Clinical Summary

Los Angeles ECG study reports high sensitivity and specificity for LIFEPAK® 15 monitor/defibrillator's STEMI detection algorithm

Bosson N, Eckstein M, Sanko S, Stickney R, et al. Causes of false positive and false negative software interpretation of ST-elevation myocardial infarction in out-of-hospital electrocardiograms. *Annals of Emergency Medicine.* 2015;66:S47-8 (abstract).

Sanko S, Eckstein M, Bosson N, Taylor TG, et al. Accuracy of out-of-hospital automated ST detection by LIFEPAK 12 and 15 devices: the Los Angeles experience. *Annals of Emergency Medicine.* 2015;66:S6-7 (abstract).

Sanko S, Eckstein M, Bosson N, Stickney R, et al. Differences in out-of-hospital electrocardiogram test characteristics by patient sex and ethnicity in a large urban area. *Annals of Emergency Medicine.* 2015;66:S49-50 (abstract).

Purpose:

Physio-Control, Los Angeles Fire Department (LAFD) and Los Angeles County EMS Agency (LACEMSA) collaborated on a clinical study primarily to identify opportunities for improvement in cath lab activation for STEMI. The ECGs recorded by LIFEPAK 15 monitor/defibrillators were run through LIFEPAK 12 defibrillator/monitors to compare STEMI accuracy between the two devices. The above abstracts were presented at the American College of Emergency Physicians (ACEP) 2015 Scientific Assembly.

Method:

- About 45,000 consecutive cases with 12-lead ECGs recorded by LIFEPAK 15 monitors in LAFD were retrospectively analyzed.

  The data were from an 18-month period from July 2011 - December 2012.

- LACEMSA's STEMI receiving center (SRC) database contained data collected from all SRCs in the county and was used to classify 99% of the ECGs as STEMI or not. The remaining 1% were classified by majority of 3 independent cardiologists who were given just the raw ECG, age and gender.

- Experts examined each STEMI false positive and false negative to determine the causes.

- 12-leads ECGs taken by the LIFEPAK 15 device were also analyzed by the LIFEPAK 12 device for comparison of the STEMI decisions derived from the use of different interpretive algorithms.

- ECGs that had discrepant results from the two devices and that were not previously reviewed by experts were classified as STEMI or not by experts who were blinded to the device decisions.

Results:

- Of the 711 out of 45,000 ECGs that were classified as STEMI false positives (1.6%), 16% could be considered appropriate for cath lab activation due to definite or borderline ST elevation in a pattern suggesting possible STEMI.

- Other causes of the 711 STEMI false positives were ECG artifact (16%), early repolarization (13%), probable pericarditis (11%), indeterminate (10%), left ventricular hypertrophy (6%), right bundle branch block (4%), and 18 other causes (< 4% each).

- Causes of the 47 STEMI false negatives were borderline ST elevation (40%), ST/T ratio low due to tall T waves (15%), and 11 other causes (≤ 3 occurrences each).

- LIFEPAK 15 device sensitivity and specificity were high for all races and both genders, but large differences in STEMI prevalence between races and genders caused large differences in positive predictive value (PPV).

  - PPV = the % of LIFEPAK 15 device STEMI statements that were truly STEMIs

  - Or PPV = when the LIFEPAK 15 device said STEMI, in what % of cases was it correct? Clinicians are often interested in the % of STEMI statements that are incorrect, which is simply 100% - PPV.

- LIFEPAK 15 and LIFEPAK 12 device STEMI accuracy (all p < 0.001):

	LIFEPAK 15	LIFEPAK 12
Sensitivity	87.4%	74.2%
Specificity	98.4%	99.2%
Positive predictive value	43.1%	54.4%
Negative predictive value	99.8%	99.4%

- STEMI prevalence was very low (1.2%) because 76% of cases did not have chest pain or discomfort. The low STEMI prevalence was the primary cause of low PPV with both devices.

