

Reduction of response time for the assessment of invasive bacterial disease in bacteriology by using h24 molecular tests at low operational impact

Nicoletta Corbo, Cristina Comi

Microbiology and Virology Unit, A. Manzoni Hospital, Lecco, Italy

Summary

In February 2017, the Lombardy Region (Italy) provided some indications for the surveillance of invasive bacterial diseases, including the need to perform molecular tests together with culture and other diagnostic tests. Starting from September 2017, the Microbiology and Virology Unit of ASST Lecco has acquired the FilmArray system (BioMérieux, Marcy-l'Étoile, France) which includes the Meningitis/Encephalitis (ME) panel, able to identify 14 common pathogens responsible for community acquired meningitis or encephalitis including virus, bacteria and yeast with molecular technology directly from cerebrospinal fluid (CSF). In 2018, the organizational model implemented has provided to use of the FilmArray system by the TSLB dedicated to microbiology during routine hours (8.00-16.30) and by the TSLB of Clinical Pathology on active guard from 16.30 to 8.00 with validation of the analysis by the Manager available. The new organization, which involved the use of the FilmArray ME h 24 panel by the TSLB who works belonging to Clinical Pathology and Microbiology and Virology, has allowed a considerable reduction of response times in case of suspected meningitis.

Correspondence: Nicoletta Corbo, Microbiologia e Virologia, Azienda Socio-Sanitaria Territoriale (ASST) di Lecco, Via dell'Eremo 9/11, 23900 Lecco, Italy.
Tel.: +39.0341/489617 -Fax: +39.0341/489601.
E-mail: n.corbo@asst-lecco.it

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Introduction

In recent years, laboratory diagnostics has undergone important changes both in terms of technology and organization. Among the causes is the most important, certainly the advent of new techniques among which low-impact molecular biology.

These techniques have allowed to replace the long and traditional methods with faster but equally specific tests that better meet the clinician's requests.

The rapidity of response times is an essential element in the management of invasive bacterial diseases (MIB). With note G1.2017.0005186 dated 10/02/2017, the Lombardy Region has communicated some indications for MIB surveillance, including the need to perform molecular tests together with culture and other diagnostic tests. In particular, the note highlights the importance of ascertaining the aetiological agent as soon as possible. Our paper demonstrates that molecular tests (based on PCR technique), performed simultaneously with culture analysis and other diagnostic tests as appropriate, show higher sensitivity and specificity than the gold standard (culture analysis alone) when cerebrospinal liquor is collected during or after the antimicrobial treatment (decapitated meningitis).

Materials and Methods

In September 2017, the U.O.C. of Microbiology and Virology of ASST of Lecco acquired the FilmArray system (BioMérieux, Marcy-l'Étoile, France) which uses nested multiplex PCR technology and high-resolution melting analysis to detect and identify the nucleic acids of numerous microorganisms (bacteria, viruses and yeasts). The system includes the FilmArray Meningitis/Encephalitis (ME) panel, able to directly identify 14 etiological agents of meningo-encephalitis in liquor samples (Figure 1). The analysis is simple to perform, it is completely automated and requires no more than 10 minutes with simple and manual sample preparation steps that can be performed by the technician on active watch, providing results in 1 hour. According to the previous organizational model, the identification times for bacteria and mycetes exceeded 24 h, while it had times longer than 7 days for viruses. The organization of the TSLB staff of Clinical Pathology and Microbiology and Virology provides for the assignment of 28 TSLBs, of which 13 specifically dedicated to the U.O.C. of Microbiology and Virology. The TSLBs belonging to the two Structures carry out active duty shifts from 16.30 to 8.00 for emergencies relating to both operational units.

Results

The organizational model, implemented in 2018, involved the use of the FilmArray system by the TSLB dedicated to microbiology during routine hours (8.00-16.30) and by the TSLB on call active from 16.30 to 8.00 with validation of the analysis at care of the Manager available. This model was achieved after several meetings to share with TSLB staff on the clinical and prophylaxis importance of reducing the response time of liquor samples and a widespread training program concerning the use of molecular technology.

The new organizational model made it possible to deal urgently from 01/01/2018 to 31/12/2018, 71 liquor samples that presented the objective cytochemical characteristics required in the related PDTA drawn up at company level in December 2017 and verified and approved by the Hospital Infections Committee (Figure 2). 71 liquors showed the characteristics of cell count (reported below) indicated in the PDTA.

The molecular investigation through FilmArray cannot be accepted by the department, but is inserted in laboratory care based on the following indications.

In particular, the FilmArray: i) is not performed if the cell count is less than or equal to 5 cells/mm³; ii) between 6 and 49 cells/mm³ it will be considered the possibility to carry out the method according to results obtained from the chemical-physical analysis of the liquor and possibly after interview with the clinician by the Reportable Director; iii) 50 cells/mm³ are recommended for execution.

