Studie/Poster

«IMPACT OF STUDY DURATION ON DETECTION OF ATRIAL FIBRILLATION IN PATIENTS UNDERGOING AMBULATORY EXTERNAL ECG MONITORING»

2019

IMPACT OF STUDY DURATION ON DETECTION OF ATRIAL FIBRILLATION IN PATIENTS UNDERGOING AMBULATORY EXTERNAL ECG MONITORING

Pooja Mehta, Michael McRoberts, Ben Teplitzky, PhD, Preventice Solutions, Rochester, MN, and Suneet Mittal, MD, FHRS, The Valley Hospital, Ridgewood, NJ
Disclosure: P. Mehta: K - Salary; Preventice. M. McRoberts: K - Salary; Preventice. B. Teplitzky: K – Salary; Preventice. S. Mittal: None

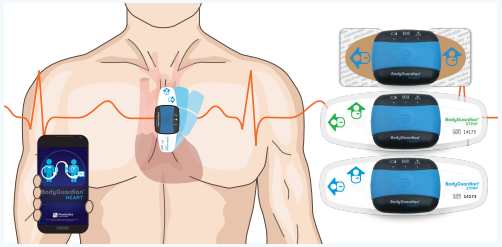
Preventice SOLUTIONS | Valley Health System | In affiliation with Cleveland Clinic Heart and Vascular Institute

BACKGROUND

Single-lead patch-based ambulatory external ECG (AECG) monitoring devices are being used for diagnosis of atrial fibrillation (AF). These AECG systems enable continuous long-term monitoring outside of the clinic. AECG service providers leverage human technicians and algorithms to analyze raw data and distill clinically relevant metrics like AF burden into a daily or end-of-study report for the prescribing clinician. The AECG monitoring devices can be used for up to a month; however, in many instances, monitoring is terminated after just 1-2 weeks. The loss of diagnostic yield with respect to AF remains unknown.

DATA

In a retrospective analysis, AF statistics were noted for 25457 randomly selected patients who had undergone AECG monitoring in the mobile cardiac telemetry (MCT) mode for at least 28 days with the BodyGuardian Heart device (Preventice Solutions, Inc.). MCT is the only non-invasive ambulatory service that provides comprehensive holter-like data for up to 30 days.



For these patients, each detected AF episode duration was noted, to calculate the AF burden, as well as the time it took from the start of the monitoring period for AF episodes of different minimum durations to manifest. The data was analyzed altogether, as well as in groups by diagnosis code. The groups formed based on diagnosis codes were:

- Palpitations patients
- Syncope patients
- Stroke patients
- AF patients

AF episode detection was performed by Preventice Solutions which combines certified ECG technician oversight with algorithmic AF detection using the Preventice BeatLogic™ deep learning platform. Rhythm 2019;15(5S): S-PO02-197 (Real-world Performance of Atrial Fibrillation Detection From Wearable Patch ECG Monitoring Using Deep Learning).

RESULTS

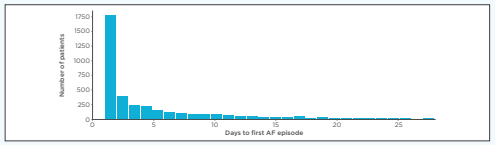


Figure 1 Days to first AF detection

At least one AF event was present for 4,033 patients (15.8%), with the majority of detections occurring on the first monitoring day. For 424 patients, the first AF event detection occurred after monitoring day 14.

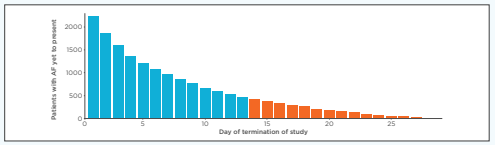


Figure 2 Patients with AF yet to present

Out of the 4,033 patients with at least one AF episode, 2,250 were captured after one day of monitoring. Had the monitoring study ended at 14 days, the first AF event would have been missed for 424 (10.5%) patients.

