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54.8%

of first time ICD recipients were candidates for S-ICD.[1]

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REFERENCE
1. Friedman DJ, et al. Trends and In-Hospital Outcomes Associated with Adoption of the Subcutaneous Implantable Cardioverter Defibrillator in the United States. JAMA Cardiology 2016.

Diagnostic Yield of Asymptomatic Arrhythmias Detected by Mobile Cardiac Outpatient Telemetry and Autotrigger Looping Event Cardiac Monitors

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Running Title: MCOT™ vs Autotrigger Event Remote Monitoring

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W.M. Derkac and J.R. Finkelmeier report stock ownership in BioTelemetry and are named on a patent pending relevant to this technology.

Abstract:

Introduction: Asymptomatic arrhythmias can have important therapeutic implications in certain patient populations, for example, atrial fibrillation in patients with prior ischemic stroke. We sought to compare the diagnostic yield of two commercially available monitoring systems with automated arrhythmia detection algorithms.

Methods: We queried a large, proprietary database containing rhythm data for patients receiving ambulatory EKG monitoring (BioTelemetry, Malvern, PA). We compared all patients prescribed Mobile Cardiac Outpatient Telemetry (MCOT™) versus Autotrigger Looping Event Recorder (AT-LER) devices over a consecutive 8-month period. Data from both device types was analyzed for diagnostic yields in detecting asymptomatic (device-triggered) arrhythmias consisting of atrial fibrillation (of any detected duration), bradycardia (ventricular rate ≤ 40 bpm), ventricular pause (≥ 3 seconds), supraventricular tachycardia (≥ 6 consecutive supraventricular beats) and ventricular tachycardia (≥ 4 consecutive premature ventricular contractions). The mean time to first diagnosis of each arrhythmia for each device was determined. Physician-designated diagnostic codes for patients prescribed each device were also determined from the database.

Results: The MCOT™ device had significantly higher diagnostic yields of all evaluated asymptomatic arrhythmias than the AT-LER. The MCOT™ device also produced an earlier mean time to diagnosis for all evaluated asymptomatic arrhythmias. These findings were noted despite a shorter average prescription length for MCOT™ monitored patients.

Conclusions: In patients with conventional diagnostic monitoring indications, MCOT™ had significantly higher diagnostic yields for five asymptomatic arrhythmias compared to the AT-LER.

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Keywords

mobile cardiac outpatient telemetry, autotrigger looping monitor, atrial fibrillation

Introduction:

Early long-term external cardiac monitoring devices were able to detect only symptomatic arrhythmias, with patient input required to initiate recording of these events. Recognition of the clinical importance of asymptomatic arrhythmias promoted the development of monitoring devices with automatic (i.e., autotrigger) arrhythmia detection capabilities. Despite the widespread use of mobile cardiac outpatient telemetry (MCOT™) and autotrigger looping event recorders without wireless connectivity capability (AT-LER) to detect asymptomatic cardiac arrhythmias, little information is available comparing their diagnostic yields. While both the MCOT™ and AT-LER devices share autotrigger capabilities, the diagnostic algorithms used by the devices are different. In this study we sought to compare the diagnostic accuracy of the MCOT and the AT-LER devices to detect asymptomatic (i.e., autotrigger) events using a large proprietary monitoring database.

Methods:

The study protocol was reviewed by the Institutional Review Board at the University of Arizona College of Medicine and determined not to constitute human research. We queried the BioTelemetry database retrospectively for the 8-month period (1/1/2016 – 8/31/2016) to evaluate data for every MCOT™ and AT-LER device with analyzable data during this timeframe. The 8-month database sample time window was chosen as a representative sample of recent patients from our entire database with no selection restrictions applied. All information lacked specific patient-related data other than age and gender; we stratified the resulting cohort based on these factors as both are associated with arrhythmia occurrence.

The MCOT™ device consists of a sensor with three leads providing two EKG channels for analysis by the monitor, which is a cell phone sized device communicating wirelessly with the sensor. The monitor contains embedded EKG analysis algorithms that analyze every heartbeat received from the sensor. The EKG signal is analyzed for threshold triggers related to rate, rhythm irregularity, QRS morphology and p-wave analysis. When trigger thresholds are met, the monitor wirelessly sends representative arrhythmia diagnostic strips to an independent diagnostic testing facility (IDTF), which is staffed continuously, for further adjudication by monitoring center trained technicians who also generate daily and end of service summary reports for final physician approval. If the arrhythmia characteristics meet notification criteria established for that patient, then the designated physician, and in emergency situations the patient/family, is notified. The device is prescribed for up to 30 days and has unlimited memory capacity due to its wireless connectivity. Specific timeframe data can be searched during the monitoring period and EKG strips for any time period can be examined. This device type also provides atrial fibrillation burden, heart rate trend data calculations, and can send unlimited patient-triggered events.

