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Wireless remote monitoring of reconstructed 12-lead ECGs after ablation for atrial fibrillation using a hand-held device☆

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Abstract

Objective: Atrial fibrillation (AF) surveillance using a wireless handheld monitor capable of 12-lead electrocardiogram reconstruction was performed, and arrhythmia detection rate was compared with serial Holter monitoring.

Methods: Twenty-five patients were monitored after an AF ablation procedure using the hand-held monitor for 2 months immediately after and then for 1 month approximately 6 months postablation. All patients underwent 12-lead 24-hour Holter monitoring at 1, 2, and 6 months postablation.

Results: During months 1-2, 425 of 2942 hand-held monitor transmissions from 21 of 25 patients showed AF/atrial flutter (Afl). The frequency of detected arrhythmias decreased by month 6 to 85/1128 ($P < .01$) in 15 of 23 patients. Holter monitoring diagnosed AF/Afl in 8 of 25 and 7 of 23 patients at months 1-2 and month 6, respectively ($P < .01$ compared with wireless hand-held monitor). Af/Afl diagnosis by wireless monitoring preceded Holter detection by an average of 24 days.

Conclusions: Wireless monitoring with 12-lead electrocardiogram reconstruction demonstrated reliable AF/Afl detection that was more sensitive than serial 12-lead 24-hour Holter monitoring.

Keywords: Wireless remote monitoring; 12-lead ECG; Ablation; Atrial fibrillation; Hand-held monitor; Holter monitoring

Introduction

Multiple rhythm monitoring options are currently used in clinical research and practice for atrial fibrillation (AF) detection including variety of pocket carried, wearable, and implantable devices.[1-3] The choice of monitoring modality depends on the desired electrocardiographic (ECG) end point, which can vary widely.[4] In clinical trials, detection of a single arrhythmia recurrence is a recommended end point to evaluate efficacy of specific ablation techniques.[5] Estimation of arrhythmia burden can be useful in assessment of device-based therapies[6] and quality of life.[7] Time to the first recurrence of symptomatic arrhythmia has been used to compare drug effects.[8]

The wide variety of monitoring devices available reflects the fact that not a single one of them offers an ideal solution for every clinical scenario. Although increasing monitoring time by using continuous monitoring via implantable subcutaneous devices appears to be an attractive concept,[9] it is associated with high cost and labor intensity, significant amount of false-positive results, and occasional complications.[1,10] In routine practice, the monitoring intensity has to be sufficient to reliably detect clinically significant events (ie, associated with symptoms or pose thromboembolic risk) while maintaining patient compliance in diverse patient populations at reasonable cost.

Frequent short-term ECG monitoring can be an effective alternative to continuous monitoring while being superior to more episodic wearable monitoring[9] given highly unpredictable patterns of AF recurrence.[11-13]

The overall purpose of the study was to assess the feasibility of long-term postablation rhythm monitoring

☆ Conflicts of interest: I.G., D.P., and G.S. are employees of NewCardio. S.G. is a consultant for NewCardio.

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using a wireless hand-held monitor with 12-lead ECG reconstruction and to compare its sensitivity of atrial arrhythmia (AF and atrial flutter, Afl) detection with that of a periodic 24-hour Holter monitoring applied on a typical schedule used for postablation arrhythmia surveillance.[3,5]

Methods

Inclusion criteria

Consecutive patients with AF scheduled to undergo an ablation procedure were enrolled in a single center study if they satisfied the following inclusion criteria:

1. age between 18 and 80 years;
2. symptomatic paroxysmal or persistent AF with at least 1 episode per month;
3. provision of an informed consent.

Patients with any of the following criteria were excluded from this analysis:

1. reversible cause for AF (such as hyperthyroidism);
2. asymptomatic AF;
3. unavailable for in-person or transtelephonic follow-up.

Preablation testing

All patients underwent 12-lead ECG or 12-lead 24-hour Holter monitoring documenting AF within 1 month before ablation.

