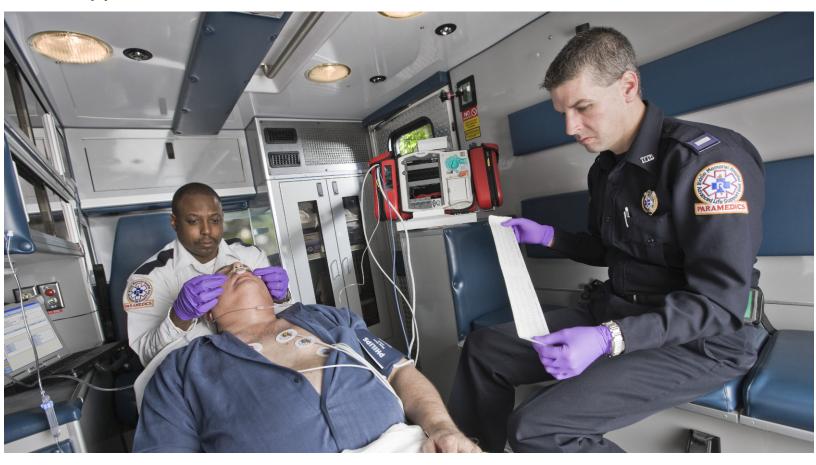
Philips ACI-TIPI

Application Note



Introduction

In healthcare, there is a constant need to increase and improve a clinician's ability to quickly and correctly diagnose a patient's condition. This need is paramount in cardiac care where patients may have a critical condition that needs to be assessed and treated immediately, such as acute cardiac ischemia (ACI). In support of your efforts to reduce *discovery to treatment* time for STEMI patients, Philips has incorporated a cardiac decision support tool into its HeartStart MRx monitor/defibrillator: the Philips ACI-TIPI (Acute Cardiac Ischemia Time-Insensitive Predictive Instrument). This application note provides both pre-hospital and emergency department (ED) clinicians with an overview of the development and functionality of this tool that aids the decision making process to systematically improve patient outcomes.



Why Use the Philips ACI-TIPI

The Philips ACI-TIPI is a software tool that enhances the computerized 12-lead ECG analysis capabilities of the HeartStart MRx. It generates a predicted probability score of ACI based on ECG features and patient demographic information such as age, gender, and chest pain status.

The probability score supports EMS personnel's efforts to decrease time from the onset of ACI symptoms to treatment with interventional cardiology. For example, one pre-hospital study demonstrated ACI-TIPI probabilities of ACI were comparable to those based on physician ECG interpretations and may be useful in the prehospital evaluation of chest pain.¹

Studies have also shown the ACI-TIPI benefit to ED and other acute care setting personnel by providing a second opinion for decision making prior to cath lab activation or patient release. Specifically, the ACI-TIPI was useful in:

- determining when additional diagnostic testing was not required in a low-risk ED population with symptoms suggestive of acute coronary syndrome,²
- identifying the likelihood of ischemia to help determine the need for stress testing before hospital release,³
- determining the probability of ischemia to influence the initial triage disposition of AMI patients to CCUs or intermediate wards.⁴

It has been projected that if ACI-TIPI were used widely throughout the United States, its potential incremental impact may be more than 200,000 fewer unnecessary hospitalizations and more than 100,000 fewer unnecessary CCU admissions each year, for an overall annual savings of \$728 million.⁵

The ACI-TIPI: A Closer Look

The Difficulty of ACI Diagnosis

Diagnosing ACI depends heavily on obtaining an accurate medical history and cardiac enzyme test results, and on interpretation of the ECG tracings. Unfortunately, patients with chest pain in the pre-hospital environment and in the ED may not be responsive to questioning and/or may not remember previous chest pain history. Likewise, once an ECG is taken, the early signs of ACI identified in the ECG can be confusing, even to highly trained readers.

ACI-TIPI Development

The inception of the ACI-TIPI resulted from researchers' recognition of the need to increase the clinician's ability to quickly and correctly diagnose ACI. Reasoning that a single numerical probability value might be easily incorporated into clinical decision making, a "predictive instrument" was created to compute a patient's likelihood of having ACI. The instrument generates a 0-100%

predicted probability score using an algorithm based on weighted values for the patient's age, gender, chest pain status, and ECG waveform criteria.