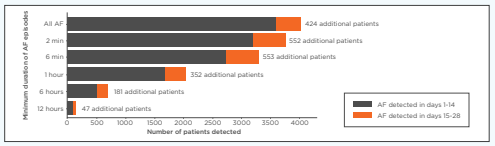


Figure 3 Additional patients detected at 28 days as a function of minimum AF episode duration

Filtering AF events by duration highlighted cases where the first AF detection was sustained for several minutes or hours and occurred after 14 days. In this analysis, AF episodes with duration shorter than the specified minimum specified were excluded. For example, for '2 min' minimum duration, all AF episodes that were shorter than 2 min were filtered out, for '6 min', all AF episodes that were shorter than 6 min were filtered out, and so on. Patients had sub-clinical (< 2 min) episodes of AF more consistently throughout their studies compared to longer episodes of AF which leads to the higher additional patients detected at 28 days vs 14 days for the longer AF episodes. Monitoring for 28 days verses 14 days resulted in 352 (8.7%) more patients with at least one AF episode that was longer than 1 hour, and 181 (4.5%) more patients with at least one AF episode that was longer than 6 hours.

Figure 4 shows a scatter plot of the AF burden in days 15-28 vs that in days 1-14. The deviation from the diagonal here indicates different burdens in the two time periods.

Additional analysis was carried out by grouping the data by the diagnosis code for the patient study. Four broad categories were considered – palpitations patients (n=10012), syncope patients (n=4072), stroke patients (n=1219) and AF patients (n=4678). Kaplan Meier curves for the first documented AF episode for each of these subpopulations are shown in the figures below. Each plot contains 6 curves for the different minimum duration requirements of an AF episode.

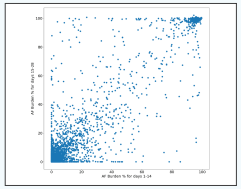


Figure 4 AF burden scatter plot

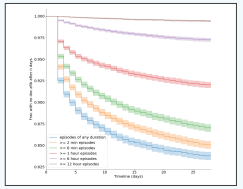


Figure 5 First documented AF for all patients

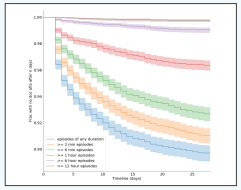


Figure 6 First documented AF for patients diagnosed with palpitations

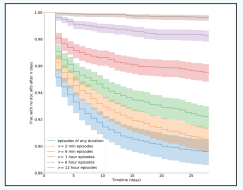


Figure 7 First documented AF for patients diagnosed with syncope

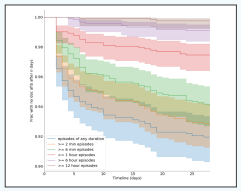


Figure 8 First documented AF for patients diagnosed with stroke

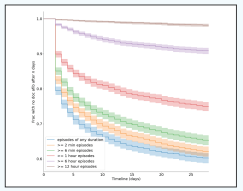


Figure 9 First documented AF for patients diagnosed with AF

Detailed results for additional patients detected by monitoring for 28 days vs 14 days for each diagnosis code and minimum duration of an AF episode are shown in the table below.