Conclusions:

- The leading opportunities for reducing STEMI false positives were ECG transmission for physician overread (potential 65% reduction), reducing ECG artifact (10%) and using the study data to improve the automated program (10-15%).

- There were no actionable opportunities for improving LIFEPAK 15 device sensitivity for STEMI.

- LIFEPAK 15 monitor sensitivity and specificity were higher than reported in two previous studies, but PPV was lower due to low STEMI prevalence.[1,2,3]

- Compared to the LIFEPAK 12 monitor and with this ECG set, the LIFEPAK 15 monitor has higher STEMI sensitivity and negative predictive value, but lower specificity and PPV.

- LIFEPAK 15 monitor sensitivity and specificity for STEMI were similar across all races and both genders.

- With this ECG set, neither the LIFEPAK 15 nor the LIFEPAK 12 device had high enough PPV to use for cath lab activation without ECG overread.

Physio-Control Discussion Points:

- This study approach, in which local data were used to determine the leading causes of STEMI false positives and false negatives, was effective at identifying opportunities for improving accuracy of STEMI detection assisted by automated ECG interpretation. Local data drives local solutions, therefore this study approach would be likely to generate actionable results if done in other regional STEMI systems of care.

- STEMI detection by any computerized interpretive algorithm is not accurate enough for activating the cath lab without ECG overread. The AHA Guidelines 2015 recommend against it, as well.[4] The algorithms are intended to be used as a STEMI screening tool by providing a second opinion. Clinicians factor in the patient's symptoms, medical history, and, when available, a baseline ECG retrieved from a medical records system; the additional information makes the clinician more accurate than any computerized algorithm.

- False cath lab activations can be minimized in two ways:

  1. Using trained paramedics to make the STEMI call in the field

  2. Transmitting 12-lead ECGs for physician overread

- For EMS systems that do not train their paramedics to identify STEMI, the optimum STEMI solution may be to use the LIFEPAK 15 monitor's relatively high sensitivity for STEMI to identify ECGs to transmit, via the LIFENET® System, for physician overread. With continuous quality improvement, this STEMI solution may achieve both an acceptably low STEMI false negative rate and an acceptably low cath lab false activation rate, while minimizing time from first ECG to definitive treatment for STEMI.

- The study results show a higher percentage of false positives with the LIFEPAK 15 device compared with the LIFEPAK 12 device, BUT we also saw a higher percentage of TRUE positives with the LIFEPAK *15* compared with the *12*. While a *15* may lead to more false cath lab activations without overreads, the important benefit is that it is also LESS LIKELY to miss true STEMIs.

- ECG artifact is widely known to be a common problem with all ECG devices from all manufacturers and a common cause of STEMI false positive 12-lead statements. Physio-Control has a new quick reference guide titled "Minimizing ECG Artifact" (GDR 3306627_A) which is intended to help paramedics determine the causes of artifact and take appropriate steps to minimize the artifact. The Minimizing ECG Artifact guide, in enough quantity to supply each paramedic or each LIFEPAK monitor, can be requested from a local Physio-Control sales or service representative.

1. Macfarlane P, Browne D, Devine B, et al. Modification of ACC/ESC criteria for acute myocardial infarction. *J Electrocardiol.* 2004;37(suppl):98-103.

2. Macfarlane P, Hampton D, Clark E, et al. Evaluation of age and sex dependent criteria for ST elevation myocardial infarction. *Computers in Cardiology.* 2007;34:293-6.

3. Clark E, Sejersten M, Clemmensen P, et al. Automated electrocardiogram interpretation programs versus cardiologists' triage decision making based on teletransmitted data in patients with suspected acute coronary syndrome. *Am J Cardiol.* 2010;106:1696-702.

4. O'Connor R, Al Ali, A, Brady W. Part 9: Acute Coronary Syndromes. 2015 American Heart Association Guidelines Update for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care. *Circulation*. 2015;132[suppl 2]:S483–S500.

For further information, please contact Physio-Control at 800.442.1142 (U.S.), 800.895.5896 (Canada) or visit our website at www.physio-control.com.