Dr. Harry Selker and his colleagues conducted a multicenter predictive instrument study in six New England hospitals to develop and prospectively test a method to reduce unnecessary CCU admissions.⁶ The study was conducted in two phases, each lasting about one year. The first phase developed a predictive instrument from data on 2,188 patients who participated in the study. The second phase was a prospective clinical trial to test the usefulness of the predictive instrument in improving CCU admitting practices. The study included 2,320 patients seen in the six hospitals' EDs.

The instrument was shown to be effective in helping clinicians identify patients with ACI and in reducing false positive identifications of ACI. Through the study, the efficacy of the instrument was confirmed in hospital EDs ranging from urban major teaching centers to rural non-teaching hospitals and was widely considered to represent an important new technology for the ED diagnosis and treatment of patients with chest pain or other symptoms suggestive of ACI.

Since the original study, Dr. Selker and his colleagues have continued to improve on the predictive performance of the instrument. Extensive work was done by Philips with Dr. Selker to produce a version of his ACI-TIPI for the Philips PageWriter cardiograph, resulting in the Philips ACI-TIPI.

Understanding the ACI-TIPI Variables

During development of the ACI-TIPI, seven predictors of ACI were established - four clinical factors and three ECG features.

The four clinical factors are:

- Patient's age (yrs.)
- Patient's gender
- The presence or absence of chest pain or pressure, or left arm pain
- Whether chest pain or equivalent symptom is the patient's most important presenting symptom

The three ECG features are:

- The presence or absence of pathological or significant Q waves
- The presence and degree of ST segment elevation or depression
- The presence and degree of T wave elevation or inversion

While none of these features alone is diagnostic, together they represent the most prominent indication of ACI. To be considered significant, ECG features must be apparent in at least two contiguous leads and must not be due to any of the five exclusionary conditions that can skew ECG interpretation:

- right bundle branch blocks,
- left bundle branch blocks,
- "early repolarization variant,"
- left ventricular hypertrophy, and
- right ventricular hypertrophy.

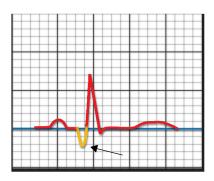
ECG Features

This section briefly describes the ECG features that are used by the ACI-TIPI in computing the probability of ACI.

Abnormal Q Waves

The presence of abnormal Q waves generally indicates myocardial infarction. In some cases, infarction can occur without the generation of abnormal Q waves. Truly pathological Q waves (see Figure 1) may be due to previously unrecognized infarction. Conversely, a prior infarction may mask new ischemia in the same area.

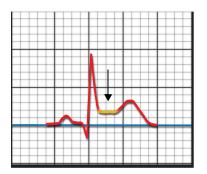
Figure 1 Pathological Q Wave



ST Segment Elevation

ST segment elevation (see Figure 2) is seen in over two-thirds of patients admitted to the CCU who have had an infarction. The percentage is even higher for patients with both abnormal Q waves and ST segment elevation. However, ST segment elevation can occur in the absence of ischemia. For example, it can be due to early repolarization, pericarditis, or left ventricular hypertrophy.

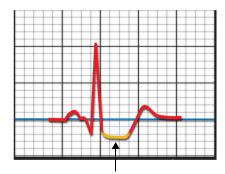
Figure 2 ST Elevation



ST Segment Depression

ST segment depression (see Figure 3) usually indicates ischemia. Over half of patients admitted to CCUs with ST segment depression have infarctions. ST segment depression may also occur in normal individuals during hyperventilation, in patients with hypokalemia or left ventricular strain, and in those taking digitalis.

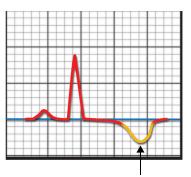
Figure 3 ST Depression



T Wave Inversion

Inverted T waves (see Figure 4) may also indicate ACI. Isolated T wave inversion can be an indicator of AMI and may also reflect prior myocardial damage, or non-ischemic causes such as left ventricular strain.





ST and T Measurements

The ACI-TIPI's probability score depends on the ST segment and T wave measurements. However, ventricular conduction abnormalities and ventricular hypertrophy can cause secondary ST and T wave changes that, if misinterpreted as primary, could cause erroneously high ACI-TIPI scores. To avoid this, the ACI-TIPI sorts out the primary ST and T changes from the secondary changes when conduction abnormalities are present. In certain cases, this distinction cannot reliably be made and the ACI-TIPI issues a warning message. See the following Exclusionary Conditions section for more information.

