Sunday, 10 April 2016 – 12:30 - 13:30
Poster session - Bone and prosthetic joint infection

P0523 – Evaluation of BJI Inoplex test for diagnosis of prosthetic joint infection in one French reference centre


1 Service de Microbiologie, AP-HP, Hôpital Raymond Poincaré ;
2 Service de Microbiologie, AP-HP, Hôpital Ambroise Paré ;
3 Service de Chirurgie Orthopédique , AP-HP, Hôpital Ambroise Paré ;
4 INSERM U1173 - Université de Versailles Saint-Quentin-en-Yvelines.

Background: The diagnosis of prosthetic joint infections (PJI) represents a critical challenge for orthopedic surgeons and infectious disease specialists. The diagnosis of PJI is often delayed because non-invasive assays lack sensitivity and specificity. A novel multiplex immunoassay detecting antibodies against *Staphylococci*, *Propionibacteria* and *Streptococcus agalactiae* was developed. The Luminex-based assay measures serum IgG against a panel of recombinant purified antigens from *Staphylococcus aureus*, *Staphylococcus epidermidis*, *Streptococcus* *lugdunensis*, *Streptococcus agalactiae* and *Propionibacterium acnes*. This non-invasive serological approach should improve the diagnosis of PJI and optimize the care of patients.

Material/methods: We conducted a prospective non-interventional study to evaluate the diagnostic interest of the BJI Inoplex™ test in patients with suspected PJI in association with clinical and biological data in a French reference center. Patients undergoing revision arthroplasty were included from September 2014 up to March 2015 in one French reference center in compliance with IRB and French regulations. PJI cases were defined microbiologically (≥2 intraoperative samples yielding the same microorganism) for confrontation of microbiological and immunoassay data.

Results: 80 patients were eligible for study analyses. 25 patients met the criteria for the indication of the test (patients with prosthesis and signs of infection dating more than three months after joint replacement). Of the 25 patients, 15 had a total hip prosthesis, 9 a total knee prosthesis and 1 an ankle prosthesis. The sensitivity and specificity values of the test were, respectively, 90% and 90% for staphylococci (*S. aureus, S. epidermidis, S. lugdunensis*). The sensitivity/specifictiy of *Streptococcus agalactiae* and *Propionibacterium acnes* antigens could not be calculated because of too few patients tested positive in culture to these two bacterial species.

Conclusions: This novel multiplex serological test allows the rapid and non-invasive diagnosis of the most frequent PJI pathogens, showing a good correlation with microbiological culture. It appears to be a new promising tool in the management of PJI, adding sensitivity to the current serological assays and enhancing the management of patients with PJI.
Evaluation of BJL Inoplex test for diagnosis of prosthetic joint infection in one French reference center
A.-L. ROUX-1, F. EL SAYED2, B. COMBOURIEU1, T. BAUER3, J.-L. GAILLARD4, J.-L. HERRMANN1, M. ROTTMAN1

Service de Microbiologie, AP-HP, Hôpital Raymond Poincaré ; (2) Service de Microbiologie, AP-HP, Hôpital Ambroise Paré; (3) Service de Chirurgie Orthopédique ; AP-HP, Hôpital Ambroise Paré; (4) INSERM U1173 - Université de Versailles Saint-Quentin-en-Yvelines.

Abstract

Background: The diagnosis of prosthetic joint infections (PJI) represents a critical challenge for orthopedic surgeons and infectious disease specialists. The diagnosis of PJIs is often delayed because non-invasive assays lack sensitivity and specificity. A novel multiplex immunoassay detecting antibodies against Staphylococcus, Propionibacterium and Streptococcus agalactiae was developed.

The Luminex-based assay measures serum IgG against a panel of recombinant purified antigens from Staphylococcus aureus, Staphylococcus epidermidis, Streptococcus lugdunensis, Streptococcus agalactiae and Propionibacterium acnes. This non-invasive serological approach should improve the diagnosis of PJIs and optimize the care of patients.

Material/Methods: We conducted a prospective non-interventional study to evaluate the diagnostic interest of the Bill Inoplex® test in patients with suspected PJIs in association with clinical and biological data in a French reference center. Patients undergoing revision arthroplasty were included from September 2014 up to March 2015 in one French reference center in compliance with a French regulations. PJIs were defined microbiologically (≥2 intraoperative samples yielding the same microorganism) for confrontation of microbiological and immunoassay data.

Results: 80 patients were eligible for study analyses. 23 patients met the criteria for the indication of the test (patients with prosthetic and signs of infection dating more than three months after joint replacement). Of the 23 patients, 15 had a total hip prosthesis, 9 a total knee prosthesis and 1 an ankle prosthesis. The sensitivity and specificity values of the test were, respectively, 90% and 90% for staphylococci (S. aureus, S. epidermidis, S. lugdunensis). The sensitivity/specitivity of Streptococcus agalactiae and Propionibacterium acnes antigens could not be calculated because of too few patients tested positive in culture to these two bacterial species.

Conclusions: This novel multiplex serological test allows the rapid and non-invasive diagnosis of the most frequent PJIs pathogens, showing a good correlation with microbiological culture. It appears to be a new promising tool in the management of PJIs, adding sensitivity to the current serological assay and enhancing the management of patients with PJIs.

Material and Methods

Test principle: Diagnose Staphylococcus, Streptococcus agalactiae and P. acnes PJIs

1) Patient generates a humoral response
2) Draw blood
3) Simultaneously quantify IgG binding 16 bacterial proteins
4) Antibody profiling

Result: Prosthetic joint infection with
Staphylococcus sp. YES/NO
Streptococcus agalactiae YES/NO
Propionibacterium YES/NO

Cloning, purification and validation of recombinant bacterial antigens

Case report

Medical history of Mr B, 77 years
- Tibial fracture 20 years ago
- 2008 - Total knee prosthesis
- April 2014 : aseptic replacement
- December 2014 : red inflammatory knee
  - Fever

Radiological evaluation

- C-reactive protein : 37 mg/L
- Bill Inoplex
  - Staphylococcus : positive
  - S. lugdunensis : negative
- P. acnes : positive
- Bone biopsy results: S. lugdunensis (5/5 samples)
- Intrasporative samples: S. lugdunensis (3/5 samples) + P. acnes (2/5 samples)

Biological results

Results

Study population and microbial findings

<table>
<thead>
<tr>
<th>Organisms</th>
<th>Sensitivity</th>
<th>Specificity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staphylococci</td>
<td>90%</td>
<td>90%</td>
</tr>
<tr>
<td>S. agalactiae</td>
<td>/</td>
<td>80%</td>
</tr>
<tr>
<td>P. acnes</td>
<td>/</td>
<td>76%</td>
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</tbody>
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ASMR

Reference

Bill Inoplex® is a novel multiplex serological test which allows the rapid and non-invasive diagnosis of the most frequent PJIs pathogens, showing a good correlation with microbiological culture and appears to be a new promising tool in the management of PJIs.

The sensitivity and specificity values of the test were, respectively, 90% and 90% for staphylococci.

Studies are currently underway to demonstrate the value of the test in monitoring patients.

References: