Comparative Effectiveness of Ambulatory Monitors for Arrhythmia Diagnosis: A Retrospective Analysis of Medicare Beneficiaries

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Background

- Ambulatory cardiac monitors (ACM) are important diagnostic tools for the assessment and treatment of asymptomatic and symptomatic cardiac arrhythmias and conduction abnormalities.
- There are several classes of ACM device types and monitoring strategies: 1) short-term, continuous (≤ 48 hours) (Holter); 2) long-term continuous (> 48 hours to 14 days*) (LTCM); 3) non-continuous, event-based (up to 30 days) (AEM); and 4) mobile cardiac telemetry (MCT) (direct cellular transmission; up to 30 days). Choice of ACM is based on the actual or suspected clinical diagnosis and frequency and severity of symptoms.
- Although professional societies have provided a general framework for which devices to consider, there are no evidence-based professional society recommendations regarding monitor selection, which may be due to a variety of factors including limited comparative data.

Objective

- To compare effectiveness using U.S. national data to understand variation in monitoring strategy and clinical outcomes and healthcare utilization.

Methods

- The Cardiac Ambulatory Monitor EvaLuation of Outcomes and Time to Events (CAMELOT) study is a retrospective cohort study using the full (100%) Medicare Fee-For-Service sample, including inpatient and outpatient medical claims between January 1, 2016, and December 31, 2019, using Part A, Part B, and Part D data.
- We developed a cohort of Medicare beneficiaries age ≥ 65 years without a preceding arrhythmia diagnosis ("diagnosis-naïve") to investigate usage and clinical outcomes associated with different ACM monitoring strategies.
- The cohort was defined by 1) identification of first occurrence of ACM monitoring ("index date") between January 1, 2017 and December 31, 2018 per identification of a CPT code; 2) no arrhythmia diagnosis during the 12-month period prior to the index date (baseline period); 3) no evidence of an intervention for a conduction disturbance during the baseline period.
- Devices of interest including LTCM, Holter, External AEM, and MCT were ascertained by identification of at least one medical claim with a technical component CPT code ("technical code") for an ACM during January 1, 2017 through December 31, 2018. The date of the first observed claim for an ACM was defined as the index date. The manufacturer of the index ACM was determined from the National Provider Identifier (NPI) number attached when available to the corresponding medical claim with technical code.
- Within each device category, we also evaluated monitoring strategy by ACM-brand sub-cohort, including LTCM with the iRhythm Zio® XT patch-based device (iRhythm Technologies, San Francisco, CA).
- Specified arrhythmias included the following, which qualify for Medicare Hierarchical Condition Code (HCC) 96 as a comorbidity that increases the potential future healthcare costs: atrial fibrillation, atrial flutter, SVT, VT, AV block, sick sinus syndrome, and junctional premature depolarization.
- The following clinical endpoints were evaluated:
  - 90-day diagnostic yield
  - 180-day retest (another ACM)
  - Annualized healthcare resource utilization (HCRU)
  - Differences-in-Differences of HCRU

* *Based on CPT coding information for LTCM is > 48 hours to 14 days.*

Figure 1. CONSORT Diagram

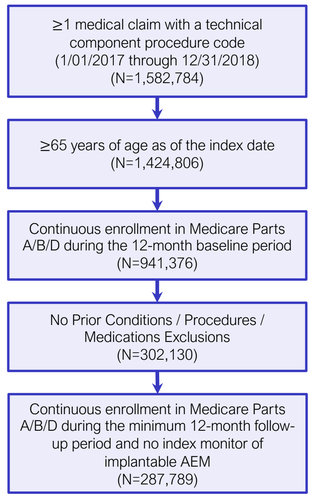


Figure 2. Diagnostic Yield by ACM Type

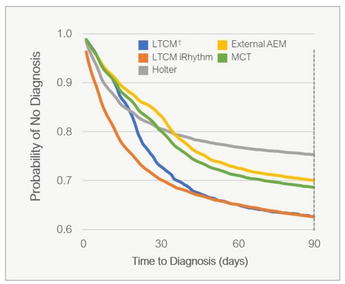
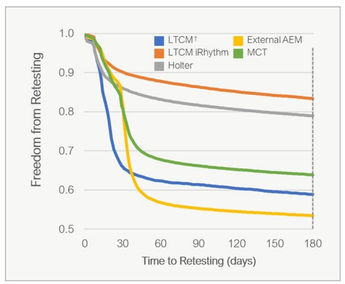


