

Implementation of a Computer-Based Decision Support System for Outcomes Prediction and Clinical Triage: Initial Results of Two Pilot Studies

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Abstract: *Objective:* To develop a custom-built, computer-based clinical decision-support tool to help determine the underlying cause of the patient's clinical presentation, its severity level and predicted outcome.

Materials and Methods: A novel, customized, computer-based decision-support tool, rooted in the Bayesian Network technology was constructed. Based on documented data from patients' medical records, the probabilistic predictive model was utilized to validate patients' triage in two different clinical scenarios:

1. Prediction of neurologic deficits in patients resuscitated from cardiac arrest following an Acute Coronary Syndrome/ST-Elevation Myocardial Infarction (ACS/STEMI), and thus likelihood of benefit from (or futility of) emergent coronary revascularization. Study group consisted of 99 patients resuscitated from NSTEMI. For this particular study, the endpoints were in-hospital death, neurologic recovery and the accurate prediction of outcomes by the program.

2. Prediction of the likelihood of presence of and readmission for Acute Decompensated Heart Failure syndrome. Study groups consisted of 20 randomly generated patient clinical profiles (Phase I) and 100 cases from our emergency room electronic medical records: 55 cases of acute heart failure, 14 cases of pneumonia, 7 cases of COPD exacerbation and 11 cases of "other" conditions. End points were the accurate prediction of the underlying diagnosis and the correct disposition.

In both studies, observed data from our institutional electronic medical records registry was utilized to populate the computer program and to validate its initial results. Subsequently, multiple, random clinical case scenarios were used to validate the predictive properties of the computer tool (Phase I) Finally (Phase II), the program was tested using real-world data from our institutional emergency room electronic medical records.

Results: First study: Overall, 64 (65%) patients survived, while 35 (35%) died. On initial examination, 25% of patients were alert, 14% were minimally responsive and 60% were unresponsive.

First Group (5 Hypothetical Case scenarios): Diagnostic accuracy rate 4/5 (80%)

Study Cohort (99 cases) 95/99% (95%); Overall Accuracy: 87%

Second study:

Phase I: Diagnostic accuracy rate of 85%; Disposition accuracy rate of 80%; Overall Accuracy rate 82%

Phase II: Diagnostic accuracy rate of 98%; Disposition accuracy rate of 91%; Overall accuracy rate of 94%

Conclusions: A custom-built, computer based predictive model, utilizing a probability engine software and based on population-wide real-life clinical data, can be a useful adjunct in clinical decision making and medical triage. This takes special significance in such high-risk, fast-paced environments such as the emergency department and the intensive care unit.

Keywords: Predictive modeling, Bioinformatics, Clinical Risk Assessment, Clinical Decision-making.

"Prediction is very difficult, especially if it is about the future." ---Niels Bohr

BACKGROUND

(a) The recent healthcare reform law in the United States included the "Health Information Technology for Economic and Clinical Health (HITECH) Act" with the aim of improving the quality, safety and delivery of healthcare in the

country. Another provision of this landmark legislation is the "meaningful use" clause, which has spawned several programs aiming to increase the scope and efficiency of Health Information Technology in various areas of healthcare practice and administration. These legislations have also included provisions for significant financial incentives for clinicians and hospitals to invest in health information technology. In 2009, the US federal government allotted an amount of US\$ 1.1 billion to promote Comparative Effectiveness Research, which is designed to improve healthcare decisions by utilizing research to disseminate the results of

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research, identify emerging new evidence of effectiveness, safety of healthcare decisions [1-4].

- (b) Acute Coronary Syndrome due to ST-elevation myocardial infarction (STEMI) remains a significant clinical problem, responsible for 330,000 hospital admissions per year. According to the American College of Cardiology/American Heart Association guidelines [1], emergent percutaneous coronary intervention with intent for revascularization within the ideal time window of 90 minutes remains the goal of therapy. However, cardiac arrest in STEMI often presents a dilemma in clinical management, where the level of consciousness at the time of resuscitation plays a major role in decision making. Clinicians are often hesitant or reluctant to pursue a more aggressive approach of coronary revascularization in the face of a comatose patient after initial resuscitation from cardiac arrest. No clear guidelines have been developed for this situation. [5-8] An earlier report by our group [9] has examined this situation with the identification of certain factors with significant predictive effects in a small sample of patients.
- (c) Congestive heart failure continues to be one of the major issues in healthcare, affecting nearly 5 million patients in the United States alone, with hospitalization for acute decompensated heart failure (ADHF) syndromes becoming more frequent. Acute Heart Failure Syndrome is defined as the gradual or rapid change in the signs and symptoms resulting in the need for urgent therapy. Usually this situation requires admission to the hospital for control of the deteriorating clinical picture. The impact of repeated hospitalization for acute heart failure syndromes continues to be a considerable burden on the US healthcare system, both financially and in terms of resource utilization. To date, no comprehensive, consistent statistical or mathematical models to assess patients' risk for readmission to the hospital are currently in clinical use. Recent reports [10-24] demonstrate the lack of evidence-based practice guidelines in the treatment of ADHF Syndromes, in addition to the lack of reliable predictive models for readmission to the hospital. Therefore, the need for novel approaches to clinical triage design has been proposed.

