Diagnostic performance of a new multiplex PCR in patients with meningitis and/or encephalitis

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Background

- Infectious meningitis and encephalitis, can lead to significant long-term morbidity, mortality and high health care costs.
- Rapid and accurate molecular diagnostic tests for the most common causes of these infections have the potential for high clinical impact.
- We present our experience using the FilmArray Meningitis/Encephalitis (ME) panel in comparison with standard diagnostic methods.

Material/methods I

Over an 8-month period (April-November 2016):

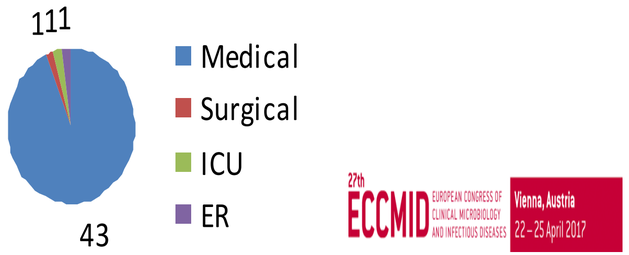
- Forty six (46) cerebrospinal fluid (CSF) specimens obtained from individuals suspected to have meningitis and/or encephalitis (**Figure 1**) were collected in the University Hospital of Ioannina
- The specimens were tested with the **FilmArray ME panel** (FilmArray, bioMerieux) (**Figure 2**) which is a qualitative nested-multiplexed nucleic acid-based diagnostic test for simultaneous detection and identification of the following 14 common agents capable of causing community-acquired ME.

❖**6 bacteria**: *E. coli K1, N. meningitis, H. Influenzae, S. pneumoniae, S. agalactiae, L. monocytogenes*

❖**7 viruses**: *CMV, Enterovirus, HSV1, HSV2, HHV-6, VZV, H. parechovirus*

❖**1 fungus**: *C. neoformans/gattii*

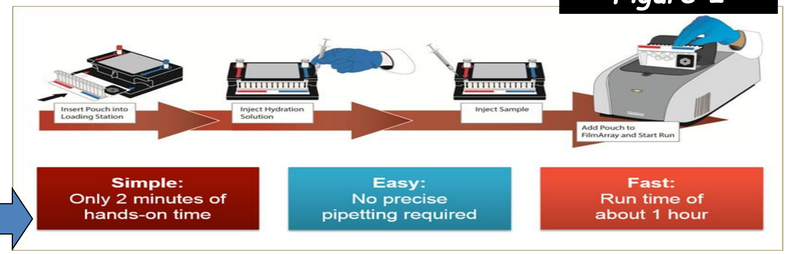
Figure 1 CSF specimen distribution by ward



Material/methods II

- Bacterial and fungal testing was also performed by **Gram stain** and **culture** on solid and broth media and isolates were identified using the automated **VITEK 2** system and **API** (bioMerieux, France).
- Testing for Enteroviruses and Herpesviruses group were in parallel carried out using the Enterovirus and Herpes **Consensus PCR** methodology respectively (Argene, BioMerieux, France). Nucleid acid extraction was performed using the QIAamp Viral RNA and DNA mini kit, respectively (Qiagen, Valencia).
- Samples with discrepant viral PCR results were retested by a **single house PCR.**

Figure 2



Results

- Pathogens were identified in 10 (21.7%) CSF samples by routine evaluation and in 11 (23.9%) by ME panel (Table 1) .
- The sensitivity and specificity of FilmArray ME panel:
  - was 100% in detecting bacterial and fungal pathogens compared with conventional methods.
  - in viral detection, one discrepant result across FilmArray and Consensus PCR was observed. The FilmArray result was also confirmed by the in-house PCR (Table 1)
  - routine evaluation identified no pathogens in 35 FilmArray ME negative results.
- The time from receipt of CSF to report the organism identification was estimated for the FilmArray ME panel at 2.5 hours while for the standard methods at 16.5 hours.
- The distribution of microbial pathogens by age are shown in Table 2.

Table 1

Pathogens detected	Positive with standard diagnostic methods (Gram and/or culture, PCR)	Positive with FilmArray ME Panel	Positive with house PCR (discrepant results)
N.meningitis	2 (1 only in Gram stain)	2	-
Enterovirus	2	2	-
VZV	5	6	1
C.neoformans /gattii	1	1	-

Table 2

Pathogens detected	<2 ms	2-23 ms	2-17 yrs	18-34 yrs	35-64 yrs	>64 yrs
N.meningitis				2		
Enterovirus	1		1			
VZV				1	2	3
C.neoformans /gattii					1	

Conclusions

- The FilmArray PCR panel offers a promising platform for the rapid diagnosis of ME and would be useful to overcome some of the challenges for conventional laboratory-based diagnosis of these infections.
- Further studies are needed to prospectively evaluate the clinical impact and cost-effectiveness of FilmArray ME panel.

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