Figure 3. Retesting by ACM Type



† *Includes all LTCM vendors by NPI number, inclusive of iRhythm Technologies, Inc.*

Table 1. Baseline Demographics

Characteristic	LTCM	Holter	External AEM	MCT	p-value
Total (N)	38,318	154,970	29,724	64,777	
Age, yrs, mean (SD)	76.3 (7.0)	76.1 (7.0)	75.8 (6.9)	75.8 (6.8)	< 0.001
Female, %	60.8	60.8	64.1	62.1	< 0.001
CCI Score, mean (SD)	2.5 (2.5)	2.2 (2.3)	2.5 (2.5)	2.8 (2.6)	< 0.001

CCI, Charlson comorbidity index.

Table 2. Multivariable Models of Clinical Outcomes by ACM Type

	Diagnostic Yield		ACM Retest	
Monitoring Strategy	OR (95% CI)	p-value	OR (95% CI)	p-value
LTCM iRhythm (Ref.)	Ref.	-	Ref.	-
LTCM Other/Unknown	0.80 (0.76-0.85)	< 0.001	3.51 (3.33-3.72)	< 0.001
Holter	0.51 (0.50-0.53)	< 0.001	1.35 (1.30-1.39)	< 0.001
External AEM	-	-	4.27 (4.11-4.44)‡	< 0.001‡
AEM BioTelemetry	0.60 (0.57-0.63)	< 0.001	4.20 (4.00-4.42)	< 0.001
AEM Preventice	0.50 (0.47-0.53)	< 0.001	5.74 (5.43-6.07)	< 0.001
AEM Other/Unknown	0.61 (0.58-0.64)	< 0.001	3.68 (3.51-3.86)	< 0.001
MCT	-	-	2.83 (2.73-2.93)‡	< 0.001‡
MCT BioTelemetry	0.71 (0.69-0.74)	< 0.001	3.47 (3.34-3.61)	< 0.001
MCT Preventice	0.64 (0.61-0.67)	< 0.001	4.02 (3.83-4.22)	< 0.001
MCT Other/Unknown	0.65 (0.63-0.68)	< 0.001	1.79 (1.71-1.86)	< 0.001

Model variables included Age, Sex, Race/ethnicity, Geographic region, Baseline comorbid conditions, and Baseline all-cause inpatient hospitalizations. Multivariable models were run at both "above-brand" level (i.e., regardless of manufacturer) and at brand-level (i.e., specific manufacturers). ‡Denotes "above-brand" analysis, based on roll-up of brand-level (main model) odds ratios. All other data presented at brand-level.

Table 3. Follow-up Healthcare Resource Utilization and Costs

	By Monitoring Strategy (ACM Type)					By Monitoring Strategy (ACM Manufacturer)					
Annualized Utilization/Cost	LTCM	Holter	External AEM	MCT	p-value	LTCM iRhythm	External AEM BioTelemetry	External AEM Preventice	MCT BioTelemetry	MCT Preventice	p-value
Total (N)	38,318	154,970	29,724	64,777		30,994	10,382	7,157	29,042	11,675	
F/U all-cause HCRU, Mean (SD)											
Inpatient hospitalizations	0.45 (3.12)	0.45 (2.03)	0.60 (3.14)	0.60 (3.19)	< 0.001	0.45 (3.37)	0.61 (2.54)	0.63 (2.28)	0.62 (3.20)	0.66 (4.21)	< 0.001
Δ from baseline	0.21 (3.13)	0.30 (2.03)	0.32 (3.14)	0.30 (3.20)	< 0.001	0.21 (3.37)	0.32 (2.54)	0.33 (2.28)	0.30 (3.21)	0.36 (4.20)	< 0.001
D-in-D compared to LTCM (p-value)	Ref	0.08 (<0.001)	0.10 (<0.001)	0.09 (<0.001)		Ref	0.11 (0.004)	0.12 (0.004)	0.09 (0.001)	0.15 (0.000)	
ED visits	0.70 (1.40)	0.78 (3.31)	0.87 (1.92)	0.85 (4.91)	< 0.001	0.69 (1.41)	0.84 (1.65)	0.90 (2.23)	0.84 (4.70)	0.88 (3.91)	< 0.001
Δ from baseline	-0.04 (1.59)	0.15 (3.35)	0.00 (2.03)	0.05 (4.96)	< 0.001	-0.05 (1.60)	-0.01 (1.82)	0.02 (2.31)	0.00 (4.77)	0.05 (3.95)	0.082
D-in-D compared to LTCM (p-value)	Ref	0.18 (<0.001)	0.04 (0.014)	0.08 (0.002)		Ref	0.04 (0.081)	0.07 (0.008)	0.05 (0.095)	0.09 (0.001)	
Outpatient visits	25.3 (16.5)	24.5 (16.9)	24.5 (15.9)	26.1 (17.4)	< 0.001	25.4 (16.6)	24.3 (15.6)	24.3 (16.0)	25.8 (16.6)	26.3 (19.4)	< 0.001
Δ from baseline	3.11 (13.72)	4.03 (14.40)	4.00 (13.41)	4.28 (14.74)	< 0.001	2.95 (13.81)	3.73 (13.03)	4.13 (13.59)	4.06 (14.06)	4.70 (17.15)	< 0.001
D-in-D compared to LTCM (p-value)	Ref	0.92 (<0.001)	0.89 (<0.001)	1.17 (<0.001)		Ref	0.78 (0.002)	1.18 (<0.001)	1.10 (<0.001)	1.75 (<0.001)	

