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## QUALITY ASSESSMENT

# Electrocardiograph-based emergency department risk management tool based on the ACI-TIPI: potential impact on care and malpractice claims

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### Introduction

Approximately 7 million patients present to emergency departments (EDs) in the United States each year with chest pain or other symptoms suggestive of cardiac ischemia.<sup>(1)</sup> Correctly identifying those with acute cardiac ischemia (acute myocardial infarction [AMI] or unstable angina pectoris) for hospitalization, while not unnecessarily admitting the approximately two-thirds of such ED patients who do not have acute ischemia, is one of the ED clinician's most challenging tasks.<sup>(2)</sup> Although generally over half of those admitted for suspected acute ischemia prove not to have it,<sup>(2, 3, 4)</sup> fortunately, a relatively small proportion of patients with acute ischemia are inadvertently sent home: approximately 2-4 percent of those with AMI<sup>(5, 6, 7)</sup> and about 2 percent of those with unstable angina.<sup>(7)</sup> Nonetheless, given the large numbers of patients with acute ischemia, the number of inappropriate discharges home is substantial: about 10,000-20,000 with AMI and 10,000-20,000 with new onset or unstable angina.<sup>(7)</sup> Indeed, medical malpractice claims for ED patients sent home with AMI or unstable angina represent one of the highest claims cost made against emergency physicians.

The reasons that patients are sent home with acute cardiac ischemia and the reasons that malpractice claims are made and awarded have substantial, although not complete, overlap. In a few cases, when the diagnosis is not recognized, a claim of malpractice may be legitimate. To prevent such malpractice claims, and more importantly to avoid harm to patients, approaches are needed that reduce failures to properly diagnose acute cardiac ischemia and subsequent failures to hospitalize such patients.<sup>(9)</sup>

We previously found that the most common feature related to inappropriately sending a patient home with acute infarction was a problem in the physician's use of the electrocardiogram (ECG).<sup>(6, 7)</sup> Among ED patients sent home with AMI, 35 percent had ECG

abnormalities consistent with ischemic heart disease *noted* by the physician, but not given sufficient weight in the triage decision.<sup>(6)</sup> Additionally, 25 percent had ECG abnormalities suggesting AMI (ST elevation) that were *missed* by the ED physician.<sup>(6)</sup> In another analysis of a multicenter study, over a third of abnormal ST segments and T waves were misread in the ED as normal, which was associated with a doubling of the ED suboptimal triage rate.<sup>(10)</sup> Such results suggest that a method that assists physicians in appreciating the importance of the ECG abnormalities they recognize, and that also highlights abnormalities that might otherwise be missed, would potentially reduce inadvertent failures to hospitalize.

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A different reason for a malpractice claim to be made and potentially awarded is inadequate documentation of the basis for the triage decision in the ED medical record.<sup>(8)</sup> If the good reasons that acute ischemia was felt to be highly unlikely are not documented, a malpractice claim may appear warranted. This could be avoided by a method that improved documentation of the critical features of the ED evaluation.<sup>(11, 12)</sup>

To address these issues, we developed a risk management form for ED use that would both facilitate physician use of the ECG and improve medical record documentation of care. Also, because physicians' ED diagnostic and triage performance are improved by automatically printing, the acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI) 0-100 percent probability that the patient truly has acute ischemia<sup>(13, 14, 15, 16)</sup> particularly for less-trained and less-supervised trainees,<sup>(14, 15, 17)</sup> we included

CHEST PAIN / POSSIBLE MYOCARDIAL INFARCTION  
EMERGENCY MEDICAL RECORD SUPPLEMENTAL FORM

Name: JOHN DOE  
ID: 123456  
Dept: Emergency

Age: 56 years Male  
12/16/2001 23:53

CHEST PAIN/DISCOMFORT: Yes, chief complaint (MD Agree:  YES  NO, CORRECT: \_\_\_\_\_)

