Studie/Poster

«REAL-WORLD VALIDATION OF A DEEP LEARNING ALGORITHM FOR FULLY-AUTOMATED PREMATURE VENTRICULAR BEAT CLASSIFICATION DURING AMBULATORY EXTERNAL ECG MONITORING»

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Real-World Validation of a Deep Learning Algorithm for Fully-Automated Premature Ventricular Beat Classification During Ambulatory External ECG Monitoring

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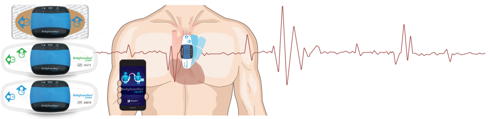
B. Teplitzky: K - Salary; Preventice. M. McRoberts: K - Salary; Preventice. S. Mittal: None.

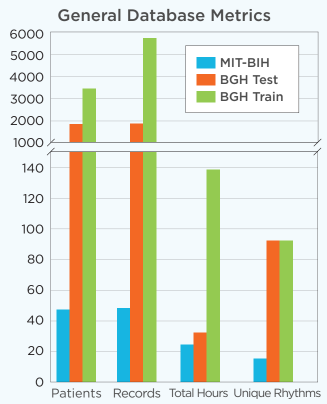
BACKGROUND

Ambulatory external ECG (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 into a daily or end-of-study report for the prescribing clinician. One key aspect of this reporting relies on the accurate detection and classification of ventricular ectopic beats (VEBs). VEB detection underlies the ability of service providers to accurately detect and notify clinicians of potentially life-threatening and treatable cardiac irregularities.



VEB algorithm validation is typically performed using 47-patient MIT-BIH arrhythmia database (MIT-BIH) in FDA submissions, and using an 11-patient sub-set of VEB MIT-BIH records in academic publications. It currently remains unclear whether these validation methods accurately reflect real-world performance for modern patch-based AECG systems (above), which capture ECG waveforms that are objectively different from the MIT-BIH signals; and for deep learning algorithms, which have the unique capacity to "memorize" training data.

DATA



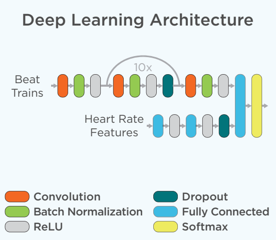
Beats recorded from a total of 5,407 BodyGuardian® Heart (BGH) patients were annotated and adjudicated by 3 certified ECG technicians, each with more than 5 years of experience. Algorithm training was performed using beats from 3,493 patients and performance was measured using both the MIT-BIH arrhythmia database and beats from 1,914 BGH patients. The BGH records were split to ensure no patient overlap between training and test datasets. The number of patients, number of records, total hours, and unique rhythm types contained within each BGH dataset significantly exceeded that of the MIT-BIH database (left). BGH beat counts for all categories except fusion and paced were significantly higher than MIT-BIH (below).

Beat Counts

N	S	A	B	V	F	P
75,052	2,629	150	15,334	7,130	803	7,028
118,145	11,894	600	14,807	9,878	137	173
523,079	32,105	2,528	66,881	46,433	785	805

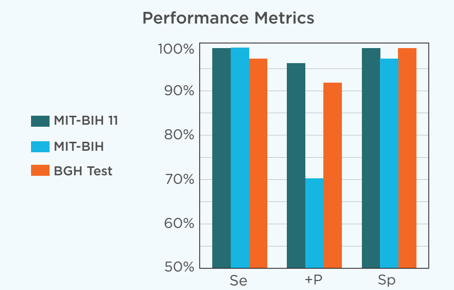
N: Normal beat
S: Supraventricular ectopic beat
A: Aberrated atrial premature beat
B: Bundle branch block beat
V: Premature ventricular contraction
F: Fusion of ventricular and normal beat
P: Paced beat

ALGORITHM

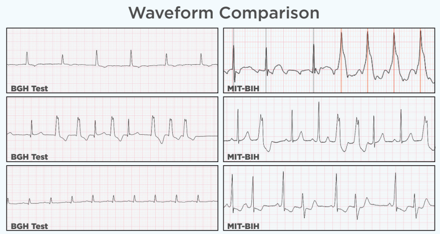


A deep learning algorithm was trained using the BodyGuardian® Heart training dataset to assign four classification labels: VEB (including fusion), non-VEB, not-a-beat, and unclassifiable. Not-a-beat was used to invalidate incorrect beat detections, which were derived from a modified Pan-Tompkins beat detection algorithm. The unclassified label was used to qualify low confidence classifications. The network incorporated a small two-layer network, which was fed heart rates, and a deep convolutional network, which was fed 3-beat trains. The convolutional network consisted of a repeating series of layers: 1-D convolution, batch norm, ReLU, and dropout (left). Dropout was excluded from the first and last series'. Classification was performed by a final fully-connected layer using the flattened output of the two networks.

RESULTS



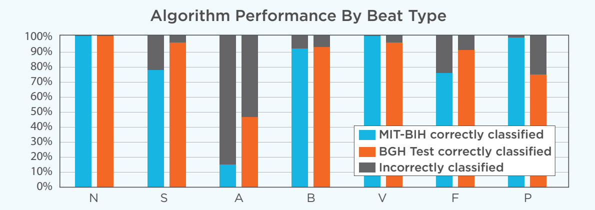
The beat classification algorithm achieved >90% sensitivity (Se), positive predictive value (+P), and specificity (Sp) on each test set, with one exception: positive predictive values on the full MIT-BIH dataset (left). Sensitivity and positive predictive value were higher when measured using the MIT-BIH 11 VEB records verses the real-world data. Evaluation using the MIT-BIH data resulted in higher sensitivity, lower positive predictive value, and lower specificity in comparison to the real-world data.



A comparison between representative data captured using the single channel AECG BodyGuardian® Heart device with data from the MIT-BIH arrhythmia database illustrates common differences, which result from the short dipole in patch-based monitors. The reduced amplitude and less prominent t- and p-waves demonstrate how validation using only MIT-BIH is insufficient for algorithms used in patch-based AECG applications.

Representative annotations performed by the classification algorithm demonstrate correct classification of large beats (top), removal of a false beat detection (middle), application of the unclassified label in the case of low-confidence (bottom).

DISCUSSION



N: Normal beat
S: Supraventricular ectopic beat
A: Aberrated atrial premature beat
B: Bundle branch block beat
V: Premature ventricular contraction
F: Fusion of ventricular and normal beat
P: Paced beat

Breaking down performance by beat type within the real-world BGH test dataset (above, orange), the algorithm correctly classified greater than 95% of ventricular ectopic and normal beats and greater than 90% of supraventricular ectopic, bundle branch block, and fusion beats. Sub-optimal performance was seen for paced and aberrated atrial premature beats. Evaluation using MIT-BIH resulted in underestimates of algorithm performance on supraventricular ectopic, aberrated atrial premature and, bundle branch block; and over-estimates of performance on ventricular ectopic beats. Interpretation of the discrepancy in performance for fusion and paced beats is difficult due to higher prevalence of these beats in the MIT-BIH dataset.

CONCLUSIONS

- Validation using real-world beats from nearly 2000 ambulatory patients demonstrates the deep learning algorithm to be accurate and real-world generalizable.
- State-of-the-art performance was achieved due to the development of a novel deep learning architecture combined with the largest ever training data set applied to beat classification.
- Performance measured using the MIT-BIH database was inconsistent with real-world results, underestimating or overestimating depending on if the full (used in FDA submissions) or VEB only (common in academic publications) dataset was used.
- Deep learning algorithms have the capacity to simply memorize training data. This results in systems that perform near-perfectly under controlled conditions, but do not generalize in real-world environments. For this reason, it is vital that validation be performed using large diverse real-world datasets.

