in the mobile phone. All recordings were done in the mobile device provided by the Gadgeon. The quality of AECG signal was ascertained before start of the procedure, using the WebCardio setup system. The AECG was analysed using proprietary software by a qualified Holter technician in the remote centre and report was generated. The entire AECG and report were available online in the WebCardio site for evaluation which was accessed by the investigating cardiologists using unique password.

The quality of the AECG was evaluated by the cardiologist in all cases in both systems. Evaluation was done by scrolling the entire AECG page by page. Periods of no-recording and artefacts were analysed. Occurrence of at least one episode of no-recording lasting 30 seconds and at least one episode of continuous artefacts lasting 30 seconds were compared in both systems. For evaluation of the quality of P waves, those cases having definite AF were excluded. P and QRS were considered good quality if they were clearly identifiable. The quality of both P and QRS was assessed in the arrhythmia and events picked up by the system. The P and WRS were also analysed at pre-specified timings of 15 minutes from the start, at the beginning of every 30 minutes during recording and at the end of the 24 hour recording. An opinion was formed by the investigators in each case regarding the overall quality of ECG.

Individual reports of the AECG had events or outcomes that were generated using the algorithms for the respective ECG analysing system. The maximum heart rate, minimum heart rate and the longest RR interval during the 24 hour period identified by the system in WebCardio and Holter were compared. When the values were same or had less than 10% difference, they were considered to be picked up accurately by both systems. In case of a difference of more than 10% in the value of these events between the two types of recordings, the investigating cardiologist analysed the respective events and the entire AECG in both Holter and WebCardio and a decision was made as to which system made correct identification of the event.

The evaluation of the quality of the ECG was done by two senior cardiologists. Data was coded and entered in excel sheet and analysed. Comparison was done using McNemar's test to assess the significance of the difference between two correlated proportions.

RESULTS

Age of the patients ranged from 9 years to 77 years with mean age of 44.41 years (SD 19.409). Maximum number of patients was in the age group of 40 to 60. There were 67 males (47.5%) and 74(52.5%) females. Average duration of recording was 23.65 hours (SD 2.791) for the Holter and 23.71 hours (SD 1.98) for WebCardio. In two cases of Holter, the recording stopped after first 30 minutes possibly due to disconnection. In one case of WebCardio, recording was available for 6 hours only. In all others 24 hour recording was obtained in both systems.

	Not seen in Holter and WebCardio	Only in WebCardio	Only in Holter	Seen In both Holter and WebCardio	Statistical Significance
Artefacts lasting thirty seconds or more	83	18	32	8	McNemars test, two tail, p = 0.065
No-recording lasting 30 seconds or more	119	11	9	2	McNemars test, two tail, p= 0.82

Table 1. Artefacts and Periods of No Recording in Holter and WebCardio. Total 141 Cases

Quality of ECG	Acceptable In both Holter and WebCardio	Not Acceptable in Holter and WebCardio	Acceptable in Holter but not in WebCardio	Acceptable in WebCardio but not in Holter	Statistical Significance
P wave (n=138, AF patients excluded)	120	1	2	15	McNemars test, two tail, p=0.002
QRS (n=141)	137	0	2	2	
Overall AECG (n=141)	123	1	2	15	McNemars test, two tail, p= 0.001

Table 2. Comparison of Quality of P, QRS and Overall AECG in Holter and WebCardio

Event	Both by Holter and WebCardio	Holter Correct	WebCardio Correct	Statistical Significance
Maximum heart rate	126	5	10	McNemars test, two tail, p=0.30
Minimum heart rate	136	2	3	McNemars test, two tail, p = 1
Longest RR interval	129	4	8	McNemars test, two tail, p= 0.39

Table 3. Ability to Identify Maximum Heart Rate, Minimum Heart Rate and Longest RR Interval Correctly

In all the three where recording failed in one system, other simultaneous recording system got 24-hour AECG. All 141 cases were evaluated, and the absence of recording was considered as poor quality AECG. The occurrence of at least one episode of artefact lasting for 30 seconds was more in Holter compared to WebCardio (40 Vs 26, p = 0.065), though the difference was not significant. Occurrence of no-recording lasting for more than 30 seconds were similar in the Holter and WebCardio (11 Vs 13), (Table 1). The quality of P and QRS obtained with WebCardio and conventional Holter were compared. There were 3 cases with AF and hence quality of P was evaluated in remaining 138 cases only. The quality of P was better in the WebCardio with 135 having acceptable P compared to 122 in Holter (p=0.002). Quality of QRS was not different between two types of recordings (139 out of 141 in both types being considered acceptable). Overall quality of ECG was better in more number of recordings using WebCardio than with Holter (138 Vs 125, p=0.001), (Table 2).