OBJECTIVE AND AIM OF WORK

To design and construct a custom-built, computer-based clinical decision-support tool in a real-life clinical environment, with specific focus on outcomes prediction and clinical triage in high-risk, high impact environments.

For the first study, the objective was to help determine the benefit of emergent percutaneous intervention with intent for coronary revascularization in patients presenting with an abnormal level of consciousness (defined as GCS scale 12-15, 9-12, 6-9 and < 6) within the context of cardiac arrest and acute ST-elevation myocardial infarction (STEMI) based on the probability of death or significant neurologic deficits. Study endpoints were (i) likelihood of death and the presence of significant neurologic deficit and subsequently (ii) recommendation for coronary revascularization versus medical management.

For the second study, the objective was: To test the predictive power of the program in detecting the probability of acute decompensated heart failure in the emergency department.

Study endpoints were: (i) The frequency in which the program-predicted diagnosis accurately correlates with the documented physician decision for diagnosis and (ii) the frequency of recommending the correct disposition in patients who have presented to the Emergency Department with a clinical picture suggestive for ADHF.

TOOLS AND METHODS

Based on the principles and guidelines described in the work published previously by our group as well as others [25-28], a novel, customized, computer-based decision-support tool was designed and constructed for this specific study. The probabilistic predictive model program is rooted in the Bayesian Network technology, and was built using a licensed version of the commercially available Hugin[®] decision support software (Hugin Expert A/S, Aalborg, Denmark).

In building this computer program, the set of clinical variables utilized in each series was determined utilizing the nationally and internationally recognized data relevant to the specific clinical setting. The probability values for each corresponding clinical factor were extracted and used to populate the computer program and to validate its initial results. Chart review was then conducted, with harvest of data from patients'

medical records. The computer program was then used utilizing these individual data sets. In addition, the computer model also incorporates a “Disposition”: Based on the calculated probability hierarchy of the conditions examined, the program assigns an advisory note about the recommended course of action (“Disposition”) to each condition, based on the urgency, expected benefit and/or appropriateness of intervention.

The objective was to examine the number of instances where the predictive software correctly identified the previously determined diagnosis and course of action (disposition).

For the first study, the medical records of 99 patients resuscitated from NSTEMI were reviewed. For this particular study, the endpoints were in-hospital death and neurologic recovery. The following variables were included: Age; degree of obesity as reflected by the Body Mass Index (BMI); history of congestive heart failure; location of cardiac arrest; whether the arrest was witnessed; whether cardiopulmonary resuscitation (CPR) was initiated at the scene; the time until emergency medical services (EMS) arrived at the scene; transport time to the hospital emergency department (ER); initial cardiac rhythm on admission; time to spontaneous return of circulation (“Down time”); initial level of consciousness; the presence of hemodynamic instability (cardiogenic shock) as well as

the final outcome. The computer program was constructed (Figure 1) to predict the Outcomes (Survival, Gross neurologic deficit or Limited neurologic deficit).

The second study included the review of medical records of 100 patients who were admitted to the hospital for the following differential diagnoses incorporated in the triage model: Acute Decompensated Heart Failure (ADHF), Stable Congestive Heart Failure, Chronic Obstructive Pulmonary Disease (COPD) Exacerbation, Pneumonia as well as “Other” for conditions likely to be due to another cause. Patients were included in the study if they presented to the Emergency Department with shortness of breath or exertional dyspnea, and thus were suspected to be in ADHF. Patients’ charts were reviewed and a set of selected clinical variables (Table 1) were extracted from the medical records. These clinical variables were chosen as the most easily obtainable during routine evaluation in an emergency room. Data was also collected about the final disposition of each patient; i.e.: “in-hospital Admission”, “Observation” or Discharge”. A second computer program was constructed (Figure 2) and populated with these datasets, to predict the Diagnosis (ADHF, Stable CHF, COPD, Pneumonia, Other). An additional “Disposition” feature was added to suggest the appropriate management strategy for each predicted diagnosis.