CHARACTER OF CHEST PAIN OR CHIEF COMPLAINT: \_\_\_\_\_

DURATION: \_\_\_\_\_

MADE WORSE BY: \_\_\_\_\_ RELIEVED BY: \_\_\_\_\_

SUGGESTIVE OF ISCHEMIA?  YES  SOMEWHAT  NO

PATIENT REPORTS PRIOR HEART ATTACK:  YES  NO PRIOR NITROGLYCERIN USE:  YES  NO

ECG ISCHEMIA RELATED Q, ST, & T WAVE FINDINGS: (ECG DONE: 12/16/2001, 23:53:52 )

CHEST PAIN AT TIME OF THIS ECG?  YES  YES, BUT IMPROVED  NO COMMENT \_\_\_\_\_

Anterior significant Q Waves in two or more of leads V1-V4..... MD Agree:  YES  NO\*  
Anterior ST depression of 0.05 mV or more in two or more of leads V1-V4..... MD Agree:  YES  NO\*  
Anterior T Wave inversion of 0.1 mV or more in two or more of leads V1-V4..... MD Agree:  YES  NO\*

\*ADDITIONAL ECG FINDINGS/CORRECTIONS TO ABOVE: \_\_\_\_\_

COMPARED TO PRIOR ECG:  NO CHANGES  CHANGES: \_\_\_\_\_

NO PRIOR ECG DONE  PRIOR ECG NOT AVAILABLE  PRIOR ECG NOT REQUESTED

HP ACL-TIPI PREDICTED PROBABILITY OF ACUTE ISCHEMIA= 74%, based on this information collected at the time of the ECG:

Patient is male, age greater than 50  
Patient has chief complaint of chest pain/discomfort or left arm pain  
Patient's ECG Q, ST, & T Wave findings as noted above

TRIAGE DECISION:  CCU/ICU  INTERMEDIATE CARE  WARD  HOME  OTHER: \_\_\_\_\_

IF SENT HOME, SPECIFIC FOLLOW-UP INSTRUCTIONS GIVEN TO PATIENT:  YES  NO  COPY IN ED MEDICAL RECORD

ADDITIONAL COMMENTS: \_\_\_\_\_

PHYSICIAN SIGNATURE: \_\_\_\_\_ DATE: \_\_\_\_\_ TIME: \_\_\_\_\_

FIGURE 1  
Electrocardiograph risk management form



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the ACI-TIPI's predicted probability of acute ischemia as part of the risk management form. We also included items for the physician to complete, prompt and document proper evaluation and triage.

In this study, we assessed the potential impact of implementing such a form, either entirely manually-completed or automatically electrocardiograph-generated. We approached this by expert review of completed cases of malpractice litigation, determining whether either version might have either averted the occurrence of a malpractice claim and/or, were a claim made, changed the outcomes and costs of litigation.

## Methods

Based on input from eight legal and medical experts in risk management (members of the Risk Management Committee of the Massachusetts College of Emergency Physicians, physicians from several Massachusetts hospitals, and senior management and staff of two medical malpractice liability insurers), we devised both manually-completed and electrocardiograph-based versions of a form that provides a patient's ACI-TIPI's predicted probability of acute ischemia. The form also serves to collect key clinical data and factors related to the admission decision, act as a risk management tool and is intended to become part of the medical record. The manual version was designed to be entirely completed by the ED physician: the electrocardiograph version was designed to be automatically printed with the patient's presenting ECG, with the ECG interpretation, including ACI-TIPI, included in its text (**Figure 1**).

To investigate the risk management form's potential impact, we applied it to 20 consecutive cases that came to malpractice litigation on which expert opinions had been requested by the Massachusetts Joint Underwriting Association (now ProMutual Group), the malpractice carrier for the majority of Massachusetts physicians. Each case was a patient who presented to an ED with chest pain or other symptoms consistent with acute cardiac ischemia, who was not hospitalized and subsequently sustained AMI or cardiac arrest at home, usually leading to death.

