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MALDI-TOF: driving change in microbiology laboratories

Direct diagnosis of urinary tract infections by combining MALDI-TOF (Matrix-assisted laser desorption ionization time-of-flight), Coral UTI Screen TM system and Gram stain

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Background: Urinary tract infections (UTI) are one of the most frequent infections. Around 20-30% of patients with septic focus as urinary tract infection. Complicated UTIs can cause severe kidney damage and increase mortality of patients admitted. An early and targeted therapy based on the identification of the causative agent is critical for a favorable outcome.

Classic diagnostic systems for UTIs are based on urineculture combined or not with a screening system that determines whether or not a given sample needs to be cultured. In this study we propose a sequential algorithm based on determination of bacterial ATP production by luminometry and Gram stain, followed by identification by mass spectrometry.

Material/methods: A prospective randomized study was performed, in which positive urine samples by the luminometry screening Coral UTI Screen TM system were selected (luminometry forming units, LFU). All selected samples underwent Gram staining and identification of the causative organism by MALDI-TOF mass spectrometry. Subsequently the results were compared with the results of conventional culture (WIDER MIC/id, Francisco Soria Melguizo SA, Spain).

Results: Three hundred and twenty positive samples were selected by Screening. Sixty two samples (20.4%) belonged to patients admitted, and 38.7% (24 samples) belonged to kidney transplants. The most frequently isolated microorganisms were *Escherichia coli* (58.7*%), Klebsiella pneumoniae* (16.8%), and *Enterococcus faecalis* (10.3%).

Considering the culture as a gold standard, identification by MALDI-TOF showed a positive predictive value (PPV) of 98.6%, negative predictive value (NPV) of 93%, Sensitivity of 92.3% and Specificity of 98.8%. Positive likelihood ratio was 74.7 (95% CI: 18.84-296.48) and Negative likelihood ratio was 0.08 (95% CI: 0.04-0.13). The concordance between the two tests on the scale of Landis and Koch was almost perfect with a kappa index of 0.931 with a p-value <0.05.

After the analysis of the ROC curve of LFU compared to Gold standard we obtained an AUC=0.801, getting the optimal cutoff in 40.5% of LFU. Based on this we propose a sequential diagnostic algorithm beginning with screening by luminometry, followed by gram stain and MALDI-TOF when the LFU>40.5% and positive gram staining. With this algorithm we obtained a Sensitivity of 74.2%, Specificity of 99.4%, PPV of 99.1% and NPV of 80.1%. Positive likelihood ratio was 120.19 (95% CI: 117-850) and Negative likelihood ratio was 0.26 (95% CI: 0.20-0.34).

Conclusions: The proposed diagnostic algorithm that combines sequential algorithm by detection of bacterial ATP, along with Gram-staining, and subsequent identification of the UTI-producing microorganism by MALDI-TOF is useful in advancing the diagnosis of UTI. Depending on the workload of each laboratory it could be implemented for selected patients with severe clinical situation where an early and targeted therapy based on the identification of the causative agent is crucial to a favorable outcome.