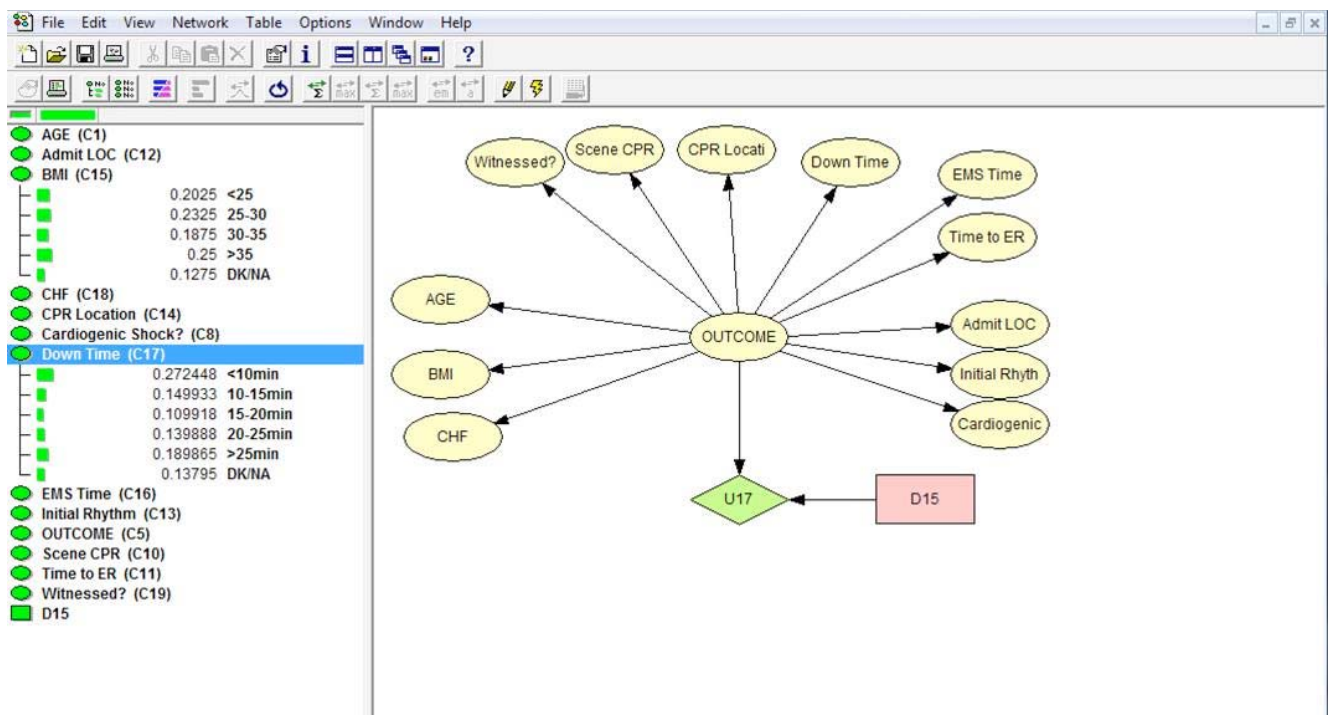


Figure 1: Screen capture of the program built for the first study.

Table 1: Selected Patient Parameters for Second Study

| | |
|--------------------------------------|---|
| Patient Factors: | |
| | -Age |
| | -Gender |
| | -Documented History of Congestive Heart Failure |
| | -Prior Admission for Acute Decompensated CHF |
| Symptomatology: | |
| | -Shortness of Breath |
| | -Orthopnea/Paroxysmal Nocturnal Dyspnea |
| | -Palpitations |
| | -Chills |
| Physical Examination: | |
| | -Heart Rate |
| | -Systolic Blood Pressure |
| | -Fever |
| | -Presence of a Third Heart Sound |
| | -Jugular Venous Distension |
| | -Dependent Edema |
| Laboratory Data: | |
| | -Serum Sodium |
| | -Serum Creatinine |
| | -White Blood Cell Count |
| | -Serum Uric Acid |
| | -Serum BNP |
| Findings on Chest Radiograph: | |
| | -Unilateral Lung Infiltrates |
| | -Bilateral Pleural Effusions |

