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Diagnostic Utility of a Novel Point-of-Care Test of Calprotectin for Periprosthetic Joint Infection in Total Knee Arthroplasty Patients

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Introduction: Several synovial fluid biomarkers for diagnosis of periprosthetic joint infection (PJI) are being investigated, however point-of-care (POC) tests are not widely available. Synovial calprotectin can effectively exclude PJI diagnosis and a novel lateral flow POC test for synovial calprotectin has shown potential to be an effective PJI diagnostic tool. