

Xpert® EV Bibliography

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Clinical and cost-benefit value of a rapid PCR test for EV

Slika, et al.

Implementation of the Cepheid Xpert EV assay for rapid detection of enteroviral meningitis: experience of a tertiary care center and a technical review

Genetic Testing and Molecular Biomarkers, 2013

- Rapid detection of enteroviral meningitis successfully implemented in the laboratory and used by physicians as a major tool in assessing and managing patients with meningitis.

Menasalvas-Ruiz, et al.

Enterovirus reverse transcriptase polymerase chain reaction assay in cerebrospinal fluid: An essential tool in meningitis management in childhood

The Pediatric Infectious Disease Journal, 2013

- The EV RT-PCR assay in CSF has played a crucial role in the management of children with EV meningitis. Efficient and accurate testing results in avoiding inappropriate antibiotic treatments and overmedication as well as decreasing the length of hospital stays from 4.5 days to 2 days.

Ninove, et al.

Comparative detection of enterovirus RNA in cerebrospinal fluid: GeneXpert system vs. real-time RT-PCR assay

Clinical Microbiology and Infection, 2011

- Point-of-Care detection of EV RNA provides easy-to-read results in less than 4 hours.
- The rapidity of the molecular diagnosis of EV meningitis has increasingly helped with improving management of patients and therapeutic attitude, as well as reducing hospitalization costs.

Huizing, et al.

Rapid enterovirus molecular testing in cerebrospinal fluid reduces length of hospitalization and duration of antibiotic therapy in children with aseptic meningitis

Pediatr Infect Dis J, 2011

- The median duration of hospitalization and the duration of antibiotics were significantly reduced to, respectively, 2 days and 1 day in the study group when compared with the control group ($P < 0.001$).
- Mean costs per patient calculation showed an average reduction of more than US \$1450 / €1151 ($P < 0.001$).
- The EV test results were available within: 3 days to 7 days (homebrew), 3 hours to 24 hours (Xpert EV)
- Duration of antibiotics treatments was shorter with Xpert EV: 3.1 days (homebrew), 0.8 days (Xpert EV)
- Duration of hospitalization significantly reduced with Xpert EV: 3.9 days (homebrew), 1.9 days (Xpert EV)
- Cost: \$2520 / € 2002 (homebrew), \$1042 / € 828 (Xpert EV).



Cohen-Bacrie, et al.

Revolutionizing Clinical Microbiology Laboratory Organization in Hospitals with In Situ Point-of-Care
PLoS One, 2011

- The mean length of the hospital stay decreased from 2.91 ± 2.31 days in 2005 to 1.43 ± 1.09 days from 2008 to 2010 ($P=0.0009$) when compared with Homebrew US Xpert EV.
- The authors showed the highest demand to POC labs came from the emergency wards, with a smaller demand from the pediatrics and infectious diseases departments.
- Enterovirus was the most frequently detected pathogen (234 diagnoses) with a peak of detection during summer and fall.
- A bacterial pathogen was detected in 49 patients, and HSV-1/2 was detected in six patients
- In cases of bacterial meningitis, the microscopic examination and cerebrospinal fluid culture were negative in 25 of the 49 infected patients, so the POC tests were the only diagnostic tests used to guide antibiotic treatment.

Archimbaud, Peigue-Lafeuille et al.

Impact of Rapid Enterovirus Molecular Diagnosis on the Management of Infants, Children and Adults with Aseptic Meningitis
JMV, 2009

- After positive PCR results, 63% of children were discharged immediately (mean 2hr 30 min) and 95% within 24 hr.
- The availability of EV-PCR results decreased the median duration of antibiotic and acyclovir treatment
- Reduction in length of stay estimated to generate benefits for the community of 442€ per patient.

Seme, et al.

GeneXpert® Enterovirus Assay: One-Year Experience in a Routine Laboratory Setting and Evaluation on Three Proficiency Panels
JCM, 2008

- Initial and resolved sensitivities of 90.4% and 98.8% for Xpert® EV
- It delivers enterovirus PCR results on a STAT basis, and meets a critical patient need for definitive diagnostic results in the evaluation of meningitis.

Michos, et al.

Aseptic meningitis in children: Analysis of 506 cases.
PLoS One, 2007

- Enterovirus PCR identification reduced significantly the length of hospital stay.

Lee, et al.

Paediatric Investigators Collaborative Network on Infections in Canada (PICNIC) study of aseptic meningitis.
BMC Infectious Diseases, 2006

- Children who had proven EV meningitis were less likely to have diagnostic imaging than were those with clinical aseptic meningitis or possible aseptic meningitis



Robinson, et al.

Impact of rapid polymerase chain reaction results on management of pediatric patients with enteroviral meningitis.

Pediatr Infect Dis J, 2002

- Patients with EV-positive results reported < or = 24 h after specimen collection had 20 h less of antibiotic use and \$2,798 less in hospital charges than patients with positive results available in >24 h.

Nigrovic, et al.

Cost Analysis of Enteroviral Polymerase Chain Reaction in Infants With Fever and Cerebrospinal Fluid Pleocytosis

Arch Pediatr Adolesc Med, 2000

- The results suggest that total patient costs would be reduced by the ePCR strategy if enterovirus accounts for more than 5.9% of all meningitis cases
- Total cost savings of 10%, 20%, and 30% would occur at an enteroviral meningitis prevalence of 36.3%, 66.7%, and 97.1%, respectively.

Ramers, et al.

Impact of a Diagnostic Cerebrospinal Fluid Enterovirus Polymerase Chain Reaction Test on Patient Management.

JAMA, 2000

- A positive EV-PCR result may affect clinical decision making and can promote rapid discharge of patients
- Unnecessary diagnostic and therapeutic interventions can be reduced by use of EV-PCR testing
- EV positive patients with results known before discharge had significantly fewer ancillary tests, received IV antibiotics for less time, and had shorter hospital stays.

Performance

Nolte, et al.

Evaluation of a Rapid and Completely Automated Real-time Reverse Transcriptase Polymerase Chain Reaction Assay for the Diagnosis of Enteroviral Meningitis

JCM, 2010

- PCR evaluation of CSF specimens and NAATs has emerged as the new gold standard for diagnosis of EV and the Xpert EV provides this test on-demand with less than 15 minutes of hands-on time.
- Due to its high degree of accuracy, the test improves patient management, reduces hospitalization costs, decreases antibiotic usage, and lessens hands-on time for the clinician.

Marlowe, et al

Performance of the GeneXpert® enterovirus assay for detection of enteroviral RNA in cerebrospinal fluid

JCV, 2008

- Sensitivity superior to NASBA and Taqman: the sensitivities of the Xpert® EV, NASBA, and TaqMan were 100%, 87.5%, and 96%, respectively.
- Specificity of 100% for the 3 tests
- The ease of use, random access capability, and minimal hands-on time with the automated GeneXpert® System affords laboratories with little molecular diagnostics expertise an opportunity to complete a clinically useful testing within 2.5 h.



Technical Review

Sefers, et al.

Prevalence and Management of Invalid GeneXpert Enterovirus Results Obtained with Cerebrospinal Fluid Samples: a 2-Year Study

JCM, 2009

- 1:5 dilution allows a 82.1% diminution of invalid rates, with minimal decrease of sensitivity (1.7%)
- Freeze-thaw cycle allows a 96% diminution of invalid rates, with minimal decrease of sensitivity (3.2%)

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