ACKNOWLEDGMENTS

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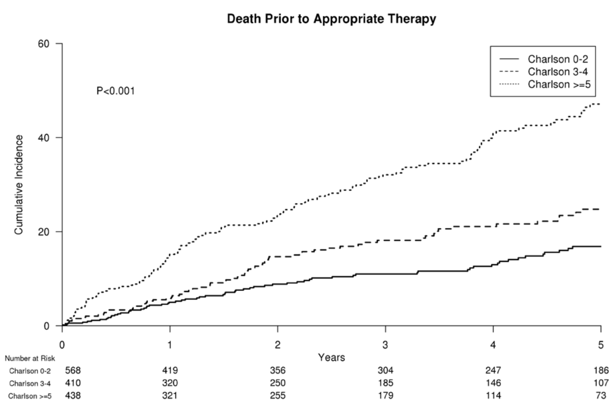
co-morbidities) and death prior to appropriate therapy.
Methods: Patients who received their first ICD generator replacement between 2001 - 2011 at two academic centers were identified (n=1421). CCI score was grouped as low (0 - 2) n=569; moderate (3, 4) n=412; and high (≥5) n=440. Multivariable Cox proportional hazards model was used to identify independent associations.
Results: Cohort characteristics: age 69.6 ± 12.1 y, 81% M, 66% ischemic, 52% secondary prevention. Over a follow-up of 2.7±2.6y, 336 (23.6%) died prior to appropriate therapy. Compared to those with low CCI score, high CCI score [HR 1.94 (1.29-2.92) p=0.002] was a significant predictor of death prior to appropriate therapy, but not moderate CCI score [1.43 (0.93-2.21) p=0.1]. LVEF was not a predictor of the outcome [0.99 (0.98-1.00) p=0.08]. Figure shows Kaplan Meier curve of time to death prior to appropriate therapy stratified by CCI score.
Conclusion: Presence of multiple medical co-morbidities as assessed by high Charlson co-morbidity index is associated with death without prior ICD therapy after ICD generator replacement. Future studies must evaluate the incremental value of the CCI in addition to cardiac factors in determining the benefit of ICD replacement.



B-PO03-043

DETECTION OF ARRHYTHMIAS IN PEDIATRIC AND CONGENITAL HEART DISEASE PATIENTS WITH IMPLANTABLE LOOP RECORDERS

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Background: Rhythm disorders are the leading cause of morbidity and mortality in patients with congenital heart disease (CHD). Non-invasive arrhythmia monitoring may not detect infrequent or asymptomatic arrhythmias. Implantable loop recorders (ILRs), such as the Reveal LINQ™ (Medtronic), have been shown to be useful in long-term arrhythmia monitoring in adult patients.
Objective: We proposed that the Reveal LINQ™ will detect arrhythmias, missed by other monitoring modalities, which results in change in management in pediatric and CHD patients.
Methods: This is a retrospective review of Reveal LINQ™ use in pediatric and CHD patients followed at a single center from December 2014 to October 2017. Medical records were reviewed to determine cardiac diagnosis, indication for implant, ILR findings, and changes in management.
Results: Thirty seven patients, mean age 20 years (range 4 - 40 years), with diagnosis of CHD (60%), inherited arrhythmia syndrome (16%), cardiomyopathy (5%), and no known cardiac diagnosis (19%) were followed for an average of 21±10 months. Reasons for implant were syncope (51%), arrhythmias (38%) and/or palpitations (38%); several patients had multiple indications for implant. Arrhythmias resulting in change in therapy were documented in 5 (14%) patients; 2 (5%) patients had ICD placements, 2 (5%) had ablations and 1 (3%) had medication change. Symptomatic events without arrhythmia occurred in 7 patients (19%), thus avoiding more invasive procedures, and occurred more often in patients with inherited arrhythmia syndrome. Oversensing, including T wave oversensing and QRS double counting, occurred in 7 patients (19%). Problems with accurate detection occurred in 2 (5%) patients when arrhythmia detection rate was close to patient's sinus tachycardia rate, requiring reprogramming.
Conclusion: ILRs are a useful adjunct for arrhythmia monitoring in the pediatric and CHD population with findings affecting management in 35% of patients. ILR is rate-based detection without morphology discrimination; therefore, programming consideration should focus on primary indication for implant and patients' underlying conduction system.

