Monday June 1 2015 – 12:30PM – 1:45PM – Poster Session

BJI Inoplex, a Novel Serological Assay for the Genus Level Diagnosis of Prosthetic joint Infection: a Prospective Study

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¹Groupe Hospitalier Diaconesses Croix Saint-Simon, Paris, France. ²Hôpital Ambroise Paré (AP-HP), Boulogne-Billancourt, France. ³UMR 1173, UFR Simone Veil, Université de Versailles Saint-Quentin-en-Yvelines, France. ⁴DIAXONHIT, Paris, France. ⁵Laboratoire de Microbiologie, Hôpital Raymond Poincaré (AP-HP), Garches, France.

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 and its performance evaluated in a prospective, multicenter, non-interventional study.

Methods: The Luminex-based assay measures serum IgG against a proprietary panel of recombinant purified antigens from Staphylococcus aureus, Staphylococcus epidermidis, Staphylococcus lugdunensis, Streptococcus agalactiae and Propionibacterium acnes. Patients undergoing revision arthroplasty were included over a 2-year period (from 2012 up to 2014) in two French reference centers 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: 455 patients were eligible for study analyses. 149 patients (32.7%) were found to be infected. Among the most frequent infecting species recovered were S. aureus (30%), S. epidermidis (26%), P. acnes (9%), S. lugdunensis (6%), and group B streptococcus (4%). The sensitivity and specificity values of the test were, respectively, 75.9% (63/83) and 82.2% (180/219) for staphylococci (S. aureus, S. epidermidis, S. lugdunensis), 38.5% (5/13) and 81.9% (190/232) for P. acnes, and 66.7% (4/6) and 92.4% (208/225) for group B streptococci. Interestingly, all cases (9/9) involving S. lugdunensis were detected by the test and the sensitivity for S. epidermidis reached 89.5% (17/19) in the subpopulation with elevated inflammatory markers (ESR>30 and CRP>10).

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, and appears to be a new promising tool in the management of PJI.
Novel Serological Assay for the Genus Level Diagnosis of Prosthetic joint Infection
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Conclusions
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 pauci-invasive PJI.

Test protocol: Diagnosis Staphylococcus, Streptococcus agalactiae and P. acnes PII

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 spp.
Streptococcus agalactiae YES/NO
Propionibacterium YES/NO

Microbial species assayd (%) Staphylococcus spp.
S. aureus 45 (30)
S. epidermidis 39 (26)
S. lugdunensis 9 (6)
Streptococcus species
S. agalactiae 6 (4)
Propionibacterium species
P. acnes 13 (8.7)

Cloning, purification and validation of recombinant bacterial antigens

Assay Performance

<table>
<thead>
<tr>
<th>Organisms</th>
<th>Sensitivity</th>
<th>Specificity</th>
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<tbody>
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<td>S. oralis</td>
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<td>S. pneumonia</td>
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<td>S. dysgalactiae</td>
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<td>S. sanguinis</td>
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<td>E. faecalis</td>
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<td>E. faecium</td>
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Additional results with related bacterial species: Test results from 29 patients carrying an implant infected by bacteria related to the assay targets

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<td>S. capitis</td>
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<td>S. caprae</td>
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<td>S. hemolyticus</td>
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