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For this investigation, in order to project as accurately as possible what the impact would have been had the ACI-TIPI risk management form been available during the episode of care, the form was manually filled-out for each patient as it would have been completed had it been done in real-time in the ED. Reviewers were asked to evaluate its likely impact, had the form been completed *by the ED physician* at the time of the patient's original ED evaluation, and separately had the form been generated and partially completed *automatically by the electrocardiograph* along with the patient's initial ECG.

For both the physician-completed and the electrocardiograph-generated ACI-TIPI risk management tool, each reviewer filled out forms that asked: 1) whether the use of the tool would have reduced the case's *likelihood of litigation*; and 2) if litigated, whether the use of the tool would have affected the likely *outcome of litigation*. In addition to evaluating both versions of the form separately, reviewers were asked to determine if, how and why the ECG-generated version would provide benefit over the physician-completed form. They also were asked whether the primary impact would be due to a change in the physician's care, to a change in the physician's documentation, or both/neither, including no impact whatsoever.

The six expert reviewers had particular experience in issues of ED malpractice litigation, and included two hospital ED directors (one at a major teaching hospital and the other at a non-teaching hospital), an emergency physician involved in the Massachusetts College of Emergency Physicians risk management efforts, a hospital-based attorney from its liability risk management office, a risk management staff member at the same hospital, and an experienced nurse clinician.

The liability insurer provided information on each of 20 cases, including medical and legal records and costs. Total cost data were complete for 14 cases, separated into 1) legal costs of responding to litigation, and 2) award or settlement costs. Calculations of the potential savings were based on the insurer's total costs, combined with the reviewers' judgments regarding whether a change would have resulted by use of the risk management tool, calculated in Year 2000 dollars. (18)

Differences in ratings between physician-completed and electrocardiograph-generated forms were statistically tested using Bowker's test of symmetry. Reported differences of any change in the likelihood of litigation or the outcome of litigation were tested with the McNemar chi-square.

## Results

The 20 cases reviewed included patients with a mean age of 50 years; 75 percent were men, and 90 percent presented to the ED with chest pain (Table 1).

**TABLE 1**

**Characteristics of malpractice cases of emergency department patients with acute myocardial infarction (N=20)**

Mean age (SD)	50 (12)
Male gender	75%
Chest pain presenting symptom	94%
AMI location	
Anterior	21%
Inferior	43%
Lateral	29%
Inferior lateral	7%
Mortality	30%

**TABLE 2**

**Reviewers' determinations of likelihood of cases coming to litigation had either physician-generated or electrocardiograph-generated risk management tool been used for ED failure to diagnose acute myocardial infarction malpractice cases (N=108)**

Likelihood of litigation	Physician-generated form	Electrocardiograph-generated form
No difference	35.2%	16.7%
Significantly less likely	26.9%	22.2%
Very much less likely	32.4%	44.4%
Almost certainly not	5.6%	16.7%
	<i>p</i> <0.001	

Table 2 shows reviewers' judgments of the likelihoods of the study cases coming to malpractice litigation if either the physician-completed or the automatic electrocardiograph-generated risk management tool had been used. Both were judged to reduce the likelihood of litigation; for the physician-completed form, by 65 percent of cases, for the electrocardiograph-generated version, by 83 percent (*p*<0.001). The reductions were considered more likely for the electrocardiograph-generated version: 61 percent of cases were seen as "very much less likely" or "certain not" to come to litigation, versus 38 percent for the non-automatic version (*p*<0.001).

**TABLE 3**

**Reviewers' determinations of likely outcome of litigation had either physician-generated or electrocardiograph generated risk management tool been used for ED failure to diagnose acute myocardial infarction malpractice cases (N=108)**

Likely outcome of litigation	Physician-generated form	Electrocardiograph-generated form
No difference	38.0%	20.4%
Significantly likely better	30.6%	21.3%
Very much likely better	26.9%	42.6%
Almost certainly better	4.6%	15.7%
	<i>p</i> <0.001	