B-PO03-044

REAL-WORLD VALIDATION OF A DEEP LEARNING ALGORITHM FOR FULLY-AUTOMATED PREMATURE VENTRICULAR BEAT CLASSIFICATION DURING AMBULATORY EXTERNAL ECG MONITORING

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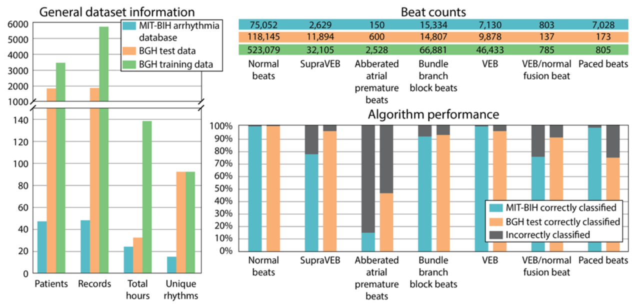
Background: Ambulatory external ECG (AECG) monitoring quantifies the burden of ventricular ectopic beats (VEBs). These systems typically incorporate algorithms that are tuned and evaluated using the 47-patient MIT-BIH arrhythmia database (MIT-BIH). However, it remains unclear whether MIT-BIH performance accurately reflects real-world performance.
Objective: To demonstrate real-world performance of a deep neural network (DNN) that empowers clinicians with accurate and timely VEB detection.
Methods: We trained a DNN using 672,616 beats from 3,493 BodyGuardian® Heart (BGH) patients. Performance was measured using MIT-BIH and a real-world BGH database of 1,914 patients with greater rhythm diversity (Figure, left).
Results: The DNN correctly classified greater than 95% of VEB and normal beats (Figure, lower right). The DNN performed well on supraventricular ectopic, bundle branch block, and fused beats. The small number of paced and abberrated atrial ectopic beats in the training dataset (Figure, upper right) resulted in sub-optimal classification performance for these beat types.
Conclusion: AECG algorithms are approved for use based on their performance against MIT-BIH. However, because DNNs possess the unique ability to simply "memorize" training data, detailed validation must be performed using real-world patients. Detailed analysis ensures that algorithms are deployed only in contexts where performance is clinically acceptable, and allows technologists to address weaknesses by curating targeted training datasets. Limitations associated with deep learning algorithm validation using small datasets like MIT-BIH must be kept in mind in day-to-day clinical practice.



B-PO03-045

EFFICACY OF NEW-GENERATION ATRIAL ANTITACHYCARDIA PACING IN PATIENTS IMPLANTED WITH AN IMPLANTABLE CARDIOVERTER DEFIBRILLATOR