The AT-LER device has single or two EKG channel functionality and uses a rate and rhythm regularity detection algorithm to automatically trigger for arrhythmias. The device has finite memory storage for autotriggered events, comprising a total of five recordings of 90 seconds each (60

seconds pre-detection and 30 seconds post-detection). The device reserves memory to receive a patient initiated event as a sixth stored event. The device lacks wireless connectivity capability and the patient is required to transmit events via landline telephone. Technicians review each patient data transmission subsequently generating reports for physician review and final interpretation. Failure to transmit data in a timely fashion can result in failing to retain future, newer events due to the limited memory capacity of the device. Since this device category captures only specific arrhythmia events, it lacks the capability to provide additional information on triggered events and also lacks the ability to search for EKG tracings during specific timeframes. This device type cannot determine arrhythmia offsets and as a result atrial fibrillation burden cannot be calculated. Notifications are also called to physicians when qualifying events are received by the IDTF based on arrhythmia criteria established for each patient with this device. Events can also be triggered by patient initiation but limited memory in the AT-LER device may restrict the number of events that can be recorded.

For each device type, analysis of diagnostic yield, mean time to first diagnosis, patient age and patient gender and patient diagnostic codes were determined for the diagnoses of asymptomatic (device-triggered) atrial fibrillation (any duration), bradycardia (ventricular rate ≤ 40 bpm), ventricular pause (≥ 3 seconds), supraventricular tachycardia (≥ 6 consecutive supraventricular beats) and ventricular tachycardia (≥ 4 consecutive premature ventricular contractions). These arrhythmias were chosen as each device detects these arrhythmias based on triggers in the device algorithm for the parameters noted. The top ten primary diagnostic codes chosen by physicians who ordered each device were determined from the database. Arrhythmia diagnoses were made by the embedded algorithms in each device type with subsequent independent confirmation or rejection by independent diagnostic testing facility trained technicians with ultimate adjudication made by independent physicians. The Cochran-Mantel-Haenszel procedure[1] was used to represent weighted average statistical comparisons of device performance for each decade of age and for each gender. P-values and 95% confidence intervals of each ratio of events across all demographic groups were calculated.

Results:

From the 8-month analysis period, data from 69,977 patients prescribed MCOT™ and 8,513 patients prescribed autotrigger looping event recorders without wireless capability was examined. MCOT™ patients consisted of 43.1% males and 56.9% females, while the AT-LER device patients were comprised of 38.0% males and 62.0% females. The same top ten primary diagnostic codes are represented in differing proportions between device groups with the same ten codes comprising 89% of MCOT™ patients and 87.8% of AT-LER patients (Tables 1-2). Prescription length averaged 19.9 days (median 20 days) for patients monitored by MCOT™ and averaged 27.4 days (median 30 days) for patients monitored by an AT-LER device. Of note is that, starting with the second decade of life, the mean age for male and female patients within each decade of age varies between devices by no more than one year.

MCOT™ patients had significantly higher diagnostic yields for all five asymptomatic arrhythmias examined compared to the AT-LER despite a 7.5 day shorter average prescription length for MCOT™ patients. Examination of these diagnostic yields of each device for each arrhythmia reveals that

MCOT™ has a 128% higher diagnostic yield for AF, a 54% higher diagnostic yield for bradycardia, a 17% higher diagnostic yield for ventricular pause, an 80% higher diagnostic yield for supraventricular tachycardia and a 222.2% higher diagnostic yield for ventricular tachycardia than the AT-LER (Table 3).

The mean time to diagnosis for each asymptomatic arrhythmia evaluated was shorter for patients monitored with MCOT™ compared to patients monitored with an AT-LER device. The MCOT™ device needed 1.9 fewer days to detect AF, 1.0 day less to detect bradycardia, 6.7 fewer days to detect ventricular pauses, 2.5 fewer days to detect supraventricular tachycardia and 3.8 fewer days to detect ventricular tachycardia than the AT-LER. (Table 3).

