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Commentary

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Safe Use of a New Implantable Cardiac Monitor in Pediatric Patients

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Abstract

Multiple types of ambulatory electrocardiogram monitors are available to help the physician work-up/diagnosis of patients with palpitations. Implantable Cardiac Monitors (ICM) have been utilized in patients for the past three decades to assist the clinician and patient with arriving at a diagnosis in those patients with palpitations and recurrent unexplained syncope. The Confirm Rx™ (Abbott, Minneapolis, MN) is a new, small, Bluetooth enabled device that has improved accuracy and safety in the use in pediatric patients with arrhythmias.

Keywords: *Implantable cardiac monitor; Loop recorder; Pediatric arrhythmia*

Description

Multiple types of ambulatory electrocardiogram monitors are available to help the physician work up/diagnose patients with palpitations. Electrocardiograms, 24 hour Holter or event monitors, and exercise stress tests tend to be the most utilized non-invasive tests to assist with this diagnosis. Implantable Cardiac Monitors (ICM) have been utilized in patients for the past three decades to assist the clinician and patient with arriving at a diagnosis in those patients with palpitations and recurrent unexplained syncope [1,2]. The first reported ICM was placed in the late 1990s with the earliest pilot study of their use in 1997 [3]. With advances in technology, decreases in size, and the ease of implant and explanation, ICM implants are becoming more popular in the pediatric population to assist with the diagnosis of unexplained syncope and palpitations.

In the article Diagnostic Accuracy and Safety of Confirm Rx™ Insertable Cardiac Monitor in Pediatric Patients, published in the journal of Pediatric Cardiology on October 9, 2020, we describe the use of a new model of implantable loop recorder manufactured by Abbott industries [4]. The Confirm Rx™ (Abbott, Minneapolis, MN), is 1.4cc in size and is equipped with

Bluetooth® connectivity through an application installed on the patient or parent's smartphone, giving them and their clinician near immediate access to their heart rhythm and the ability to correlate symptoms/rhythm in real-time [4]. In today's world, where younger people are increasingly tech-savvy, with readily available smartphones, this new technology allows for improved data gathering and communication with patients.

The purpose of the article was to assess the diagnostic accuracy and safety of this new Confirm Rx™ ICM in pediatric patients. The article highlights how even extensive workup with Holter monitors, ECGs, and even stress tests can fail to provide a formal diagnosis of arrhythmia given the episodic nature of abnormal heart rhythms [4-7]. Of the 29 patients in this study, arrhythmias were identified in 9, of which 8 (89%) were device initiated.

Meaning the device itself triggered the recording of the abnormal heart rhythm on its own [4]. This is a true attestation to the accuracy of the Confirm Rx™ device in its ability to detect arrhythmias in pediatric patients.

In addition, we investigated the improved accuracy of the device transmissions following the implementation of the SharpSense™ software in the loop recorder to avoid false-positive transmissions such as atrial fibrillation (in the setting of sinus arrhythmia), tachycardia (due to T-wave over-sensing), and bradycardia/pause (due to under-sensing). When the ICM with SharpSense™ technology-enabled sensed bradycardia or a pause, the episode is automatically reviewed through a lower/more aggressive threshold to rule out false-positive detections. Additionally, the software reviews device-initiated atrial fibrillation episodes by averaging all P-waves 30 seconds before the triggered event. The added accuracy was well demonstrated, resulting in 0 false-positive device initiated transmissions in the group with SharpSense™ technology compared to 158 (55.4%) inappropriate transmissions pre- SharpSense™ technology.

Out of the 29 device implants, 1 complication, cellulitis at the insertion site was noted 7 days post-procedure in an 11-month-

old male. This complication was successfully treated with the removal of the device and a 10-day course of oral antibiotics [4]. We feel that this speaks to the safety profile of the small size and low profile of the device. Despite the low complication rate, we modified the implantation approach, to avoid skin tenting or migration of the device into the breast tissue in younger females. This modified implantation technique involves implanting the device 5 mm from the sternum, parallel to the bone at the 3rd intercostal space. This non-classical device orientation continues to yield excellent P and R waves.

As stated in the article, "ICMs are proven diagnostic tools to establish symptom-rhythm correlation in cases where symptoms present infrequently, unpredictably, or in circumstances where an external monitor may be unfeasible" [4]. Even in unconventional positions, the Confirm Rx™ ICM with SharpSense™ software has yielded accurate capture at implantation and transmissions with decreased incidence of false-positive results. The novel implant approach has helped to avoid migration of the device into the breast tissue and has made removal of the device infinitely easier. As newer technological advances become available in the adult world, in pediatrics we will continue to extrapolate the data and results from our adult colleagues for use in our pediatric population, as evident by the success of this article. As Nano-technology begins to invade the medical field, we anticipate even greater benefits to our smaller patients and their families regardless of age, body habitus, or presence of congenital heart disease.

Conflict of Interest

The authors of this article have no conflicts to disclose.

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