47 were processed by routine staff before 4.30 pm (opening hours of routine microbiological activity) and 24 liquors were processed urgently after 4.30 pm (closing time of routine microbiological activity) allowing the verification of possible etiological agent of all samples received within 2 hours from arrival in the laboratory. Of these 47 liquors processed in routine, 7 were positive against the 10 positive of the remaining 24 processed during the closing time of the microbiology (16.30-8.00).

The organisms identified during routine time were the following: 3 *Streptococcus pneumoniae*; 2 *Varicella zoster* viruses; 1 *Neisseria meningitidis*; 1 *Listeria monocytogenes*.

The microorganisms identified during urgency were the following: 2 *Streptococcus pneumoniae*; 2 *Streptococcus agalactiae*; 1 *Varicella zoster* virus; 1 *Enterovirus*; 1 *Neisseria meningitidis*; 1 *Cryptococcus neoformans*; 1 *Herpes simplex*; 1 *Haemophilus influenzae*.

Conclusions

The new organization, which involved the use of the FilmArray ME h 24 panel by the TSLBs belonging to Clinical Pathology and Microbiology and Virology, has therefore a considerable reduction in response times in case of suspected meningitis. Good organization, a widespread training program and, not least, the involvement of Clinical Pathology personnel in the importance of the real-time processing of the liquors that arrive in urgency, are essential results to reach the proposed objective.

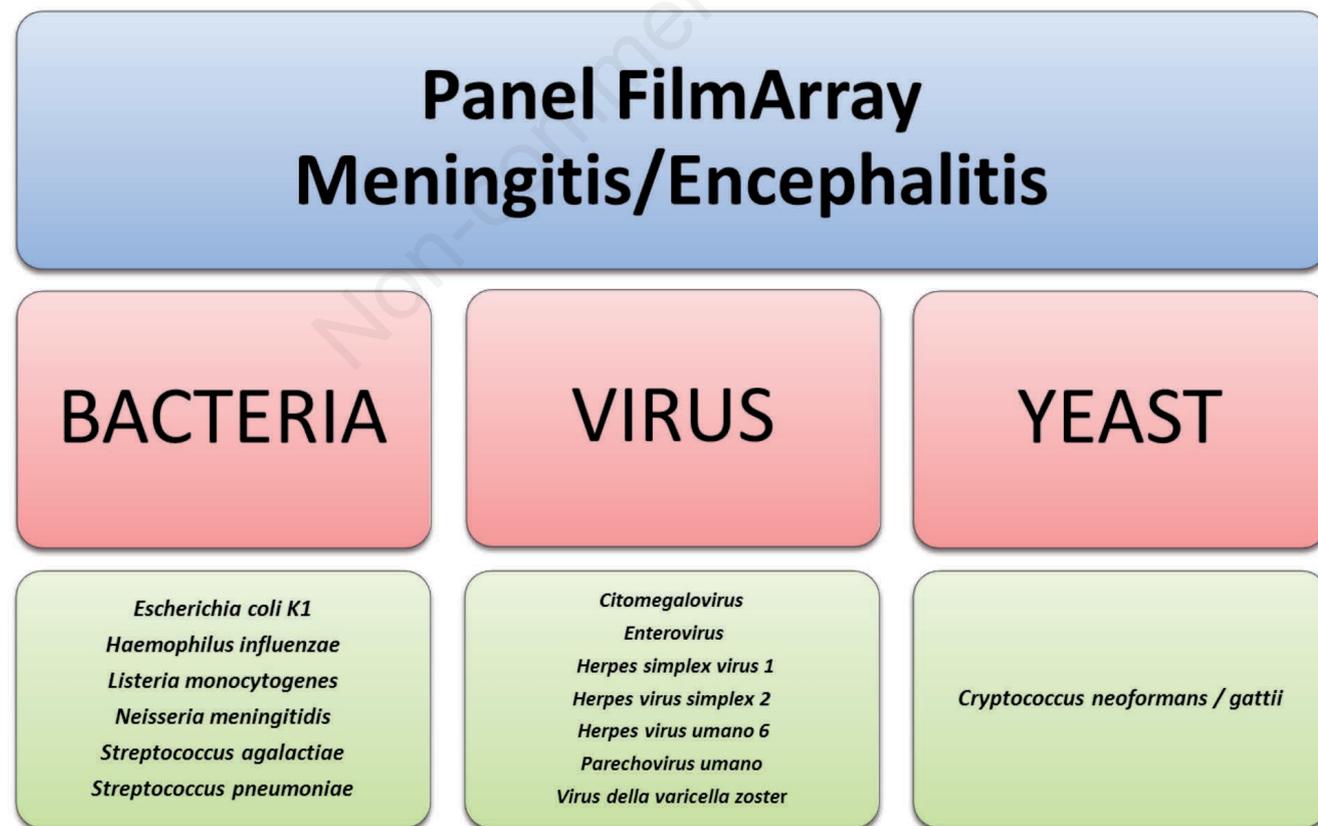


Figure 1. FilmArray Meningitis/Encephalitis (ME) panel.