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Background: New-generation atrial antitachycardia pacing (ATP) (Reactive ATP) has been shown to reduce the incidence of progression to persistent atrial fibrillation (AF) in patients implanted with a pacemaker (PM) in the MINERVA trial.
Objective: We aimed to investigate whether Reactive ATP can suppress the incidence of progression to persistent AF, inappropriate therapy by an implantable cardioverter defibrillator (ICD) and heart failure (HF) hospitalization in patients implanted with an ICD.
Methods: Consecutive 134 patients (97 males, mean age: 64.3 ± 13.6 years) implanted with an ICD have been followed with Reactive ATP function since 2014 (ATP-ON group). The incidence of progression to persistent AF, inappropriate ICD therapy and HF hospitalization was compared with that in 59 patients (39 males, mean age: 60.8 ± 14.0 years) who were implanted with a dual-chamber ICD without ATP function during the same period (ATP-OFF group). Patients with persistent AF were excluded from this study.
Results: During 550 ± 250 days of follow-up period, 7195 atrial tachyarrhythmia (ATA) episodes were treated by ATP in 29 of 134 patients (21.6%) in the ATP-ON group. The mean ATP success rate was 43.1%, which was comparable to the results of the MINERVA trial. AF burden decreased in 33% of the patients after Reactive ATP was programmed. However, there were no significant differences in the incidence of progression to persistent AF (ATP-ON vs. ATP-OFF: 1.6% vs. 3.4%, p=0.33) and inappropriate ICD therapy due to AF (2.6% vs. 1.7%, p=1.0) between patients in the ATP-ON and ATP-OFF groups. No patients experienced HF hospitalization due to AF in both groups. There were no severe complications related to ATP delivery such as induction of ventricular arrhythmias. Of 219 Successfully terminated ATA episodes by ATP, 92% were regular and relatively slow episodes (mean cycle length 263ms).
Conclusion: Reactive ATP was similarly effective in patients implanted with an ICD, and could reduce AF burden in 33% of the patients without severe complications. However, Reactive ATP did not reduce the incidence of progression to persistent AF, inappropriate ICD therapy and HF hospitalization in patients implanted with an ICD.

B-PO03-046

LEADLESS PACEMAKER IMPLANTATION: FEASIBLE AND REASONABLE OPTION FOR TAVR PATIENTS

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Background: Atrioventricular (AV) block is a common post-operative complication of transcatheter aortic valve replacement (TAVR) for severe aortic stenosis, often resulting in the placement of a permanent pacemaker PPM. The novel leadless pacemaker (LPM) has benefits over transvenous pacemakers (TPM), such as less risk for infection and less likely to cause tricuspid regurgitation.
Objective: This study provides the first analysis of the use of leadless pacemakers in TAVR patients compared to conventional single chamber transvenous PPM (TPM).
Methods: A retrospective chart review was performed for all TAVR patients undergoing LPM and TPM placement at Columbia University, New York, NY (CUMC) from July 2008 to July 2017. 5 TAVR patients received LPM and 22 received single chamber TPM.
Results: There was no significant difference in mean age of TAVR patients who received LPM and TPM (81 ± 4.4 years vs. 84 ± 1.4 years, p=0.3). 50% of TPM recipients were women. Of the LPM recipients 60% were men and the average BMI was 30.4 ± 4.3. The indication for TPM and LPM placement was atrial fibrillation with slow ventricular response. There was no significant difference in pre-TAVR LVEF in patients who received LPM and TPM (LVEF 54.2 ± 4.0% vs. 56.8 ± 4.4%, p=0.79). The same access site (right groin) was utilized for TAVR and LPM in 4 of the 5 patients. There was no significant difference in % pacing between LPM and TPM (35.1 ± 7.7% vs. 49.8 ± 47%, p=0.56). There were two patients who were candidates for LPM but could not receive one due to vascular access issues such as presence of a large hematoma or IVC filter. Echocardiography after pacemaker placement showed 0% of LPM recipients had had moderate/severe tricuspid regurgitation, whereas, 37% of TPM recipients had moderate/severe tricuspid regurgitation (p=0.22).
Conclusion: LPMs can be successfully utilized in TAVR patients without major complications. LPMs show similar clinical outcomes to patients with single chamber transvenous pacemakers with a trend towards less tricuspid regurgitation after pacemaker placement. LPM should be considered for use in TAVR patients.

B-PO03-047

VENOPLASTY TO FACILITATE TRANSVENOUS LEAD PLACEMENT: A SINGLE-CENTER EXPERIENCE

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Background: Cardiovascular Implantable Electronic Devices