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PREHOSPITAL ACUTE ST-ELEVATION MYOCARDIAL INFARCTION IDENTIFICATION IN SAN DIEGO: A RETROSPECTIVE ANALYSIS OF THE EFFECT OF A NEW SOFTWARE ALGORITHM

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□ Abstract—Background: A significant increase in false positive ST-elevation myocardial infarction (STEMI) electrocardiogram interpretations was noted after replacement of all of the City of San Diego's 110 monitor-defibrillator units with a new brand. These concerns were brought to the manufacturer and a revised interpretive algorithm was implemented. Objectives: This study evaluated the effects of a revised interpretation algorithm to identify STEMI when used by San Diego paramedics. Methods: Data were reviewed 6 months before and 6 months after the introduction of a revised interpretation algorithm. True-positive and false-positive interpretations were identified. Factors contributing to an incorrect interpretation were assessed and patient demographics were collected. Results: A total of 372 (234 preimplementation, 138 postimplementation) cases met inclusion criteria. There was a significant reduction in false positive STEMI (150 preimplementation, 40 postimplementation; p < 0.001) after implementation. The most common factors resulting in false positive before implementation were right bundle branch block, left bundle branch block, and atrial fibrillation. The new algorithm corrected for these misinterpretations with most postimplementation false positives attributed to benign early repolarization and poor data quality. Subsequent follow-up at 10 months showed maintenance of the observed reduction in false positives. Conclusions: This study shows that introducing a revised 12-lead interpretive algorithm resulted in a significant reduction in the number of false positive STEMI electrocardiogram interpretations in a large urban emergency medical services system. Rigorous testing and standardization of new interpretative software is recommended before introduction into a clinical setting to prevent issues resulting from inappropriate cardiac catheterization laboratory activations. © 2018 Elsevier Inc. All rights reserved.

□ Keywords—computer interpretation; ECG; false positive; paramedic; prehospital; STEMI

INTRODUCTION

The prehospital diagnosis of ST-elevation myocardial infarction (STEMI) leading to activation of the cardiac catheterization laboratory (CCL) is associated with reduced "door-to-balloon" time and reduced mortality (1–8). With emergency medical services (EMS) transporting >50% of all patients with STEMI, prehospital personnel are at the forefront of rapidly and accurately triaging chest pain patients to appropriate care. Several different systems exist for making the rapid diagnosis of a STEMI. Attempted solutions have included to rely solely on the paramedic's interpretation, to transmit electrocardiograms (ECGs) to a "base station" hospital for physician interpretation, to rely strictly on computer algorithms to provide interpretation,

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or some combination of these approaches (9,10). The reported test characteristics of each method vary widely. Variation may be related to differences in the training of personnel, differences in computer software, and differences in prehospital system design (11-34). Multiple factors have been identified as affecting the accuracy of prehospital STEMI diagnosis (31,32). For some, controlling has proven difficult, such as for patient gender and underlying heart rhythm. Other factors can be influenced, such as the technical quality of the ECG and software used to analyze it. Of particular interest is the variability between software algorithms of different manufacturers, or between different versions from the same manufacturer, regarding their programming to derive a diagnosis of a STEMI. False positive STEMI interpretations can lead to unnecessary CCL activations, thereby putting patients at risk of adverse events, while simultaneously summoning CCL teams in error, which increases costs and reduces clinical efficiency.

The City of San Diego EMS relies on computer interpretation for the diagnosis of STEMI. Once a STEMI is identified, paramedics transmit the ECG to the STEMI receiving center and provide prearrival notification via radio. When the STEMI receiving center receives this notification, the radio room nurse delivers the ECG to a physician for interpretation and determination of CCL activation. The physician's specialty varies between facilities. Some use emergency physicians while others use cardiologists for interpretation.