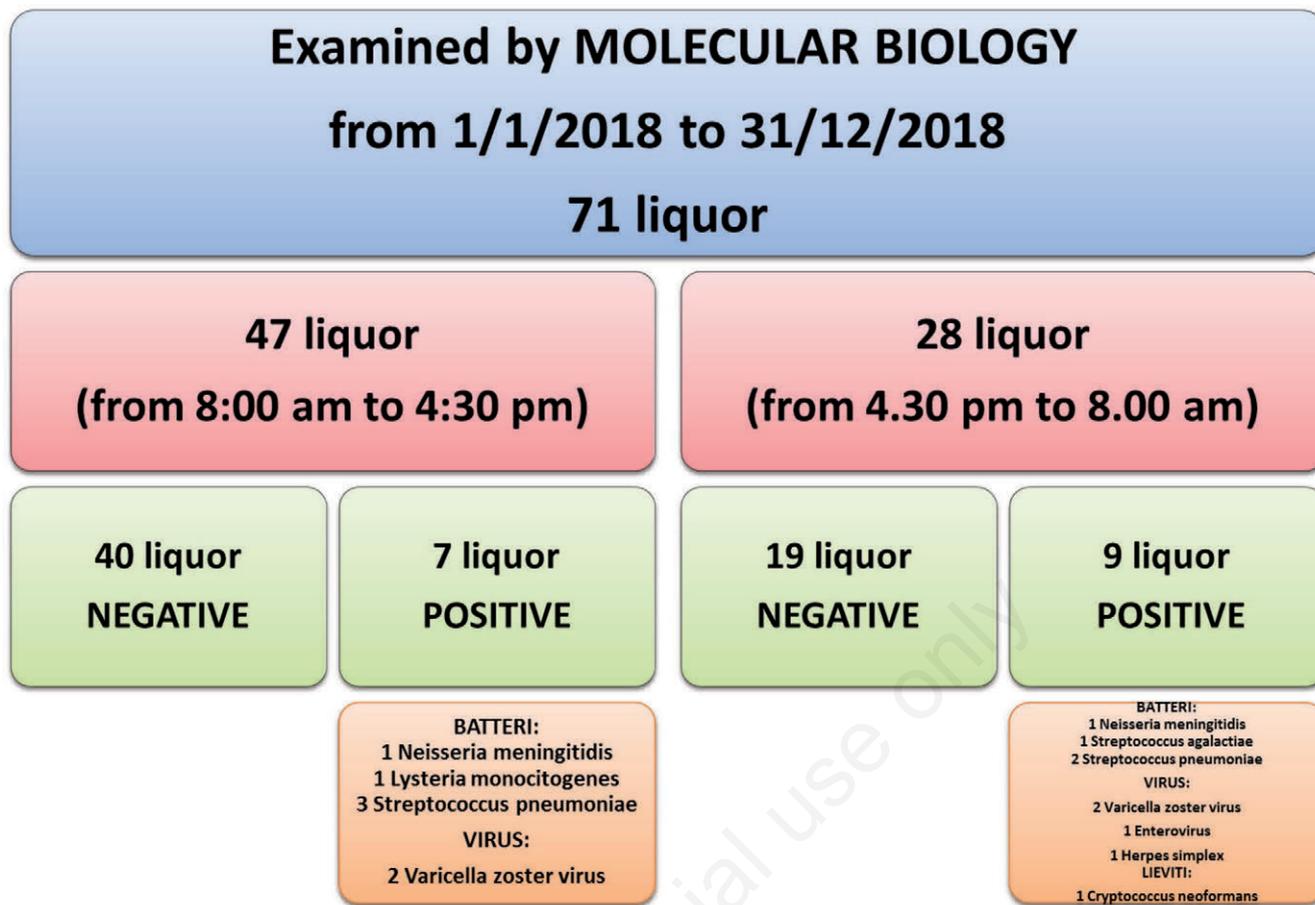


Figure 2. The new organizational model.

The new organizational model has also made it possible to fully comply with the regional indications concerning the MIBs. The greater involvement and responsibility on the part of technical

personnel in the process of carrying out such high diagnostic impact tests will increasingly stimulate the achievement of awareness of their role.