**TABLE 4**

**Legal expenses and malpractice awards or settlements for study cases (N=14)**

	Mean (S.D.)	Range
Legal expenses (\$)	29,901 (14,992)	12,050 - 60,073
Award/settlement (\$)	438,959 (347,785)	57,384 - 1,075,949
TOTAL (\$)	470,288 (341,691)	76,963 - 1,091,227

Table 3 shows the reviewers' judgments about the likely litigation outcome, assuming study cases came to litigation. Had the non-automatic form been used, a different litigation outcome in favor of the physician defendant was considered likely for 62 percent of cases, including 31 percent judged that the outcome would have been "very much better" or "certainly better." Had the electrocardiograph-generated version been used, 80 percent were considered likely to have had a better outcome for the defendant physician, including 58 percent judged likely to have had a "very much better" or "certainly better" outcome. Differences between the electrocardiograph-generated and non-automatic form were statistically significant (*p*<0.001).

As shown in Table 4, for the 14 case records for which cost data were available, the legal and processing expenses for cases averaged \$29,901 (range \$12,050-\$60,073) and settlements averaged \$438,959 (range \$57,384-\$1,075,949).

Table 5 shows the results of reviewers' assessments of the potential cost impact of the ACI-TIPI risk management tool on these 14 cases, based on reduced likelihoods of litigation and likely different litigation outcomes. For the physician-generated form, the mean projected savings per case was \$356,052, totaling \$4,984,727 for the 14 cases. For the automatically-generated form, the mean projected savings per case was \$470,288, and the total savings \$6,584,038.

TABLE 5

**Potential malpractice litigation cost savings by use of physician-generated and electrocardiograph-generated ACI-TIPI risk management tool (N=14)**

	Mean savings per case (S.D.)	Range	Total for 14 cases
Malpractice cost savings if physician-generated			
Reduced likelihood of coming to litigation (\$)	24,931 (18,215)	0 - 60,073	349,038
Different outcome of litigation (\$)	329,692 (380,506)	0 - 1,075,949	4,615,689
Total potential savings (\$)	356,052 (378,991)	0 - 1,091,227	4,984,727
Malpractice cost savings if electrocardiograph-generated			
Reduced likelihood of coming to litigation (\$)	29,901 (14,992)	12,050 - 60,073	418,619
Different outcome of litigation (\$)	438,959 (347,785)	57,384 - 1,075,949	6,145,419
Total potential savings (\$)	470,288 (341,691)	73,963 - 1,091,227	6,584,038

## Discussion

Large prospective clinical trials have found that 2-4 percent of patients presenting to EDs with AMI are inadvertently sent home, (5, 6, 7) and about 2 percent of ED patients with unstable angina are sent home. (7) Conservatively, yearly in the United States, this corresponds to approximately 12,000 patients with AMI and 14,000 with unstable angina, or a total of 26,000 with acute ischemia, inadvertently discharged from EDs. Prior studies have shown that among missed diagnoses of AMI, failure by the ED physician to see ECG ST segment abnormalities appeared responsible for 25 percent of ED inadvertent discharges, and for 35 percent of inadvertent discharges, the physician *did* note ST and T wave abnormalities, but seemed not to recognize their importance as an indicator of acute ischemia. (6) In the remaining cases, the medical record provided insufficient documentation to clearly ascertain whether there had been a good reason for the patient to be sent home. (6, 9) These problems in properly interpreting the ECG and in documenting features of care were found in malpractice cases reviewed in this study.

A number of approaches have been advanced for improving the ED evaluation and triage of patients with suspected cardiac ischemia. (19, 20) Additionally, general principles of risk management and specific approaches for AMI have been proposed to improve ED physician admission and treatment decision-making and documentation. (11, 12) A method is needed that counters the potential under-appreciation of the importance of ECG abnormalities that are seen, detects ECG abnormalities that would have been missed, improves medical record documentation, and does not overly-burden the busy ED physician.