Exclusionary Conditions

As indicated earlier, the Philips ACI-TIPI attempts to differentiate primary from secondary ST and T changes. This is done to identify non-ACI conditions often associated with secondary ST and T changes such as right bundle branch blocks (RBBB), left bundle branch blocks (LBBB), "early repolarization variant," left ventricular hypertrophy (LVH), and right ventricular hypertrophy (RVH). These interpretations must be reviewed by a physician for confirmation of primary vs. secondary ST and T changes. The ACI-TIPI excludes the ST and/or T factors (as appropriate) from its calculations when it detects the following abnormalities:

- ▶ LVH (can alter ST segment and T waves)
- ▶ RBBB
- ▶ LBBB
- ▶ Secondary repolarization (ST and T) abnormalities
- The presence of an artificial pacemaker

When it excludes such data from its calculations, the ACI-TIPI issues the statement:

NOTE: Secondary Q wave and ST-T changes were not scored due to presence of LBBB. IF ALL ST-T CHANGES WERE SCORED AS ISCHEMIC, ACI-TIPI PROBABILITY WOULD BE HIGHER.

Another exclusionary condition to keep in mind is that the ACI-TIPI score is not calculated for patients whose age is less than 18.

WARNING: If the tool issues an exclusion statement, the clinician must consider that the actual probability may be higher than what has been indicated.

The ACI-TIPI Algorithm

The Philips ACI-TIPI algorithm takes the coefficients created by Dr. Selker's logistic regression and inputs information regarding the presence and/or level of each clinical factor and ECG feature. The ACI-TIPI then calculates the predicted probability value of ACI (0-100%). Here are two calculation examples for reference:

1 For a 63 year old female presenting with chest pain as the primary complaint, 0.1 mV of ST elevation, -0.2 mV of T wave inversion, and abnormal Q waves, the ACI-TIPI predicted probability is 87%. 2 For a 52 year old male presenting with chest pain as a secondary complaint, 0.2 mV of ST depression, and -0.5 mV of T wave inversion, the predicted probability is 90%.

NOTE: Because the ACI-TIPI predicted probability was designed to assist physicians making critical care decisions, but not to replace them, a given range of probability should not be taken to indicate specific treatment decisions, such as "admit to CCU" or "send

the patient home". Nonetheless, the issue of subranges may arise as users apply the ACI-TIPI to clinical settings and Dr. Selker's article on the ACI-TIPI should be consulted for this.⁷ Based on that article, a given institution may want to make general recommendations and/or monitor triage decisions for patients with suspected ACI. Ultimately, it is the individual physician who should choose how to apply the ACI-TIPI.

Using the Philips ACI-TIPI

This section describes input data and the resulting printed report produced by the Philips ACI-TIPI.

Clinical Variable Input

The Philips ACI-TIPI is optional, but when used, it requires entry of chest pain status prior to 12-lead ECG acquisition.

Provided the chest pain is not due to non-cardiac trauma, the chest pain status is entered as follows:

- primary if chest pain or discomfort (or equivalent left arm pain) is the main reason for the patient seeking attention
- secondary if chest pain is present but is not the chief complaint.
- none if the patient has no chest pain or discomfort.

The ACI-TIPI Report

The ACI-TIPI report is meant to supplement Philips' standard 12-lead interpretation report and be used in clinical settings where ACI is a primary diagnostic concern. It contains 12-lead measurements, ACI-TIPI interpretive output statements, and a predicted probability of ACI.

As with standard 12-lead ECGs, the ACI-TIPI report can be transmitted to the Philips 12-Lead Transfer Station and the Philips TraceMaster Vue ECG Management System, and stored on the TraceMaster Vue System.

Limitations

There are no perfect tests or algorithms to exclude ACI,⁸ including the ACI-TIPI. For example, in one study assessing its effect on the ED process of care outcomes, ACI-TIPI did not appear to reduce resource utilization or decrease length of stay.⁹ In another study, the addition of the ACI-TIPI score did not improve diagnostic accuracy or significantly change triage in rural hospitals.¹⁰ These research results should be carefully weighted against a far greater number of ACI-TIPI studies with positive outcomes, as cited in this application note.

Conclusion

The diagnosis and management of ACI is a clear challenge for emergency medical personnel. Strategies must quickly and accurately identify all patients requiring treatment, monitoring, and reperfusion therapy to maximize outcomes without overdiagnosing. The ACI-TIPI is one decision-support tool designed to address this need. It has proven to be an effective diagnostic test for detecting ACI and cost-efficient at low to high rates of ACI prevalence¹¹ and shown to have excellent triage accuracy for patients with ACI.

As a result, the ACI-TIPI should be considered to help in the reduction of discovery to treatment times for STEMI patients and used according to your organization's policy and procedures.

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