The first phase of each study was conducted as a proof-of-concept, to test-run and de-bug the custom-built computer algorithm. In this phase, 5 (first study) and 20 (second study) individual clinical profiles were constructed as hypothetical cases and then applied to the model, based on the set of clinical variables previously utilized to build the program. During the second phase, the triage software program was run using the data from the actual study cohort profiles. The Diagnosis and recommended Disposition action identified by the program in each case scenario was compared to the documented data from medical records. Prediction accuracy rate for the Diagnosis and Disposition was then calculated based on the total number of correct predictions and suggestions by the program.

The Institutional Review Board reviewed and approved the research protocol for data collection. All patient identifiers will be removed prior to data collection, and anonymity maintained throughout each study.

RESULTS:

Study No. 1

Survival: 45% survived until discharge.

Neurologic Outcomes: 38% had a full neurologic recovery, while 7% sustained a partial neurologic deficit.

Predictors of favorable survival outcome: Age, time of cardiopulmonary resuscitation (CPR), time until return of systemic perfusion ("down time") and the initial level of consciousness.

Phase I

Diagnostic accuracy rate: The program correctly identified the target diagnosis in 4 of the 5 hypothetical scenario cases (80% accuracy)

Disposition accuracy rate: The program correctly recommended the appropriate disposition level in 4 of the 5 hypothetical scenario cases (80% accuracy)

Phase II

Total number of cases: 99

Diagnostic accuracy rate: 95/99 (95%); Disposition accuracy rate: 95/99 (95%); Overall accuracy rate: 87%.

Study No. 2

Phase I

Diagnostic accuracy rate: The program correctly identified the target diagnosis in 17 of the 20 hypothetical scenario cases (85% accuracy)

Disposition accuracy rate: The program correctly recommended the appropriate disposition level in 16 of the 20 hypothetical scenario cases (80% accuracy)

Phase II

Total number of cases: 100

-- 55 Cases of ADHF

-- 45 Cases of other diagnoses:

