28

Evaluation of the proposed update of FDA guidelines on the symptomatic diagnosis of acute uncomplicated cystitis in women

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Alidjanov J.F. [1], Naber K.G. [2], Pilatz A. [1], Abdufattaev U.A. [3], Wagenlehner F.M.E. [1]

[1]Justus-Liebig University, Clinic and Polyclinic for Urology, Pediatric Urology and Andrology, Giessen, Germany, [2]Technical University of Munich, Dept. of Urology, Munich, Germany, [3]State Inst. Republican Specialized Scientific-Practical Medical Center of Urology, Dept. of Radiology, Tashkent, Uzbekistan

Introduction & Objectives: Recently, US Food and Drug Administration (FDA) has proposed to use at least two of the four following symptoms for diagnosis of acute uncomplicated cystitis (AC) in women: dysuria, urinary frequency, urinary urgency, and suprapubic pain. We aimed to reevaluate the diagnostic values of symptoms for AC, using the Acute Cystitis Symptom Score (ACSS), validated in several languages.

Materials & Methods: We have analyzed the data derived from the ACSS database and used the results of the analysis for validating the proposed respective update of FDA guidelines. Different diagnostic values of the signs, symptoms and their severity were assessed. “Model fit” analysis of the developed linear models and 2x2 contingency tables were used for basic statistical analysis.

Results: Of the 911 respondents from 7 different countries, 872 (median for age [IQR] 33[25-46]) were selected for the analysis. Respondents were allocated to groups of Patients (n=453) and Controls (n=418) according to the diagnosis of a physician concerning the presence or absence of AC, based on physical and laboratory findings. The accuracy of the diagnosis increased significantly for all symptoms when the severity of a symptom was included in the analysis. Highest diagnostic values were shown by dysuria in the “model fit” and odds ratio analyses, both for the presence and severity of this symptom. Urinary frequency and visible blood in the urine had no significant association with the diagnosis of AC when the analysis was based only on the presence or absence of signs. Inclusion the severity of urinary frequency into the analysis increased the strength of its association with AC up to significant values. The diagnostic values of suprapubic pain and sense of incomplete bladder emptying were about the same and had a significant positive association with AC. The inclusion of the severity into the analysis decreased the association of suprapubic pain with AC to insignificant values.

Conclusions: The severity of the symptoms rather than their presence itself is essential for an accurate diagnosis of AC. Dysuria has the highest diagnostic value among the typical symptoms. In addition to the four symptoms proposed by the FDA, we suggest to include a sense of incomplete bladder emptying into the list of additional symptoms for the diagnosis of AC. It is, however, necessary to consider the severity of a symptom rather than its presence alone. The ACSS could be a useful tool in this regard.