Healthcare Economic Information redacted in accordance with FDAMA 114 and 21st Century CURES Act.

* *D-in-D = Difference-In-Difference*

Results

- Diagnostic yield within 90 days was highest for LTCM (33.8%), followed by MCT (27.1%), external AEM (24.6%), and Holter (22.7%) cohorts. Zio® XT (LTCM-iRhythm) subgroup had highest 90-day diagnostic yield (35.2%). In multivariable analysis, compared to LTCM iRhythm as the reference, patients were less likely to have a specified arrhythmia diagnosis recorded for all device manufacturer categories.
- ACM retesting within the first 6 months was lowest for Holter (21.2%), followed by LTCM (21.4%), MCT (36.2%) and external AEM (46.6%) cohorts. LTCM iRhythm sub-cohort retest rate was the lowest at 16.8%. In multivariable analysis, compared to LTCM iRhythm (Zio® XT) as the reference, patients were more likely to have ACM retest with MCT (OR 2.83, 2.73-2.93), Holter (OR 1.35, 1.30-1.39), and AEM (OR 4.27, 4.11-4.44). Device-specific analysis showed greater odds of ACM retesting for all device manufacturer categories relative to LTCM iRhythm.
- Annualized all-cause inpatient hospitalizations during follow-up were lowest in LTCM and Holter cohorts (mean 0.45 stays for both cohorts; including LTCM iRhythm sub-cohort). Annualized follow-up all-cause ED visits were lowest in the LTCM cohort (mean 0.70 visits; mean 0.69 visits for LTCM iRhythm sub-cohort). Outpatient visits were lowest in the Holter and external AEM cohorts (mean 24.5 visits for both).
- When comparing the differences-in-differences of HCRU between LTCM and other cohorts from baseline to follow-up, Holter, external AEM, and MCT all had higher mean hospitalizations (0.08, 0.10, 0.09, respectively); ED visits (0.18, 0.04, 0.08, respectively); and outpatient visits (0.92, 0.89, 1.17, respectively). Similarly, when comparing iRhythm LTCM to the sub-cohorts, iRhythm LTCM had lower utilization for hospitalizations, ED visits, and outpatient visits.
- Increase in total healthcare costs over baseline was lowest in LTCM, followed by Holter, external AEM, and MCT.

Limitations

- These findings are observational, retrospective, and specific to a sample of Medicare beneficiaries.

Conclusions

- In this large, contemporary analysis of Medicare beneficiaries receiving ACM, there was substantial variation in monitoring strategy.
- Use of LTCM was associated with the highest diagnostic yield.
- The Zio® XT (LTCM-iRhythm) strategy was independently associated with the highest diagnostic yield and lowest risk for repeat ACM testing and for subsequent acute care hospitalization.
- Different monitoring strategies may produce different results with respect to diagnosis and subsequent outcomes and care.

Disclosures

M.R. Reynolds is a consultant for Medtronic, Edwards Lifesciences, and iRhythm and serves on a data safety and monitoring board for Affera. **R.S. Passman** receives research support and speaker fees from Medtronic, research support from Abbott, and is a consultant to iRhythm. **J.P. Swindle** and **I. Mohammadi** have no conflict of interest to disclose. **S. Mittal** is a consultant to Boston Scientific and iRhythm. **B. Wright**, **K. Boyle**, & **M. Turakhia** are employees of iRhythm Technologies, Inc.

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