Of the total 141 cases, values for maximum heart rate, minimum heart rate and longest RR interval were the same in 126, 136 and 129 cases respectively in both systems. After analysing the rest, where the values differed, it was found that the WebCardio picked up the events correctly in more number of patients than Holter (136 vs. 131, 139 vs. 138, 137 vs. 133 respectively). However, this difference was not statistically significant. (Table 3)

DISCUSSION

The study was conducted to compare the quality of AECG given by WebCardio and conventional Holter. The WiPatch was placed in the left upper part of the chest and the lead position was not directly across the heart, whereas the conventional Holter had lead placement in such a way that it could pick up forces directly across the heart. Since P is a small wave and distance from the heart can affect the wave, we had expected that the detection and quality of P wave of WebCardio could be inferior to the P of the conventional Holter. In our study the quality of P was better in WebCardio

compared to Holter. The quality of the QRS was similar in the two systems. The overall quality of ECG was better with the WebCardio influenced by the better P wave in WebCardio.

We consider the following reasons for better pickup of P wave in WebCardio in our study. The conventional Holter has wires which can produce noise during the recording due to patient movement, whereas the WiPatch has no wires. Whatever noise is produced is likely to be amplified in Holter as the leads are placed more apart. The conventional Holter is reused several times and there can be small breaks in the wires connecting the leads, with possible risk of higher noise in recording, as the system becomes older. Previous studies have addressed clarity of P wave. A study using Carnation Ambulatory Monitor (CAM), a single channel ambulatory patch ECG monitor, designed specifically to ensure that the P wave component of the ECG be visible, showed a significantly improved rhythm diagnosis and avoided inaccurate diagnoses made by the standard 3 channel Holter monitor.⁴

The maximum heart rate, minimum heart rate and the longest RR interval during the 24 hour period were better identified in the WebCardio system, though the difference was not statistically significant. These events are generated by the proprietary analysing algorithm for the AECG system. The system identification of the P and QRS waves are important in correct identification of these events. These events gave indirect evidence of quality of AECG and also on the ability of the system algorithm to classify events.

Patch based recording is recommended as an alternative to the conventional Holter by several bodies. The 2017 Heart Rhythm Society Atrial Fibrillation Consensus Statement includes patch monitors as one method of ambulatory electrocardiography monitoring.⁵ The 2017 American College of Cardiology/American Heart Association/Heart Rhythm Society Guideline for the Evaluation and Management of Patients with Syncope listed patch monitoring as one of the recommended devices.⁶

WiPatch WebCardio is a small device, with ability to record for up to 72 hours. The quality of the AECG beyond 24 hours in WiPatch WebCardio needs evaluation. The convenience factor, economics and ability to pick up different arrhythmia are to be studied separately. Since the WiPatch is disposable and recording can be done using personal mobile phone with WebCardio App downloaded in it, there is a potential advantage of avoiding hospital visit to return any device. In our study all patients returned to the hospital as there was simultaneous Holter recording also.

In our study, the analysis and reporting were independently done in both systems and verified by the cardiologist. The evaluation of the quality of the AECG was done by two senior cardiologists. There is a possibility of subjectivity in the analysis of the overall quality of the AECG. The conventional Holter recorders used is several years old and it can affect the quality of the AECG. The WiPatch was provided free of cost by Gadgeon.

CONCLUSIONS

The study showed that the overall quality of 24 hour AECG by the WebCardio was better than that of conventional Holter. This was due to the better quality of P in the WebCardio. Considering the convenience factor of the small disposable wireless patch, WebCardio system is a good tool for AECG monitoring. The pickup of arrhythmia and the quality of AECG in the total recording period of 72 hours by WebCardio merits evaluation since longer period of AECG data can be useful in several situations where the arrhythmia is intermittent.

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