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Original research article/ Artykuł oryginalny

Rapid strip tests as a decision-making tool about antibiotic treatment in children – A prospective study



Mariusz Małecki¹, Artur Mazur^{2,*}, Marek Sobolewski³,
Monika Binkowska-Bury², Małgorzata Marć², Paweł Januszewicz²

¹SOKRATES, Non-Public Health Care Institution, Rzeszów, Poland²Faculty of Medicine, University of Rzeszów, Rzeszów, Poland³Department of Quantity Methods for Economics, Rzeszów University of Technology, Rzeszów, Poland

ARTICLE INFO

Article history:

Received: 15.01.2017

Accepted: 23.01.2017

Available online: 07.02.2017

Keywords:

- Pharyngitis
- Tonsillitis
- Group A beta-hemolytic streptococcus
- Rapid strip test

ABSTRACT

Background: Although three quarters of seasonal infections of the upper respiratory tract in children are of viral etiology, majority of the patients are unnecessarily prescribed antibiotics despite the availability of rapid diagnostic tests differentiating between infections. This study aimed to assess the relation between the use of rapid strip tests which detect the antigens of group A beta-hemolytic streptococcus (*Streptococcus pyogenes*) in pharyngitis and/or tonsillitis and the frequency of antibiotic use in children and adolescents aged 2–15 years. **Methods:** The data were collected from 1307 children from the region of southeast Poland who then were divided into a sample group ($n = 581$) in which patients received a rapid strip test before treatment plan was established by the physician, and into a control group ($n = 726$) in which the decision whether to administer an antibiotic was made without the use of the rapid test. Based on statistical decision-making method, a pharmacoeconomic analysis of costs and effectiveness of strip tests was performed. **Results:** The use of the rapid strip test resulted in identifying the streptococcal infection in 31.7% of children and allowed to lessen the antibiotic use by 5.1%. The number of follow-up visits decreased (86.4% vs. 96.0%) and the anticipated cost of treatment decreased by 17%. **Conclusions:** Rapid diagnostic tests used by the family physicians in initial diagnostics of seasonal upper respiratory tract infections in children allowed to differentiate between the type of infection as well as reduce the number of follow-up visits. Also, the antibiotic spending reimbursed by the insurer decreased by 17%.

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Abbreviations: GAS – group A beta hemolytic streptococcus; CDC – Centers for Disease Control and Prevention; PHC – Primary Health Care.

* Corresponding author at: Wydział Lekarski Uniwersytet w Rzeszowie, Al. mjr. W. Kopisto 2 a, 35-310 Rzeszów, Poland.

Tel.: +48 17 872 19 41; fax: +48 17 872 19 42.

E-mail address: drmazur@poczta.onet.pl (A. Mazur).<http://dx.doi.org/10.1016/j.pepo.2017.01.006>

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Introduction

Pharyngitis and tonsillitis are the most frequent infections of the upper respiratory tract. In general, they occur in autumn, winter, and early spring [1]. The main etiological factor for bacterial pharyngitis and/or tonsillitis is group A beta-hemolytic *Streptococcus* (GAS) which occurs in approximately 37% of children, regardless of age [1, 2]. However, it is most frequent among children aged 3–14 years [3]. Clinical detection of an acute respiratory tract infection is based on finding the symptoms not characteristic of microorganism that causes them. This often hinders differentiating between viral and bacterial etiology [2, 4, 5]. Therefore physicians must rely on a clinical picture which in turn may result in antibiotic overprescription. The role of microbiological examination using the basic diagnostic method of throat swab culture is being increasingly emphasized [5, 6]. However, it seems that an antibiotic is often administered prematurely despite the possibility of performing the test. The rapid test that detects group A streptococcal polysaccharide antigens in material collected through a swab appears to be a much simpler diagnostic method [7]. Usually, these are immunoenzymatic and optical immunoassay tests providing results in the presence of a patient. However, the sensitivity of such tests varies. The Infectious Diseases Society of America guidelines recommend the use of throat swabs and/or rapid antigen detection tests (RADT). In children and adolescents a negative RADT result should be supported by a throat swab, whereas for positive RADT results, a throat swab is not recommended given the high specificity of this test [5]. In Poland, rapid tests detecting the GAS antigen are still not commonly used. Scarce number of cases in which the tests are used are not publicly funded. It is the expense of parents of individual young patients. An auxiliary method helpful in differentiating viral and bacterial etiology uses scores – which specific clinical symptoms are assigned a respective number of points [2, 8, 9].

