Philips TPI

Application Note

Introduction

Critical conditions require quick diagnosis and treatment. In the case of an acute myocardial infarction (AMI) where “time is muscle,” there is a direct correlation between time-to-treatment and the success of reperfusion therapy, leading to a positive impact on the patient’s outcome. Clinical evidence shows AMI patient outcome may depend directly on thrombolytic therapy (TT).

In an effort to predict the efficacy of TT for the treatment of AMI, Philips has incorporated a cardiac decision support tool into its HeartStart MRx monitor/defibrillator: the Philips thrombolytic predictive instrument (TPI). This application note provides both pre-hospital and emergency department (ED) clinicians with an overview of the development and functionality of this tool, which is used in cooperation with the Philips acute cardiac ischemia time-insensitive predictive instrument (ACI-TIPI).

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Why Use the Philips TPI

The Philips TPI is a software tool that enhances the computerized 12-lead ECG analysis capabilities of the HeartStart MRx. It generates a predicted probability score of patient outcome with and without thrombolytic therapy for AMI based on ECG features and patient demographic information such as age, gender, and blood pressure. TPI's benefit to acute care setting clinicians could be realized based on a study utilizing a computer-interpreted ECG during a trial of prehospital TT in AMI. In the study, prehospital screening of possible TT candidates proved feasible, highly specific, and, with further enhancement, could speed the care of all AMI patients.[2] In a subsequent 22-month clinical effectiveness trial, TPI increased use of:

- thrombolytic therapy,
- thrombolytic therapy *within* 1 hour, and
- overall coronary reperfusion from 11 to 12% for patients with inferior AMI, 18 to 22% for women, and 30 to 34% for patients with an off-site physician.[3]

The TPI: A Closer Look

Thrombolytic Therapy

Clinical evidence shows that the outcomes of patients depend directly on TT within the first hours of AMI onset.[1] If administered beyond 12 hours from ischemic symptom onset or to patients with very small AMIs, the benefits of TT are likely to be minimal with risk of complications and unnecessary costs. Complications including thrombolysis-related intracranial stroke and major bleed can occur in seemingly appropriate candidates.

In conjunction with the TPI, most clinicians will complete a thrombolytic contraindications checklist prior to administration of thrombolytic therapy. A configurable electronic thrombolytic contraindications checklist is also provided by the HeartStart MRx.

TPI Development

Following development of the ACI-TIPI and other cardiac predictive instruments, researchers recognized the need for an aid to help maximize the effectiveness of thrombolytic therapy. The TPI was developed to:

- Identify, with a high degree of specificity, those patients most likely to benefit from thrombolytic therapy in real-time clinical practice.
- Facilitate the earliest possible administration of thrombolytic therapy.

Dr. Harry P. Selker and his research team pooled data from 13 clinical trials and registries of thrombolytic clinical studies creating a database of 4,911 subjects.[4] Multivariate logistic regression was used to yield a set of predictive models showing the thrombolysis-related benefits and risks. The set of predictive models includes:

- 30 day mortality (without and with thrombolysis)
- 1 year mortality (without and with thrombolysis)
- Cardiac arrest within 48 hours (without and with thrombolysis)
- Thrombolysis-related intracranial hemorrhage
- Thrombolysis-related other major bleed

For computation, the TPI's predictive model requires patient demographics readily available at the time of presentation in the prehospital environment or ED.

The TPI analysis was first incorporated into the Philips PageWriter XLi cardiograph. This cardiograph was used in a multicenter TPI study at 28 hospitals across the US, ranging from rural community hospitals to large teaching institutions. The study investigated the effects of having the Philips TPI cardiograph decision aid in the use of thrombolytic therapy and, as mentioned earlier, the TPI increased use of thrombolytic therapy and coronary reperfusion.

The TPI has since been incorporated into the HeartStart MRx.

Understanding the Philips TPI Variables

During the development of the Philips TPI, eleven predicators of thrombolysis-related benefits and risks were established - seven clinical factors and four ECG features.

The seven clinical factors are:

- Patient's age
- Patient's gender
- Patient's weight
- Patient's blood pressure
- Patient's history of diabetes
- Patient's history of hypertension
- Time since ischemic symptom onset

The four ECG features are:

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

While none of these features alone are diagnostic, they represent the most prominent indication of the thrombolysis-related benefits and risks. To be considered significant, ECG features must be apparent in at least two contiguous leads and not due to any of the five exclusionary cases, which can distort ECG interpretation. Refer to the Exclusionary Conditions section on the next page for more information.

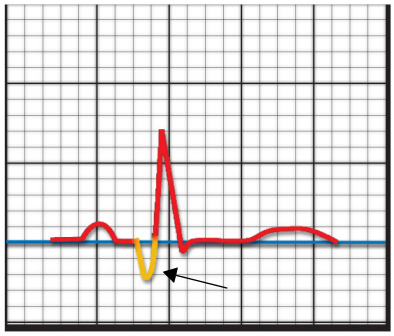
ECG Features

This section briefly describes the three ECG features that are used by the Philips TPI in computing the set of patient outcome probabilities with and without thrombolysis. These features are the same or similar as discussed for the ACI-TIPI.

Abnormal Q Waves

The presence of abnormal Q waves generally indicates myocardial infarction. In some cases, infarction can occur without the generation of "age indeterminate" Q waves. Truly pathological Q waves (see figure 1 below) may be due to a previously unrecognized infarction. Conversely, a prior infarction may mask new ischemia in the same area. A primary function of Q waves in the TPI calculation is that they generally indicate a relatively advanced state of an MI, less likely to be responsive to thrombolytic therapy.