In this study, we evaluated a medical malpractice risk management tool (**Figure 1**) that attempts to fulfill these requirements: a form that can be automatically-generated by a conventional computerized electrocardiograph along with the patient's ECG, immediately and conveniently available for real-time use designed to prompt consideration and documentation of the key clinical factors for such cases and to be included in the medical record. Its text includes the electrocardiograph's conventional computerized interpretation to lessen the likelihood of ECG abnormalities being missed, plus the

ACI-TIPI probability that the patient has acute ischemia (i.e., either AMI or unstable angina), to help the ED physician appreciate the level of risk posed by the patient's particular combination of clinical and ECG factors. Finally, the form requires that the physician complete items pertaining to key issues related to the decision to send such a patient home, to better document appropriate care, and to help deter suboptimal triage.

In our study, based on review by a range of clinician and legal experts in medical ED malpractice liability, the use of the ACI-TIPI risk management tool appeared to have substantial potential for reducing and avoiding malpractice exposure for patients with AMI who might have been inadvertently sent home. Both the manual-completed risk management form and the automatic electrocardiograph-generated version were judged to reduce the likelihood of coming to litigation; for 65 percent and 83 percent of cases, respectively. The reduction was seen as more likely being greater for the electrocardiograph-generated version: 61 percent of cases were seen as "very much less likely" or "certainly not" to come to litigation, versus 38 percent for the non-automatic version of the form ( $p < 0.001$ ).

Beyond preventing the majority of such cases from coming to litigation, for those that do, the risk management form should improve the likely outcome of litigation. Reviewers judged that had the non-automatic form been used, a different litigation outcome would have been likely for 62 percent of cases, including 31 percent for whom the outcome would have been "very much better" or "certainly better" in favor of the physician defendant having provided appropriate ED care. Reviewers judged that had the electrocardiograph-generated version been used, 80 percent would have likely had a significantly better litigation outcome including 58 percent for whom it was judged likely to have been "very much better" or "certainly better" ( $p < 0.001$ ).

Given the conservative estimate of about 26,000 ED patients with acute cardiac ischemia mistakenly sent home in this country this year, and given the respective savings per case projected in this study for the manually-completed form of \$356,052, and for the automatically-generated form of \$470,288, the national reduction in malpractice award costs could be substantial. This would reduce

malpractice costs exposure by over \$12 billion per year and assuming conservatively that only about 10 percent of such potential cases actually come to litigation, the direct savings from the use of the electrocardiograph-generated ACI-TIPI risk management form could be on the order of \$1.2 billion per year. More important than the actual monetary impact, it also would have the potential to save lives. (21) Additionally, disruption of the lives of patients, clinicians and plaintiffs could be avoided. Overall, the risk management tool could have an important role in reducing risks of malpractice by contributing to better care that is better documented.

A limitation of this study is that, although based on real cases and their actual outcomes and associated costs, by necessity, the estimates of impact on care and documentation were made retrospectively after the cases were settled and closed. However, because the reviewers were all very experienced in this area and had reviewed many such cases for just these determinations of quality of care, negligence, and likely impact on expenses and awards, it seems that their determinations should be quite accurate. Moreover, the fact that, despite their different professional roles in relation to malpractice litigation (e.g., physicians, lawyers, insurance company employees), they had near unanimity on their determinations of impact for all cases, is reassuring. Nonetheless, ideally, confirmation and quantification of this impact should be done by a prospective clinical trial. (19, 20)

## Conclusion

Since the time this study was done, the ACI-TIPI has been incorporated into conventional electrocardiographs, including in some, a version of the risk management tool we tested. It appears that such an automatically-generated risk management form, and to a lesser extent, such a form filled-in by hand by physicians, and possibly other risk management strategies based on real-time and/or retrospective use of the ACI-TIPI, should support triage decision-making as well as reduce costs of malpractice for ED patients with acute ischemia inadvertently not hospitalized.

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The authors thank John L. Griffith, Ph.D., for statistical advice, Deeb N. Salem, MD, for comments on the manuscript, and Myrla Connolly for manuscript preparation. The work was supported in part by the Agency for Healthcare Research and Quality (Grant #R01HS07360).

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