Table 1 Detailed results

Diagnosis Code	Duration of AF	Total Patients	Number of Patients Detected Days 1-14	Number of Patients Detected Days 15-28	Percentage of Patients Detected after Day 14
All	All	4033	3609	424	10.5%
	2 min	3765	3213	552	14.7%
	6 min	3298	2745	553	16.8%
	1 hr	2041	1689	352	17.2%
	6 hrs	707	526	181	25.6%
	12 hrs	145	98	47	32.4%
Palpitations	All	1016	893	123	12.1%
	2 min	898	745	153	17.0%
	6 min	734	583	151	20.6%
	1 hr	372	285	87	23.4%
	6 hrs	99	67	32	32.3%
	12 hrs	23	15	8	34.8%
Syncope	All	410	368	42	10.2%
	2 min	377	318	59	15.6%
	6 min	314	259	55	17.5%
	1 hr	182	156	26	14.3%
	6 hrs	73	57	16	21.9%
	12 hrs	15	7	8	53.3%
Stroke	All	95	80	15	15.8%
	2 min	85	67	19	22.1%
	6 min	71	52	19	26.8%
	1 hr	31	23	8	25.8%
	6 hrs	10	6	4	40.0%
	12 hrs	3	1	2	66.7%
AF	All	1814	1645	169	9.3%
	2 min	1754	1538	216	12.3%
	6 min	1618	1390	228	14.1%
	1 hr	1166	998	170	14.6%
	6 hrs	431	335	96	22.3%
	12 hrs	87	55	32	36.8%

DISCUSSION

- In an abbreviated (14 day) monitoring study, the first occurrence of AF would have been missed in 10%-32% of the patient population, depending on the minimum AF episode duration.
- First AF detections that occurred after 14 days were most common for patients with the diagnosis code, AF, but also occurred for patients with a diagnosis code of palpitations, syncope and stroke.
- Additionally, many patients were observed to have different AF burden in the monitoring days 1-14 and 15-28, which may have implications for diagnosis and treatment.
- These results establish the importance of monitoring beyond 14 days.

CONCLUSION

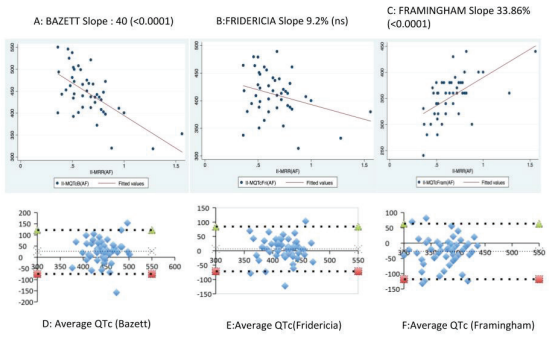
- In patients undergoing AECG monitoring, if detection of AF is the goal, monitoring should be performed for 28 days.
- While there may be value to longer monitoring, 28 days is the longest feasible duration based on current coverage guidelines.
- Monitoring for 14 days would have resulted in missing the first AF event for more than 10% of patients, including many of which completed the full 28-day duration study with sustained AF events lasting greater than 1 hour.

ACKNOWLEDGMENTS

The authors would like to thank the members of the data science and executive team at Preventice Solutions for their support of this work. We would also like to thank KW for lending their design expertise to this work.

Medical Center, Sacramento, CA, UC Davis Medical Center, Gold River, CA, Univ of California at Davis, Cardiology, Davis, CA, UC Davis, Sacramento, CA

Background: QT interval measured in the electrocardiogram (ECG) varies with RR interval; number of complexes needed to calculate QTc in Atrial fibrillation (AF) is unknown. Bazett formula overestimates the QTc, thus impacting anti-arrhythmic drug utilization in AF.
Objective: To identify the ideal lead, number of complexes and the formula that correlates best between AF and sinus rhythm (SR).
Methods: We identified ECGs from patients with AF before and after conversion to SR. We excluded patients treated with drugs and clinical conditions that prolong QT interval. QTc was calculated from all the leads using the formulae: Bazett (BF), Fridericia (FF), Framingham(FrF), Hodges (HF), Saige (SF) and Rautaharju (RF) during AF and SR. After identifying the lead with best linear correlation, we calculated QTc following the longest RR, multiple QRS complexes and average automated RR interval during AF and compared to QTc during SR.
Results: Between AF and SR in 52 patients (male 69%, age 63 + 9 yrs, hypertension 62%, Diabetes 17%), Lead II correlated best in majority of the formulae. QTc was consistently shorter with linear formulae. While BF overestimated QTc, FF correlated best comparing AF vs SR (416 + 33 vs 411 + 38 msec, ns) calculated from single, multiple or average automated RR interval. Bland Altman analysis of the average of the automated QTc compared with the delta of individual automated QTcs shows that the mean difference in the Fridericia Formula has the best agreement between the QTc values.
Conclusion: BF in commercial software is not ideal for measurement of QTc in AF, FF in lead II from the average RR from automated ECG measurement maybe utilized for the calculation of QTc.



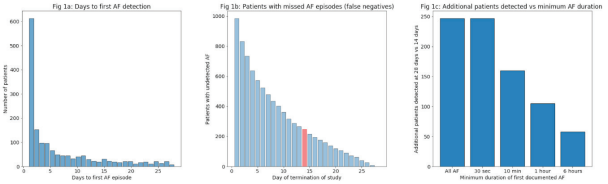
Top row: Correlation between RR interval in seconds (X axis) and QTc from a single complex in Lead II in msec (Y axis); A: Bazett formula; B: Fridericia formula; C: Framingham Formula.
Bottom row: Bland Altman Analysis of Lead II Average QTc; X axis: QTc in msec; Y axis- Delta difference between QTc in sinus rhythm and atrial fibrillation; dotted line between green triangles: upper limit of agreement; Dotted line between red squares: lower limit of agreement; Black line represents Bias.

S-PO04-195

IMPACT OF STUDY DURATION ON DETECTION OF ATRIAL FIBRILLATION IN PATIENTS UNDERGOING AMBULATORY EXTERNAL ECG MONITORING

Pooja Mehta, Benjamin Adam Teplitzky, Michael McRoberts and Suneet Mittal, BA, MD, FHRS. Preventice Solutions, Houston, TX, Preventice Solutions, Eagan, MN, Preventice Solutions, Rochester, MN, The Valley Hospital, New York, NY

Background: Single-lead patch-based ambulatory external ECG (AECG) monitoring devices are being used for diagnosis of atrial fibrillation (AF). These AECG systems can be used for up to a month; however, in many instances, monitoring is terminated after just 1-2 weeks. The loss of diagnostic yield with respect to AF remains unknown.
Objective: To determine the incremental yield of AF detection when AECG monitoring is extended from 14 to 28 days.
Methods: In a retrospective analysis, the time of the first documented AF was noted for 2684 randomly selected patients who had undergone AECG monitoring with the BodyGuardian Heart device (Preventice Solutions, Inc). Figure (1a) shows the frequency distribution of days till the first AF detection. Figure (1b) shows the number of AF patients that would remain undetected if AECG was not extended to 28 days. Figure (1c) shows the additional patients detected, for a minimum duration of AF, by monitoring beyond 14 days to the full 28 days.
Results: At least one AF event was present for 1598 patients (59.5%). Had ECG monitoring been truncated at 14 days, 247 (15.5%) patients with AF would have been missed (Figure 1b). This includes 105 (6.6%) patients with > 1 hour of AF and 58 (3.6%) patients with > 6 hours of AF.
Conclusion: In patients undergoing AECG monitoring, if detection of AF is the goal, monitoring should be extended to 28 days. This is the longest feasible duration based on current coverage guidelines. Truncating duration of monitoring is associated with “missed” AF in 15.5% of patients; many of whom have > 1 hour of AF.



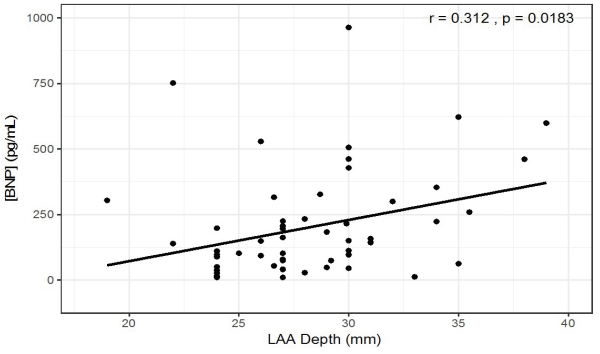
S-PO04-196

SERUM BNP LEVELS AT TIME OF LEFT ATRIAL APPENDAGE (LAA) OCCLUSION AND ASSOCIATION WITH LAA MORPHOLOGY

Arvindh N. Kanagasundram, MD, FHRS, Ricardo Miguel. Lugo, MD, Rachel Schreier, Robert Piana and Christopher R. Ellis, MD, FHRS. Vanderbilt University, Brentwood, TN, Vanderbilt University Medical Center, Nashville, TN, Vanderbilt Heart and Vascular Institute, Cardiology, Nashville, TN

Background: The left atrial appendage (LAA) is the main source of BNP in patients with AF and its myocardium has the highest density of natriuretic peptides in the heart. Serum BNP levels correlate with the presence of spontaneous echo contrast, reduced LAA ejection velocity <20cm/sec on TEE, and left atrial (LA) thrombus in patients with non-valvular atrial fibrillation (NVAF).
Objective: To determine whether the morphology of the LAA is associated with serum BNP levels adjusted for left atrial pressure (LAP) at the time of LAA device closure.
Methods: All subjects were prospectively enrolled in the Vanderbilt LAA registry. Serum BNP was collected in 59 consecutive patients with NVAF who presented for LAA occlusion (Watchman, or IDE for LARIAT, Amulet or Watchman FLX). LAA measurements were performed using biplane trans-esophageal echocardiography (TEE) with ostial dimensions in two orthogonal (0/90, and 45/135 degree) planes and maximal depth from ostium. Left atrial filling pressures were transduced at the time of sample collection.
Results: Serum BNP correlated with LA mean pressure (p=0.013), BMI (p=0.023) and LAA maximal depth (p=0.018) on Pearson’s test. In linear regression analysis, the association between BNP and LAA maximal depth persisted after normalizing for mean LA pressure (p=0.012). This relationship

persisted in multi-variable analysis after controlling for BMI, Creatinine, EF and CHADS2VASC score (p=0.028).
Conclusion: In patients with NVAF presenting for LAA occlusion, serum BNP is associated with LAA morphology with significant association with LAA depth. This may reflect that the deeper LAA has more atrial tissue leading to increased serum BNP.



S-PO04-197

PROPHYLACTIC LEFT ATRIAL APPENDAGE EXCLUSION REDUCES STROKE INCIDENCE IN HIGH RISK CARDIAC SURGERY PATIENTS: RESULTS FROM THE ATLAS RANDOMIZED CONTROLLED TRIAL

Marc William. Gerdisch, MD, FHRS, H. Edward Garrett Jr., M.D., Mubashir Mumtaz, MD, FACS, FACC, John Grehan, MD, PhD and Basel Ramlawi, MD, MMSc. Franciscan St Francis Health, Indianapolis, IN, Cardiovascular Surgery Clinic, Memphis, TN, Pinnacle Health Cardiovascular Institute, Harrisburg, PA, Allina Health Clinic, St Paul, MN, Valley Health System - Heart & Vascular Center, Winchester, VA

Background: Patients without history of AF undergoing cardiac surgery (CS) have a high incidence of new onset post-operative AF (POAF). While POAF is typically transient, it may occur several days after surgery and is a predictor of recurrent AF, which may go undetected. Since AF is a stroke risk, there may be an indication to manage patients prophylactically. As clots in AF arise frequently in the LAA, LAA exclusion (LAAE) during cardiac surgery may reduce strokes in high risk patients.
Objective: ATLAS, a prospective, multicenter, randomized trial was conducted to determine the cerebrovascular event rate (CVA, stroke + TIA) in CS patients without AF history, but with elevated AF stroke and bleeding risk (CHA2DS2-VASc=>2, HASBLED=>2) undergoing concomitant LAAE vs without LAAE.
Methods: 562 patients were randomized 2:1 to LAAE Vs No-LAAE. LAAE was done using epicardial AtriClip©. Both arms received institutional standard treatment on POAF detection. As POAF incidence is highest in early post-operative period, an analysis of CVA rates at 3 months post-procedure was done. The adverse events (AEs) were adjudicated by an independent medical reviewer. Patients are followed to 12 months, which is underway.
Results: The baseline characteristics in both arms were similar. Intraoperatively 99% patients had no flow between LAA and LA, 98.4% had LAA remnant < =10 mm. No major device or procedural AEs were attributed to LAAE.

Parameter	LAAE Arm	No-LAAE Arm	Comments
Number of treated patients (N= 562)	376	186	
CHADS-VASc (Mean ±SD)	3.4 ± 1.18	3.4 ± 1.12	p=NS
HASBLED (Mean ±SD)	2.8 ± 0.68	2.9 ± 0.65	p=NS
Post-operative AF (POAF) detected (N=284)	47% (178/376)	38% (70/186)	44% (248/562) overall POAF rate
CVA rates in patients for whom POAF was detected	1.7% (3/178)	5.7% (4/70)	p = 0.08
CVA rates in patients irrespective of POAF detection	1.6% (6/376)	4.8% (9/186)	p=0.02
Contribution of Strokes Vs TIA towards overall CVA rate	50% (3/6) Strokes, 50% (3/6) TIAs	77% (7/9) Strokes, 29% (2/9) TIA	

Conclusion: At 3 months, prophylactic LAAE in cardiac surgery patients with elevated CHADS2VASc and HASBLED resulted in significantly lower CVA incidence, without increase in AEs. Further trials to evaluate the long-term effects of LAAE during cardiac surgery are needed.

S-PO04-198

UTILIZATION AND INHOSPITAL ADVERSE OUTCOMES ASSOCIATED WITH WATCHMAN DEVICE

Abhishek J. Deshmukh, MD, FHRS, Shilpkumar Arora, Nandini Mehra, Byomesh Tripathi, Vaibhav Vaidya, MBBS, Awani Deshmukh, Apurva Badheka, MD, CCDS, Paul A. Friedman, FHRS, Thomas M. Munger, MD, FHRS and David R. Holmes, MD. Mayo Clinic, Rochester, MN, Mount Sinai St Luke's Roosevelt Hospital, New York, NY, Mount Sinai St. Luke's-West hospital, New York, NY, University of Miami, Miami, FL

Background: The FDA approval of Watchman device [percutaneous left atrial appendage occlusion (LAAO)] has resulted in widespread use of this procedure in many centers across United States
Objective: We sought to estimate the nationwide utilization and frequency of adverse outcomes associated with this procedure.
Methods: The National Inpatient Sample (NIS) was queried for all adult patients (pts) with primary diagnosis of atrial fibrillation or flutter during the year 2016 who had percutaneous LAAO during the same admission. (ICD 10 code - 02L73DK)The incidence of peri-procedural complications including mortality, stroke, major bleeding requiring blood transfusion, pericardial effusions and vascular access complications was assessed. We also compared the complication rates with the published randomized control trials and the European registry.
Results: Estimated 5175 LAAO procedures were performed in 2016. Majority of the patients were male (59.1%) , age > 75 years (58.6%) , Caucasians (83%). The overall complication rate was 1.93%. The in hospital mortality was 0.29%. Pericardial effusion requiring pericardiocentesis was the most frequent complication (0.6%).Bleeding requiring transfusion was noted in 0.1% of implants. The rates of ischemic stroke , hemorrhagic stroke and systemic embolism were 0.1% , 0.29% and 0.29% respectively. Table1 shows comparison of complication rates between NIS data , PROTECT AF , PREVAIL , CAP registry and the EWOLUTION cohort.
Conclusion: Percutaneous LAAO using the Watchman device in the US is associated with low in-hospital complications and similar safety profile to a recently published EWOLUTION cohort and lower than the RCTs.