In December 2010, the City of San Diego EMS system replaced all 110 monitor-defibrillator units (brand A) with new devices (brand B) during a scheduled equipment upgrade with a goal of achieving an enhanced ability to transmit accurate and interpretable prehospital 12-lead ECGs. Shortly after implementation, quality improvement personnel noted a significant increase in false positive STEMI ECG notifications. Specifically, the false positive rate increased from 14% to 38% when compared to 2 equivalent 3-month intervals over the 2 previous years. The positive predictive value of an apparent STEMI decreased from 70% to 37%. These concerns were brought to the attention of the manufacturer and a revised interpretive software algorithm was introduced into service on July 1, 2012.

We describe the City of San Diego's experience with a revised ECG interpretive software algorithm to identify STEMI when used by paramedics. The modified algorithm was developed by a device manufacturer, in response to our concerns regarding an increase in falsepositive STEMI diagnoses, coincident with the introduction of a new monitor-defibrillator.

The modified algorithm focused on specific rhythms identified as causing false positive prehospital STEMIs in the City of San Diego. The objective of this study was to determine if a revised algorithm improved the sensitivity and specificity of the prehospital identification of STEMI. In addition, we reviewed the stability of the revised ECG algorithm 10 months after its initial implementation.

MATERIALS AND METHODS

Data from the City of San Diego EMS electronic health record (TapChart; Imagetrend Inc., Lakeville, MN) were reviewed from 6 months before and 6 months after algorithm implementation on July 1, 2012. Records were again reviewed 10 months later for a 3-month period (May 1-August 1, 2013) for follow-up. Records from STEMI cases were identified using the following search criteria: "STEMI probable," incident narrative contains "STEMI" or "acute MI," and does not contain "no STEMI, negative STEMI, neg STEMI or systemic." Each record was reviewed manually so as to include only those ECGs that identify an apparent STEMI because of functioning of the device's interpretative software. Cases meeting the inclusion criteria were deidentified and entered into an Excel registry database (Microsoft Corp., Redmond, WA). STEMI receiving centers in the county participate in a regional database, providing information such as final diagnosis and percutaneous coronary intervention (PCI) results. Research records were matched to this database to confirmed final diagnosis with the receiving hospital. An acute STEMI was defined as the presence of a coronary occlusion requiring emergent PCI. False positives were defined as cases not warranting PCI per the STEMI receiving center physician or no significant coronary artery occlusion found on PCI. For cases determined to be false positives, factors contributing to an incorrect algorithm interpretation were identified. Each receiving hospital was requested to report any false negative ECGs via the regional database for interpretation in a similar manner to the false positive tracings. Patient demographics were assessed, including age, gender, and chief complaint. A chi-square test was used to assess gender and an independent t test was used to assess age between the pre- and postimplementation periods. A chi-square test was used to assess the change in true and false positive rates between periods. p < 0.05 was considered statistically significant. The institutional review board of the University of California San Diego Health System reviewed and approved the study protocol and considered this study to be exempt from informed consent.

RESULTS

A total of 510 cases were reviewed, and 461 of these cases met inclusion criteria (234 preimplementation, 138

Category	FP before	FP after	TP before	TP after	Follow-Up
Male	91	28	61	75	19
Female	59	12	23	23	5
Total	150	40	84	98	24
Average age (vears)	68.5	62.9	62.3	63.6	67.4
Age range (years)	19–104	28–91	33–99	39–91	22-95

Table 1. Patient Demographics

FP = False positive; TP = true positive.

postimplementation, and 89 follow-up). Forty-four cases were excluded (30 preimplementation, 14 postimplementation), because no follow-up data were available in the regional STEMI database. An additional 5 cases were excluded because the prehospital provider incorrectly interpreted the ECG, rather than the ECG misinterpretation being related to the programmed function of the ECG machine. No cases were excluded or lost to follow-up during the 10-month re-evaluation. There were no significant differences between groups with regard to age (p = 0.086) or gender (p = 0.052; Table 1).

When compared with the period 6 months before the introduction of the revised algorithm, there was both a significant reduction in the rate of false positive STEMI cases (150 preimplementation vs. 40 postimplementation; p < 0.001) and an increase in the identification of true STEMI (84 preimplementation vs. 98 postimplementation; p < 0.001) after the revised software was introduced. These cases are summarized in Figure 1. Each receiving hospital was requested to report false negative ECGs for analysis in a similar manner, though none were reported during the study period.

