Accuracy Of Arrhythmia Detection Using Confirm Rx Implantable Cardiac Monitor: A Prospective Multicenter Randomized Clinical Trial

Miki Yokokawa  
Brian Jaffe  
Randy Ip  
Carson Castellani  
Mark Castellani  
John Ip

Introduction: Implantable cardiac monitor (ICM) has been used to detect occult cardiac arrhythmias in a variety of clinical situations. The reliability and accuracy of diagnosing cardiac arrhythmia could impact patient care. Despite good sensitivity reported previously, current detection algorithms lead to an elevated number of false-positive results. The objective of this study is to analyze the accuracy of diagnosing cardiac arrhythmias using Confirm Rx SharpSense Technology.

Methods: In the prospective multicenter randomized study, a total of 48 patients (age: 58±17 years, men: 25 [52%]) with cryptogenic stroke (n=30) or recurrent unexplained episodes of palpitations (n=4) or syncope (n=14) received a Confirm Rx ICM for detection of arrhythmias. Arrhythmic events are defined as pauses of ≥3.0 seconds, bradycardia with heart rate of ≤40 bpm, tachycardia with heart rate of ≥150 bpm, and atrial fibrillation (AF). All of the arrhythmic events were adjudicated by two cardiologists to assess the accuracy.

Result: A total of 1263 arrhythmic events including 835 AFs, 121 bradycardias, 236 tachycardias and 71 pauses were transmitted over a mean follow-up of 4.9±2.9 months. Two-hundred twenty of 835 AF events (26%) and 264 of 428 non-AF events (42%) were accurately detected by Confirm Rx ICMs (P<0.0001). The reason for inaccurate AF detection was frequent ectopic beats (n=412), P-wave oversensing (n=32), T-wave oversensing (n=72), both P- and T-waves oversensing (n=23), sinus tachycardia with R-wave undersensing (n=26) and sinus arrhythmias (n=48) and others (n=2). In the retrospective analysis of the original data set, Confirm Rx SharpSense classified 41 of 63 false positive AF as non-AF and drove a 65% reduction in false positive AF detection by properly identifying ectopic beats. Confirm Rx SharpSense rejected all 47 false positive pauses.

Conclusion: The accuracy of cardiac arrhythmia detection with current algorithms in ICMs remains suboptimal. Arrhythmia detection performance by using the new algorithms, Confirm Rx SharpSense Technology, may improve the accuracy of diagnosing cardiac arrhythmias. More patients and longer follow-up are required to confirm these findings.