Frequency of clinical symptoms was the basis for creating the Centor score (or McIsaac score) which specifies the probability of streptococcal etiology of palatine tonsillitis. Nevertheless, family physicians and pediatricians in Poland seldom use the criteria in full along with point value. In addition, Poland lacks guidelines specified by regulations which could oblige the physicians to use tools like Centor score (or McIsaac score).

Due to an excessive antibiotics prescribing in pharyngitis and/or tonsillitis in primary care, the use of antibiotics should be limited especially when bacterial etiology is not confirmed. This study aimed to assess the usage of a RADT to detect the antigens of group A beta-hemolytic streptococcus (*Streptococcus pyogenes*) in pharyngitis and/or tonsillitis in children and adolescents aged 2–15 years. In addition, we determined the frequency of antibiotics use, and identified the relationships between:

- the frequency of medical visits during the primary infection and re-infection (or other infection) in the 6-week period following the initial visit in the group who underwent diagnostic tests and in the control group; and

- the use of a RADT to detect *Streptococcus pyogenes* and the costs of pharyngitis and/or tonsillitis treatment.

Methods

The present study was conducted from 17 October 2013 to 13 April 2014 in randomly selected primary health care clinics in southeast Poland. The study was conducted in cooperation with the Polish National Health Fund (NFZ). The subjects were randomly recruited and assigned to either sample or control group. In total, 72 subjects were chosen (36 subjects in each group). After the study began, 4 subjects withdrew (1 from the sample group and 3 from the control group). In each group, the number of patients aged 2–15 years who were attended to by clinics involved in the project exceeded 40 000. Subjects from both groups in total attended to 25% of the Podkarpackie voivodeship population aged 2–15 years. Data were collected using a questionnaire with structured interviews. Participants were divided into: (1) a sample group ($n = 581$), in which each patient received a RADT to detect *Streptococcus pyogenes* antigens before a treatment plan was established by their physician and (2) a control group ($n = 726$) in which the decision whether to administer an antibiotic was based on an interview and physical examination without the RADT. The patients were examined by the primary health care physicians and pediatricians in line with the Polish primary health care system which encompasses children and adolescents.

The test chosen for the sample group was the OSOM Strep A test (produced by Sekisui Diagnostics). This is a rapid immunochromatographic lateral flow strip test used to qualitatively detect the antigens of *Streptococcus pyogenes* in a throat and/or tonsils swab. The reliability of the test has been previously reported [9]. According to its producer, the test has a sensitivity of 96% and specificity of 97.8%, with the compatibility with microbiological examination confirmed as 97.3%. Material to perform the test was collected from participants using a swab as stated in the instructions on packaging.

At first, an authorized representative of each clinic gave a written consent for the clinic participation.

Inclusion criteria were:

1. Informed written consent from the patients' statutory representatives to participate in the study.
2. Symptoms (pain, irritation or scratching of throat and/or tonsil) for 3 days before the initial medical visit.
3. Signs: redness and/or swelling and/or petechiae of the mucous membrane of throat and/or tonsils.

Exclusion criteria were:

1. Antibiotic use for whatever cause on the day of the medical visit.
2. Treatment of pharyngitis and/or tonsillitis with the use of an antibiotic during the 14 days before the medical visit.

Initially, 1573 children met the criteria and were qualified also due to parental consent. However, after incomplete or incorrect questionnaires were excluded, the data eligible for analysis decreased to 1307 participants.

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