Table 2 lists the factors associated with false positive STEMI in all 3 periods. Before implementation, the

most common factor resulting in incorrect prehospital 12-lead interpretation was right bundle branch block (RBBB, 38%), left bundle branch block (15%), and atrial fibrillation (13%). After implementation, RBBB made up only 8% of false positives. The new algorithm appeared to correct for these misinterpretations with most subsequent false positives attributed to benign early repolarization (BER, 25%) or poor technical quality of the tracing (20%).

In a follow-up review 10 months postimplementation, a total of 24 ECGs were identified during a 3-month period. One year after the implementation, BER continued to be the leading source of false positives, accounting for 54% of cases.

DISCUSSION

Previous studies have shown ECG interpretive software to have generally robust specificity but sometimes lower sensitivity (35–37). Notably, positive predictive value can be near 50% (38–40). Comparison of test characteristics is difficult because of significant heterogeneity between studies. Researchers use different criterion standards for STEMI (e.g., physician consensus vs. PCI outcomes)



Figure 1. Summary of cases. STEMI = ST-elevation myocardial infarction; ECG = electrocardiogram.

Table 2. Factors Affecting False Positives

Factor	Before (%)	After (%)	Follow-Up (%)
RBBB	57 (38.00)	3 (7.50)	3 (12.50)
LBBB	22 (14.67)	1 (2.50)	3 (12.50)
Atrial fibrillation	19 (12.67)	3 (7.50)	0 (0.00)
BER	17 (11.33)	10 (25.00)	13 (54.17)
IVCD	12 (8.00)	0 (0.00)	0 (0.00)
Poor quality	11 (7.33)	8 (20.00)	0 (0.00)
LAFB	9 (6.00)	0 (0.00)	1 (4.17)
Atrial flutter	6 (4.00)	1 (2.50)	1 (4.17)
STEMI criteria met	6 (4.00)	6 (15.00)	1 (4.17)
ST	2 (1.33)	1 (2.50)	1 (4.17)
Diffuse STE	2 (1.33)	1 (2.50)	1 (4.17)
Q waves	2 (1.33)	1 (2.50)	0 (0.00)
Hyperdynamic T waves	2 (1.33)	0 (0.00)	0 (0.00)
LVH	2 (1.33)	0 (0.00)	0 (0.00)
Peaked T waves	2 (1.33)	0 (0.00)	0 (0.00)
Ventricular tachycardia	1 (0.67)	0 (0.00)	0 (0.00)
STE single lead	1 (0.67)	2 (5.00)	0 (0.00)
Diffuse STD	1 (0.67)	2 (5.00)	0 (0.00)
Diffuse PR depression	0 (0.00)	1 (2.50)	1 (4.17)
Incomplete RBBB	0 (0.00)	1 (2.50)	0 (0.00)
Sinus rhythm	0 (0.00)	2 (5.00)	0 (0.00)
PVC	0 (0.00)	0 (0.00)	1 (4.17)
Pacer malfunction	0 (0.00)	0 (0.00)	1 (4.17)
Total ECGs reviewed	150	40	24
Total no. of risk factors found	174	43	27

BER = benign early repolarization; IVCD = intraventricular conduction defect; LAFB = left anterior fascicular block; LBBB = left bundle branch block; LVH = left ventricular hypertrophy; RBBB = right bundle branch block; STD = ST segment depression; STE = ST segment elevation; STEMI = ST segment elevation myocardial infarction; PVC = premature ventricular complex; ECG = electrocardiogram.

and study different versions of different manufacturers' software. Despite these challenges, our data are generally consistent with previous literature.

After correction for RBBB misinterpretation, BER accounted for the greatest portion of persistent false positives. Previous studies have shown that differentiating STEMI from BER is difficult for cardiologists and emergency physicians alike (41). Therefore, it is not surprising that a software interpretation algorithm may also make this error.