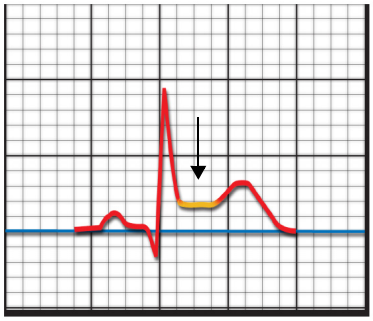
Figure 1 **Pathological Q Wave**



ST Segment Elevation

Significant ST elevation (see figure 2), defined typically as 0.1 mV or more elevation in at least two contiguous leads, which, in an appropriate patient, will signify the onset and early phase of AMI, is generally considered the prerequisite for consideration of thrombolytic therapy. The HeartStart MRx uses this fact as a basic trigger to initiate the TPI analysis, and the TPI formula uses various measures of the degree of elevation and its location and the extent of involved leads to compute patient's outcomes, including the impact of thrombolysis.

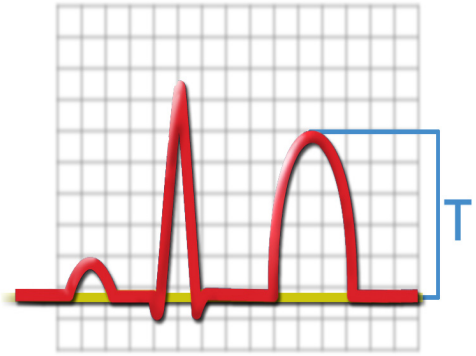
Figure 2 **ST Elevation**



T Wave Elevation

T wave elevation (see figure 3) is a hallmark of the "hyperacute" phase of AMI, which is the time that thrombolytic therapy is most likely to work. So, the TPI algorithm uses T waves both directly, and in an "Earliness Index" in generating their predictions of thrombolysis on patient outcomes.

Figure 3 **Hyperacute T Wave**



ST and T Changes

The TPI's probability scores depend substantially on the values for ST segment and T wave changes. However, certain conduction abnormalities cause secondary ST and T wave changes that, if misinterpreted as primary, could cause erroneously high TPI scores. Because the development of the TPI models used clinical data that excluded patients with conduction abnormalities, the TPI analysis will only be applicable to patients without LVH or LBBB. See the Exclusionary Conditions below for more information.

Exclusionary Conditions

As discussed earlier, the TPI formula was developed from 13 clinical trials of the treatment of patients with AMI. In these clinical studies, patients were included who were felt most likely to benefit from thrombolysis. Therefore, the Philips TPI is appropriate for patients that meet the same entry criteria as those used in the clinical studies on which the TPI was based. Exclusionary conditions include:

- RBBB with no ST elevation in leads V1-V3
- LBBB
- LVH
- Age < 35
- Age > 75
- Systolic blood pressure < 80 mmHg or > 190 mmHg
- No acute ischemic symptom or unknown time since ischemic symptom onset
- Secondary ST and T changes due to RBBB, LBBB, "early repolarization", and LVH
- The presence of an artificial pacemaker or implanted cardiac defibrillator
- Heart Rate > 130 bpm
- Mean QRS duration > 130 ms and no RBBB

When it excludes a patient from the TPI analysis, the Philips TPI issues the statement:

Patient's ECG DOES NOT meet ST criteria for acute MI or ECG DOES NOT meet inclusion criteria for TPI analysis.

The TPI Algorithm

After a 12-lead ECG is acquired, the algorithm used by the Philips TPI takes the coefficients created by logistic regression and inputs information as to the presence and/or level of each clinical factor and ECG feature. The TPI then computes the set of predicted probability values (0-100%) for each acute (30-day) and long term (one-year) mortality, of cardiac arrest, intracranial hemorrhage, and other major bleed thrombolysis-related outcomes.

NOTE: The Philips TPI predicted probability was designed to assist physicians making thrombolytic therapy decisions, but not to replace them. For that reason, a given range of predicted probability or combination of predicted probabilities should not be taken to indicate specific treatment decisions, such as "administer TT now" or "don't use thrombolytic therapy". A given institution may want to make general recommendations and/or monitor thrombolytic administration decisions for patients with suspected AMI. Ultimately, it is the individual physician who should choose how to apply the Philips TPI.

Using the Philips TPI

This section describes input data in the HeartStart MRx and the resulting printed report produced by the Philips TPI.

Clinical Variable Input

The TPI requires patient age, gender, blood pressure, weight, history of diabetes and hypertension, and time since onset of ischemic symptoms to be entered. Diabetes or hypertension history are entered as either Yes, No, or Unknown. The time since onset of ischemic symptoms ranges from 0-7 hours (with 15 min. increments) and has two special values: “Unknown” and “8+ hours”. For ease of use, the MRx automatically captures blood pressure and increments the time since AMI onset during the patient event. In addition, the clinician can enter BP if NBP was not taken by the MRx and adjust an NBP measurement that was taken by the MRx. There is also a mechanism to record a maximum of up to 20 contraindications to thrombolytic therapy prior to analysis.

The TPI Report

The TPI report is meant to supplement Philips’ standard 12-lead report and may be used in conjunction with the ACI-TIPI report that helps assess the likelihood of acute cardiac ischemia. It contains 12-lead measurements, TPI interpretive output statements, and a list of thrombolytic therapy contraindications if they are configured.

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

Conclusion

There is a constant need for diagnostic indicators and support tools to assist emergency medical personnel’s decisions regarding patient care and positive outcomes. For the AMI patient, the clinician must rapidly identify who is most likely to benefit from thrombolytic therapy. The Philips TPI can address this need and should be used according to your organization’s policy and procedures. The early use and benefit of this decision support tool is reinforced by the fact that thrombolytics are 50% effective if given within the first hour of having a heart attack but only 20% effective if given 2-6 hours later.[5]

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