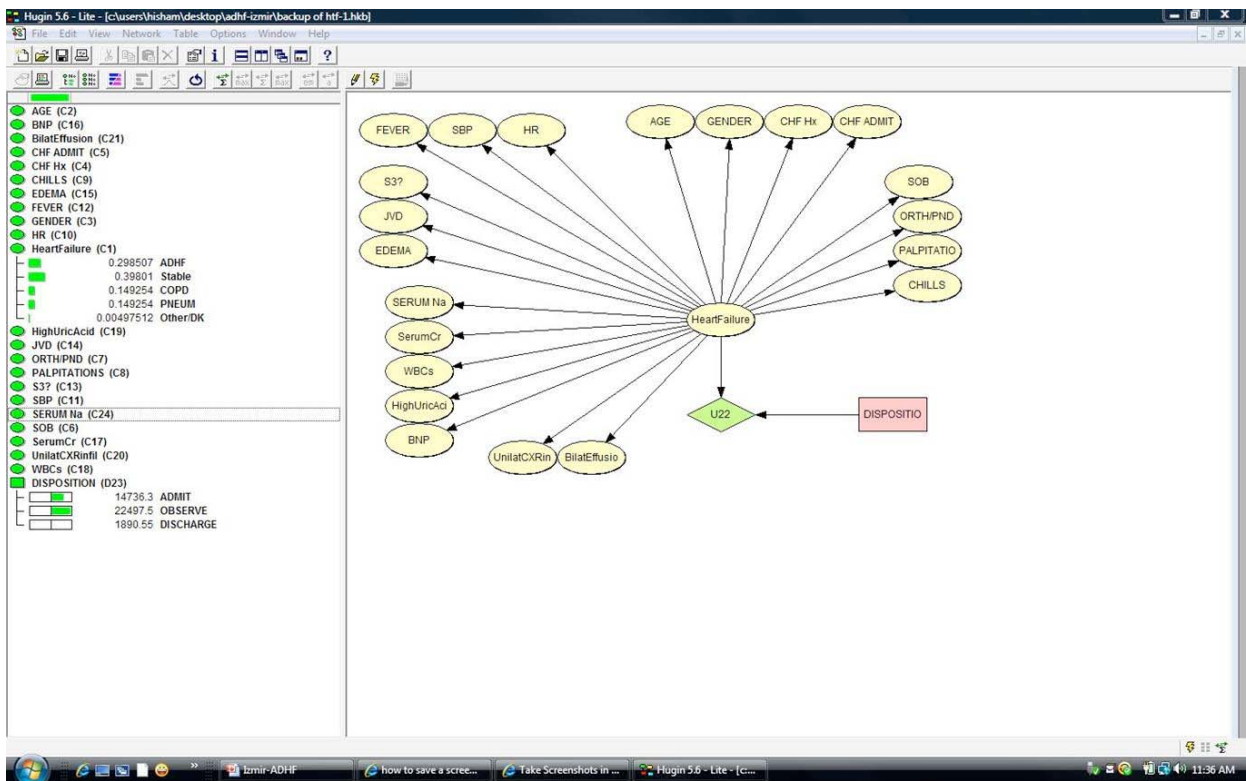


Figure 2: Screen capture of the program for the second study in “run” mode.

- Stable Heart Failure 14
- Pneumonia 8
- Exacerbation of COPD 7
- “Other” miscellaneous conditions 16
- Diagnostic accuracy rate:

The program correctly identified the target diagnosis in 54/55 target diagnosis case scenarios (98 % accuracy)

- Disposition accuracy rate:

The program correctly recommended the appropriate disposition level in 12/14 of stable heart failure cases, 8/8 of pneumonia cases, 7/7 of COPD cases and 14/16 of “Other” cases (91% accuracy) (Figure 3).

- Overall correct accuracy rate: 94%

STUDY LIMITATIONS

These are two pilot studies with the main objective of validating the predictive properties of the computer program in the context of abnormal level of consciousness following resuscitation from acute

myocardial infarction and the emergency room evaluation for acute decompensated heart failure. Both studies share the limitations of being a retrospective, chart review analysis. The sample size in both studies is small.

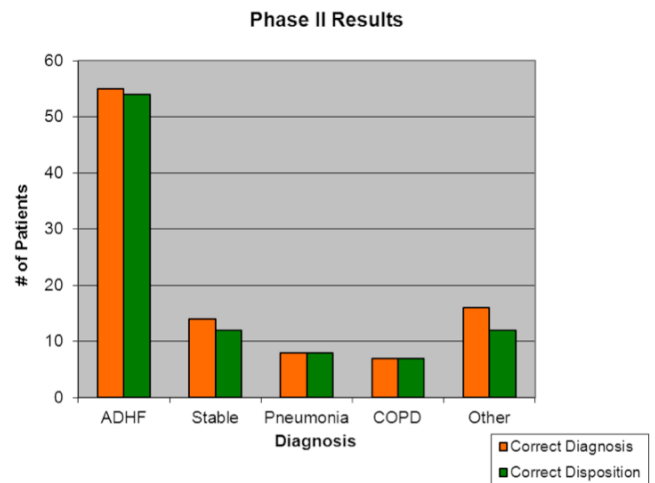


Figure 3: Graphic representation of the results of the second study.

CONCLUSIONS

Since their introduction in the late 1970s, computerized predictive models, based on the Bayesian principle have been successfully

implemented in various fields with increasing popularity. The use of such probability-based computer software programs as predictive, diagnostic and/or triage models have been demonstrated with satisfactory results in various clinical and research situations. In fact, some investigators report a superior performance of such predictive models over clinical practice, especially areas of clinical practice characterized by a fast pace, high risk and high impact and difficult choices among expensive and risky treatment modalities. Because the system can provide an accurate identification of the underlying condition, as well as an accurate prediction of the expected outcome, based on the severity of the condition, a better informed decision about the next steps in the management of the patient can be made. This optimization of the decision making process based on the utility or futility of the treatment modality as well as its cost-effectiveness can have significant implications on the quality, safety and efficiency of healthcare.

As demonstrated by previous reports [29-33], this application has proven to be reproducible, accurate, versatile and easy to use; and can offer a valuable ancillary tool for medical decision making and clinical triage in complex, high-risk and/or high impact situations.

A custom-built, computer based predictive model, utilizing a probability-based software engine and utilizing population-wide, real-life clinical data, can be a useful adjunct in clinical decision making and medical triage. This takes special significance in such high-risk, fast-paced environments such as the intensive care unit and the emergency department.

FINANCIAL DISCLOSURE

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