Previous studies have noted BER, pericarditis, previous MI, stress cardiomyopathy, myocarditis, left bundle branch block, left ventricular aneurysm, and left ventricular hypertrophy as common causes for false positive STEMI interpretation by physicians (41–44). RBBB is not traditionally a common cause of false positive interpretation, yet it was the most common cause in this study. Subsequently, RBBB accounted for the most significant reduction in false positives after implementation of the new software.

Limitations

Limitations of this study include the lack of known prevalence of false negatives. The current data collection system depends on STEMI centers to report cases that were not identified prehospital to a regional database. Prehospital and hospital records are not otherwise connected. The City of San Diego EMS system performs >1300 ECGs every month. Even if every prehospital ECGs were reviewed, outcome data were not necessarily available to classify it as a true or false negative. False negatives are likely underreported and are arguably the most concerning ECG misinterpretation. It is possible that the new algorithm decreased the false positive interpretations at the expense of an increased rate of false negatives. We attempted to obtain follow-up on all cases, specifically requesting further information from each designated STEMI center, but there remained 44 ECGs for which no data were available in the regional STEMI database nor provided after requests to the STEMI centers. These cases were excluded from the study.

While part of the case definition for a false positive test was a negative catheterization, it is possible that some of these interventions were diagnostically appropriate rather than therapeutically necessary. In cases such as cocaine vasospasm, the ECG may be indistinguishable from an acute coronary syndrome and can only be differentiated on PCI. In addition, with some difficult to interpret ECGs, an interventional cardiologist may agree that PCI is necessary to rule out acute coronary syndrome. Even in some instances where the diagnosis of STEMI is clear on the ECG, physicians may decline to refer the patient for PCI because of comorbidities, patient wishes, etc. These clinical subtleties cannot be teased out through our methods.

These data include results from the City of San Diego EMS system, which constitutes approximately 70% of EMS providers in the greater San Diego area. Data from the remaining 30% of EMS providers were not available. Finally, ECGs were reviewed by a single reviewer (CC) and not corroborated by an additional blinded reviewer.

CONCLUSIONS

This study showed that the introduction of a revised 12-lead interpretive software algorithm resulted in a significant reduction in the number of false positive STEMI activations in a large urban EMS system.

Six months after the new algorithm implementation, BER was the leading cause of false STEMIs. This finding remained stable at 10 months of follow-up with the same algorithm and with no intervening factors or changes to local protocols. This study also shows the importance of careful quality improvement to detect variance resulting from a change in equipment. EMS and other health care agencies should remain vigilant during new equipment introductions for potential effects on time-critical conditions, such as STEMI. Decreasing false positive STEMI interpretation can lead to a decrease in unnecessary cardiac catheterization laboratory activations, thereby reducing cost and improving efficiency.

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ARTICLE SUMMARY

1. Why is this topic important?

Emergency medical services plays a critical role in identifying ST-elevation myocardial infarction (STEMI) to triage to an appropriate facility and activate hospital resources before patient arrival to reduce door-to-balloon time. Monitors capable of acquiring 12-lead electrocardiograms (ECGs) are ubiquitous in the prehospital setting.

2. What does this study attempt to show?

This study shows the importance of quality improvement monitoring during the introduction of new cardiac monitoring equipment. Rigorous testing and standardization of interpretative software is recommended before that software is introduced into any clinical setting, to optimize clinical efficiency of monitoring devices.

3. What are the key findings?

After changing cardiac monitor manufacturers, the City of San Diego emergency medical services system experienced a large increase in the rate of ECGs that were false positives for the occurrence of a STEMI. After contacting and cooperating with the manufacturer, a revised interpretative algorithm was introduced. Programming this new algorithm into the software resulted in a decreases false positive rate for STEMIs. This decrease was sustained at the time of a 10-month follow-up.

4. How is patient care impacted?

False positive STEMI activations leading to cardiac catheterization exposes patients to unnecessary risk, reduces efficiency, and increases costs.