Discussion:

The main findings of our study include:

1. Compared to AT-LER, MCOT™ had a significantly higher diagnostic yield for five clinically relevant asymptomatic arrhythmias.

2. The mean time to arrhythmia diagnosis was significantly shorter with MCOT™ for all arrhythmia diagnoses.

In 2005, Reiffel and colleagues[2] performed a similar retrospective cohort study to determine the diagnostic performance of the newly developed AT-LER, compared to the standard monitoring devices of the day. This study demonstrated the benefit of both monitoring duration and the autotrigger algorithm to detect asymptomatic arrhythmias. Contemporary ambulatory monitoring devices with wireless connectivity are now widely used in clinical practice; however, their comparative diagnostic yield to the AT-LER device has heretofore been lacking. Our results suggest that the MCOT™ provides higher diagnostic yield with a shorter time to diagnosis compared to the AT-LER. Since the autotriggered arrhythmias in our trial are potentially clinically impactful, one might speculate that the increased diagnostic yield and shorter time to diagnosis may improve clinical outcomes in selected patients (e.g., patients with embolic stroke of undetermined source and asymptomatic atrial fibrillation). This concept merits further study. Other technologies present in the MCOT™ but not the AT-LER device (e.g., AF burden calculations and heart rate trend graphs) may enhance longitudinal management of arrhythmia patients including: AF thromboprophylaxis[3], catheter ablation outcomes[4] , and assessing the efficacy of anti-arrhythmic treatment[5]. These concepts merit further study.

From the study design, it is not possible to determine the relative contribution in diagnostic performance of the specific on-board detection algorithm versus the continuously attended telemetry feature inherent in the MCOT monitor. The MCOT's p-wave analysis provides an added level of sophistication to the rate and rhythm-regularity functions of the AT-LER algorithm and may have contributed to the increased diagnostic yield. The lack of QRS morphology analysis by the AT-LER may be responsible for its lower ventricular tachycardia diagnostic yields. Since patients are required to use land-based telephone lines for communication of data with the AT-LER, the enhanced performance of the MCOT™ device in arrhythmia detection is, in part, likely associated with its wireless connectivity feature that obviates patient involvement in sending data to the

monitoring center. Lack of patient compliance with land-line transmissions with the AT-LER can lead to filling the memory capacity of the device with lack of capture of future arrhythmia episodes due to the limited memory capacity of this device. Near real-time technician oversight may also improve diagnostic yield for patients using MCOT™ and should be considered when weighing the increased monitoring cost compared to the AT-LER device.

All patients receiving these devices within an 8-month time interval were included if any ECG data was received; thus, the smaller cohort of patients with the AT-LER device reflects an 8:1 preference for the MCOT device by ordering providers. This utilization disparity was noted despite more limited MCOT™ coverage by commercial health insurance carriers compared to the AT-LER device. The increased cost considerations for the MCOT™ device must be weighed in the context of potential cost savings from its improved diagnostic yield and earlier arrhythmia diagnosis and treatment.

Limitations:

The choice of a specific monitoring technology was made by the ordering physician based on personal or patient-related preferences. Despite the bias inherent in non-randomized designs, the large cohort included may mitigate the impact of selection bias to some degree.

The BioTelemetry database contains no information on patient co-morbid conditions so the distribution of co-morbidities between patients using the two devices is unknown. Patients under 40 years of age were underrepresented in our cohort, and thus our results may be less generalizable to this cohort.

While both devices have the capability of recording patient initiated events generated by patient interaction as the result of symptoms, we cannot exclude that knowledge of the autotrigger functionality may cause some patients to forgo patient initiation to record events. Since both devices have this functionality it is likely that this effect may lead to the possible inclusion of some symptomatic arrhythmias with those arrhythmias we have defined as asymptomatic (device-triggered) by the lack of patient interaction to trigger recording in each device even if symptoms existed.

Transmission of data to the monitoring center may be adversely affected by limited wireless accessibility (MCOT™) and landline connection quality (AT-LER).

Despite meticulous review of EKG data by certified EKG technicians and over-reading physicians, the possibility of arrhythmia interpretation errors may exist. Technician participation is inherent in both the collection and interpretation of the primary monitoring data.

Conclusion:

In a large patient cohort with standard diagnostic indications for cardiac monitoring, MCOT™ demonstrated a higher diagnostic yield and a shorter time to arrhythmia diagnosis compared to AT-LERs. Wireless connectivity may serve to enhance asymptomatic arrhythmia detection with MCOT™ compared to non-wireless devices by improving patient compliance in data retrieval. This study serves to further inform the provider's decision in choosing a specific monitoring device for their patient.