Ablation procedure

All patients were selected for ablation in accordance with currently accepted guidelines.[5] All had a history of recurrent paroxysmal or persistent AF that had failed to convert or recurred after a trial of at least 1 accepted antiarrhythmic drug. All patients underwent left atrial ablation procedure using RF ablation catheter (Navistar Thermocool; Biosense Webster, Diamond Bar, CA) with the end point of ostial bidirectional isolation of all pulmonary veins using a 3-dimensional electroanatomical mapping system (CARTO; Biosense Webster). No linear left atrial lesions were performed routinely and cavotricuspid isthmus line was created only if typical Afl was known to be present before the ablation or induced at the end of the procedure.

All patients received antiarrhythmic medications and anticoagulation for at least 2 months after the ablation procedure.

Rhythm monitoring

ECG monitoring using the wireless hand-held monitor was performed daily for the first 2 months after the ablation and for 30 days at month 6. The patients were instructed to perform 3 daily recordings during months 1-2 and 2 daily recordings during month 6 as well as unlimited number of symptomatic recordings. The patients underwent 12-lead 24-hour Holter monitoring at 1, 2, and 6 months after the ablation.

Wireless hand-held system for remote monitoring of reconstructed 12-lead ECGs

The wireless hand-held system consists of a mobile device for ECG data acquisition and wireless transmission and a central diagnostic center to receive the transmitted signals and transform them into full 12-lead ECGs.

The wireless hand-held device is pocket sized and battery powered, with integrated electrodes connected to amplifiers, digital control, and communication unit. The basic technical specifications are ±2.5 mV measuring range, 10-bit A/D conversion, 300 Hz sampling rate, 0.05-75 Hz pass band, and 1 MΩ input impedance. It has 5 integrated electrodes, with 2 (A and B) placed on the top of the device, to be contacted by the patient's left and right index fingers providing an analog of the standard lead I. The other 3 electrodes are positioned on the bottom of the device to contact specific points on the patient's chest. One of the electrodes (E) is passive (ground). The position of active electrodes C and D are chosen to compose, together with the electrodes A and B, a 3-lead system that is as close to orthogonal as possible (Fig. 1). The digital data processing and control unit provides analog-to-digital conversion, storage, and transmission of the signals. The 3-lead digital signal is transmitted via commercial cell phone to the diagnostic center.

At the study enrollment a regular 12-lead ECG was recorded simultaneously with 3 additional leads corresponding to the positions of the hand-held device precordial electrodes for each patient. An individual transformation matrix for 12-lead ECG reconstruction from the transmitted 3-lead signal was created as described previously.[14]

Data analysis

Reconstructed 12-lead ECGs from transmitted signals from the hand-held device were analyzed by 2 independent

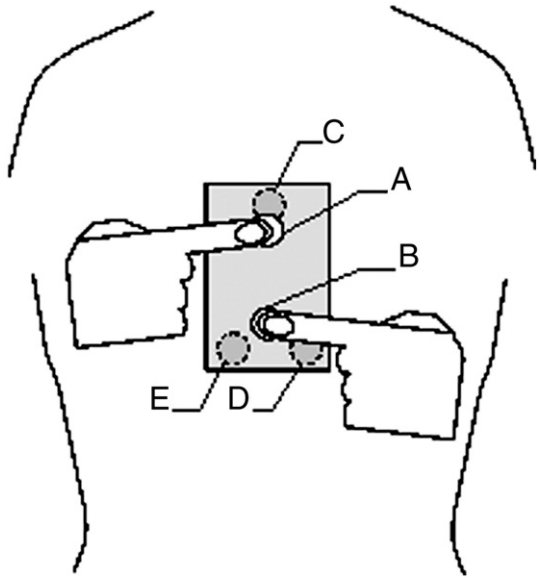

Fig. 1. The CardioBip (NewCardio Inc, Santa Clara, CA) monitor is a hand-held wireless device with 5 electrodes producing a 3-lead ECG acquisition suitable for 12-lead ECG reconstruction (see text for details).