HEART & LUNG

Feasibility and compliance with daily home electrocardiogram monitoring of the QT interval in heart transplant recipients

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ABSTRACT

Background: Recent evidence suggests that acute allograft rejection after heart transplantation causes an increased QT interval on electrocardiogram (ECG). The aims of this pilot study were to (1) determine whether heart transplant recipients could achieve compliance in transmitting a 30-second ECG every day for 1 month using a simple ECG device and their home telephone, (2) evaluate the ease of device use and acceptability by transplant recipients, and (3) evaluate the quality of transmitted ECG tracings for QT-interval measurement.

Methods: A convenience sample of adult heart transplant recipients were recruited and trained to use the device (HeartOne, Aerotel Medical Systems, Holon, Israel). Lead II was used with electrodes that were easy to slip on and off (expandable metal wrist watch-type electrode for right wrist and C-shaped band electrode for left ankle). Patients used a toll-free number with automated voice prompts to guide their ECG transmission to the core laboratory for analysis.

Results: Thirty-one subjects (72% were male; mean age of 52 $\pm$ 17 years; 37% were nonwhite) achieved an ECG transmission compliance of 73.4% (daily) and 100% (weekly). When asked, how difficult do you think it was to record and transmit your ECG by phone, 90% of subjects replied "somewhat easy" or "extremely easy." Of the total 644 ECGs that were transmitted by subjects, 569 (89%) were acceptable quality for QT-interval measurement. The mean QTc was 448 $\pm$ 44 ms (440 $\pm$ 41 ms for male subjects and 471 $\pm$ 45 ms for female subjects). Eleven subjects (35%) had an extremity tremor, and 19 subjects (55%) had $\geq$ 1+ left leg edema. Neither of these conditions interfered with ECG measurements.

Conclusion: Transplant recipients are compliant with recording and transmitting daily and weekly ECGs.

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Approximately 13% of adult heart transplant recipients do not survive to 1 year, and a major cause of death is acute cellular allograft rejection.[1,2] According to the 2009 annual US data published from the International Society for Heart Lung Transplantation Registry, acute rejection occurs in 25% to 35% of transplant recipients within the first year after transplant surgery.[3] To detect the early stages of rejection so that more aggressive and early immunosuppressant therapy can be initiated, frequent biopsies of heart tissue are performed (typically, weekly or every other week in the first 3 months and then monthly or every other month during the first year). Although endomyocardial biopsy is not a perfect "gold standard" for a correct diagnosis of acute allograft rejection, it is considered the best available test, and thus it is the current standard practice. Unfortunately, endomyocardial biopsy is an invasive and costly procedure that is not without risk.[4,5] If a simple noninvasive biomarker could be identified to detect the early stages of acute rejection, it might be possible to reduce the number of invasive biopsy procedures and to initiate earlier therapy that might prevent death from severe rejection.

In a retrospective analysis by Tenderich et al,[6] 12-lead electrocardiograms (ECGs) were recorded in 200 heart transplant recipients during the first 3 months after transplant surgery. Prolongation of the QTC interval $>$ 25 ms predicted acute cellular allograft rejection with a sensitivity of 77% and specificity of 96%.[6] In normal individuals, there are 2 major influences on the duration of the QT interval: heart rate and autonomic nervous system activity. There is an inverse relationship between the heart rate and the QT interval. In terms of the autonomic nervous system, sympathetic stimulation shortens the QT interval, whereas parasympathetic stimulation lengthens the QT interval. In the denervated cardiac allograft, both influences of heart rate and autonomic nervous system activity are almost entirely removed, so there is little diurnal variation of the QT interval.[7] A potential major benefit of allograft denervation is that without the confounding influences of heart rate and autonomic nervous system activity, an observed increase in the QT interval is likely to indicate abnormal ventricular repolarization due to another cause, such as acute allograft rejection.

No prospective study to date has investigated whether such increases in the QT interval could provide early detection of acute allograft rejection. We plan to conduct a prospective National Institutes of Health–funded clinical trial (1RO1 NR012003) to determine whether daily monitoring of the transplant recipient's ECG using a simple home device would provide an early sensitive and specific biomarker for acute allograft rejection. In preparation for this clinical trial, the current pilot study was undertaken to (1) determine whether heart transplant recipients could achieve compliance in transmitting a 30-second ECG every day for 1 month using a simple ECG device and their home telephone, (2) evaluate ease of device use and acceptability of time required for transmission by transplant recipients, and (3) evaluate the quality of transmitted ECG tracings for QT interval measurement.

Materials and Methods

Sample and Setting

In a 3-month period ending in May 2010, we selected a convenience sample from 3 transplant centers: University of California, Los Angeles Medical Center, Cedars Sinai Medical Center, also in Los Angeles, and Columbia University-New York Presbyterian Medical Center in New York City. Institutional review board approval was obtained from these 3 institutions and the University of California, San Francisco (UCSF) Medical Center, which served as the ECG core laboratory for the study. The inclusion criteria were adult heart transplant recipients living independently who were clinically stable. Demographic characteristics are detailed in Table 1.

Instruments and Procedure

Home ECG Device

After a thorough search of the available technology, the HeartOne ECG recorder (Aerotel Medical Systems, Holon, Israel) was selected (Figure 1A). The ECG device is pocket size and lightweight, and stores up to four 30-second recordings of a bipolar ECG lead.

ECG Lead and QT Measurement

The QT interval is measured from the onset of the QRS complex to the end of the T wave. T waves must be of sufficient amplitude to identify the T-wave end point. Because normal T-wave axis is between 15 and 75 degrees in adults, lead II, which is at the 60-degree axis point, often has the largest amplitude T wave. Lead II requires an electrode on the right wrist and left ankle. We used an expandable metal wristwatch type electrode for the right wrist and a C-shaped electrode for the left ankle, both of which could be easily slipped on and off (Figure 1B and C). Subjects were given spray bottles of saline to spray on the electrode site to improve conductance without the need to use more permanent adhesive-type ECG electrodes.