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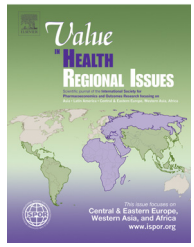

Cost-Effectiveness of Introducing Point-of-Care Test for Detection of Level of Glycogen Phosphorylase in Early Diagnostic Algorithm of Acute Coronary Syndrome

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ABSTRACT

Background: The detection of specific biomarkers in the early phase of acute coronary syndrome (ACS) is important for the early diagnosis and appropriate management of patients with ACS. **Objectives:** To estimate the cost-effectiveness of introducing a diagnostic point-of-care (POC) test for determining the levels of glycogen phosphorylase BB isoform (GPBB) in a standard diagnostic algorithm for the early diagnosis of ACS within the health system of the Republic of Serbia. **Methods:** The probabilistic decision-tree model was constructed for patients with nontraumatic chest pain comparing the use of standard diagnostic procedure, physical examination, and electrocardiogram monitoring with the use of a diagnostic test for the detection of the levels of specific biomarkers. The perspective of the health care services purchaser (the Republic Institute for Health Insurance, Serbia) was used in the model, and only direct costs were taken into account. The time horizon was set at one treatment episode of ACS, and the discount rate was not included because of the short length of the time horizon. **Results:** Using the GPBB POC test in comparison with not using it in the early diagnosis of ACS results in a significant reduction in the cost per treatment episode (10,034.48 ± 7,283.80 Serbian dinar [RSD]), increase in the number of survivors per 1000 treatment episodes (16 ± 18), decrease in the number of hospitalizations per 1000 treatment episodes (104 ± 44), and decrease in the number of performed coronarographies per 1000 treatment episodes (22 ± 19). The costs per hospitalization avoided (incremental cost-effectiveness ratio) were −145,887.57 ± 5,271.54 RSD, and the costs per coronarography avoided were −137,295.68 ± 4,681.05 RSD. **Conclusions:** In the circumstances of limited health resources, reducing hospitalizations and decreasing unnecessary treatments and invasive diagnostic procedures by a GPBB POC test could be an effective way to improve the economic status of other Balkan countries with limited health care budgets.

Keywords: acute coronary syndrome, budget impact analysis, emergency medicine, glycogen phosphorylase.

Introduction

Acute coronary syndrome (ACS) is a clinical entity that includes unstable angina, non–ST-elevation myocardial infarction, and ST-elevation myocardial infarction [1]. Early detection of ACS improves the outcomes of the treatment, reducing the number of hospitalizations and invasive interventions, which has a great impact on minimizing the treatment costs of ACS [2]. Detection of specific biomarkers in the early phase of ACS has an important role in the management of patients with ACS [3]. A glycolitic enzyme, glycogen phosphorylase (α-1,4-D-glucan: orthophosphate D-glucosyltransferase), plays a crucial role in the regulation of carbohydrate metabolism, catalyzing the process of converting glycogen to glucose 1-phosphate and providing a supply of glucose in the conditions of hypoxia and hypoglycemia [4]. There are three isoforms of this glycolitic enzyme in the human body: isoform found in the liver, isoform found in the skeletal muscles, and isoform found in the brain (glycogen phosphorylase BB [GPBB]). The structures and functions of these isoforms are determined by gene regulation. The serum level of the GPBB isoform reflects the damage of not only the brain tissue, but also the myocardium [4]. In conditions of decreased coronary blood flow and myocardial ischemia, GPBB isoforms decompose glycogen and the serum level of the GPBB enzyme rises [4].

The GPBB point-of-care (GPBB POC) test is a quick and qualitative test that measures the level of GPBB in the blood of a patient with ACS. It is simple to use and safe for medical staff and patients, and this test can even be used outside health facilities, where a patient with ACS is met for the first time. The GPBB POC test is positive for a patient with ACS if the level of GPBB in the blood is higher than 10 ng/ml [5].

The results from published clinical trials showed that the serum levels of GPBB were significantly raised in the first 4 hours after the onset of chest pain, being a very sensitive biomarker for

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early diagnosis of ACS [4,6]. GBPP can also be used for early risk estimation in patients with ACS and reversed and altered ST/T segment at the time of conducting a resting electrocardiogram on hospital admission [7]. The determination of the serum levels of GPBB has a greater sensitivity than that of creatine-kinase in patients with perioperative ischemic myocardial injury during coronary artery bypass grafting [7]. The sensitivity and specificity of the GPBB POC test in the first hours after ischemia onset were investigated in several studies, and estimates ranged from 64% to 100% for sensitivity, and from 64% to 100% for specificity [8,9]. Mean values of sensitivity and specificity weighted on the number of patients participating in a clinical trial were 77% and 65%, respectively [10]. Corresponding false-positive and false-negative rates of the GPBB POC test were 23% and 35%, respectively.

There are no published data about the economic consequences of the introduction of a diagnostic test for determining the levels of GPBB isoform for early diagnosis of ACS. Introduction of a new diagnostic procedure can affect the health budget on a larger scale in countries undergoing socioeconomic transition compared with that in developed countries.

The aim of this study was to estimate the cost-effectiveness of introducing a diagnostic POC test for determining the levels of GPBB isoform in standard diagnostic algorithm for early diagnosis of ACS (before a patient is transported to an emergency center) within the health system of the Republic of Serbia.