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References:

1. Landis, R.J., Heyman, E.R., and Koch, G.G. Average Partial Association in Three-Way Contingency Tables. A Review and Discussion of Alternative Tests. International Statistical Review. 1978; 46: 237–254.

2. Reiffel, J.A., Schwarzberg, R,and Murry, M. Comparison of Autotriggered Memory Loop Recorders Versus Standard Loop Recorders Versus 24-Hour Holter Monitors for Arrhythmia Detection. Am. J Cardiology. 2005; 95(9):1055-1059.

3. Zimetbaum, P, Waks, J.W., Ellis, E.R., Glotzer, T.V., and Passman, R.S. Pole of Atrial Fibrillation Burden In Assessing Thromboembolic Risk. Criculation: Arrhythmia and Electrophysiology. 2014;7: 1223-1229.

4. Winkle, R., Mead, R.H., Engel, G., Kong, M.H., and Patrawala, R.A. Atrial Arrhythmia Burden on Long-Term Monitoring in Asymptomatic Patients Late After Atrial Fibrillation Ablation. Am J Cardiol. 2012;110(6):840-844.

5. Prystowsky, E.N., Assessment of Rhythm and Rate Control in Patients with Atrial Fibrillation. J Cardiovsc Electrophysiol. 2006;17 (Suppl 2):S7-S10.

Table #1 - Mobile Cardiac Outpatient Telemetry (MCOT) Patient Diagnostic Codes (Top Ten)

Device Category	Diagnosis ID	Diagnosis	n=	Diagnosis Percent of Total
MCOT	R00.2	Palpitations	26,555	37.9%
MCOT	R55	Syncope and collapse	9,999	14.3%
MCOT	I48.0	Paroxysmal atrial fibrillation	9,939	14.2%
MCOT	I48.91	Unspecified atrial fibrillation	5,160	7.4%
MCOT	R42	Dizziness and giddiness	3,018	4.3%
MCOT	R00.1	Bradycardia, unspecified	2,032	2.9%
MCOT	I47.1	Supraventricular tachycardia	1,777	2.5%
MCOT	I48.1	Persistent atrial fibrillation	1,308	1.9%
MCOT	G45.9	Transient cerebral ischemic attack, unspecified	1,279	1.8%
MCOT	R00.0	Tachycardia, unspecified	1,271	1.8%

Table #2 – Autotrigger Looping Event Recorder (AT-LER) Patient Diagnostic Codes (Top Ten)

Device Category	Diagnosis ID	Diagnosis	n=	Diagnosis Percent of Total
AT-LER	R00.2	Palpitations	4,236	49.8%
AT-LER	R55	Syncope and collapse	1,106	13.0%
AT-LER	I48.0	Paroxysmal atrial fibrillation	578	6.8%
AT-LER	R42	Dizziness and giddiness	356	4.2%
AT-LER	R00.0	Tachycardia, unspecified	302	3.5%

AT-LER	I48.91	Unspecified atrial fibrillation	277	3.3%
AT-LER	I47.1	Supraventricular tachycardia	267	3.1%
AT-LER	R00.1	Bradycardia, unspecified	152	1.8%
AT-LER	I48.1	Persistent atrial fibrillation	103	1.2%
AT-LER	G45.9	Transient cerebral ischemic attack, unspecified	97	1.1%

Table #3- Diagnostic Yield of Mobile Cardiac Outpatient Telemetry (MCOT) And Autotrigger Looping Event (AT-LER) Cardiac Monitors

ASYMPTOMATIC ARRHYTHMIA	MCOT/ AT-LER DIAGNOSTIC YIELD RATIO	95% CONFIDENCE INTERVAL	P=	MEAN TIME TO DIAGNOSIS (DAYS)	
				MCOT	AT-LER
ATRIAL FIBRILLATION	2.28	2.10-2.48	<0.001	6.2	8.1
BRADYCARDIA	1.54	1.50-1.59	<0.001	5.0	6.0
VENTRICULAR PAUSE	1.17	1.02-1.34	0.026	5.4	12.1
SUPRAVENTRICULAR TACHYCARDIA	1.80	1.67-1.94	<0.001	9.2	11.1
VENTRICULAR TACHYCARDIA	23.2	18.2-29.6	<0.001	9.0	12.8