Methods

For the purpose of this pharmacoeconomic study, we constructed a probabilistic decision-tree model for patients with nontraumatic chest pain for comparing the use of standard diagnostic procedure, physical examination, and electrocardiogram monitoring with the use of a POC diagnostic test for determining the level of GPBB isoform. The model was constructed using Microsoft Excel (version 7). Considering the acute course of diagnosis and treatment of nontraumatic chest pain, the duration of the time horizon was set at one treatment episode of ACS. Discount rate was not included because of the short length of the time horizon. Our model considered the perspective of the health care services purchaser (the Republic Institute for Health Insurance, Serbia).

The structure of the decision-tree model from our study is shown in Figure 1 (the structure shown has been truncated for the sake of clarity; the full model in Excel is available from the authors on request). Because the perspective of this pharmacoeconomic study was that of the health care services purchaser (the Republic Institute for Health Insurance, Serbia), only direct costs were included in the model (i.e., costs of medications, laboratory services, outpatient services, inpatient services, thrombolysis, and coronarographies). Service utilization (on which the cost calculations were made) was estimated using guidelines for treatment of nontraumatic chest pain and already published pharmacoeconomic studies [11–14]. The prices of health services were obtained from the Republic Institute for Health Insurance Tariff Book [15]. All costs were expressed in Serbian national currency (Serbian dinar, RSD). The values for sensitivity and specificity of the GPBB POC test used in the model were weighted averages from published clinical trials (77% and 65%, respectively), as calculated by Dobric et al. [10]. The values of the input parameters, the distributions of their values used for probabilistic sensitivity analysis, and the sources of data are shown in Table 1.

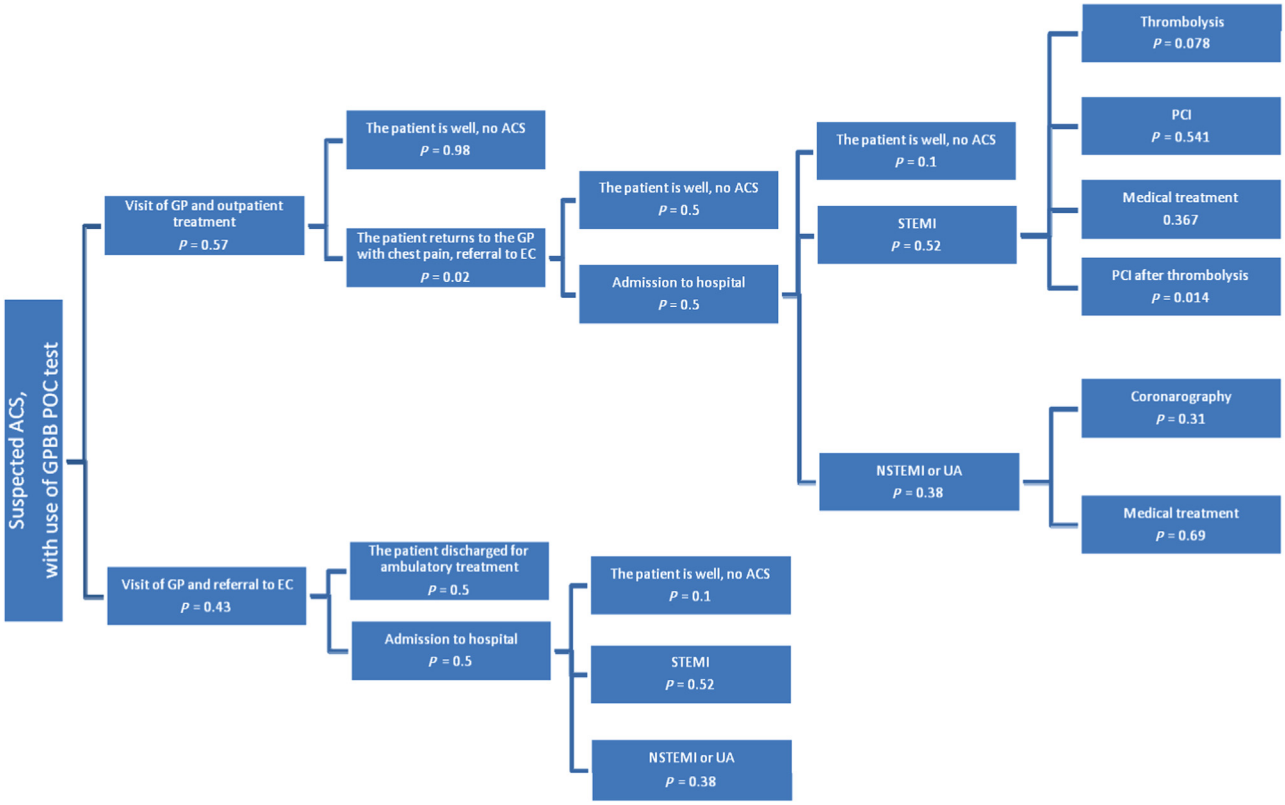

Fig. 1 – Schematic representation of one arm of the decision-tree model. The representation of the model is truncated for the sake of clarity. ACS, acute coronary syndrome; EC, emergency center; GP, general practitioner; GPBB POC test, glycogen phosphorylase BB point-of-care test; NSTEMI, non–ST-elevation myocardial infarction; PCI, percutaneous coronary intervention; STEMI, ST-elevation myocardial infarction; UA, unstable angina.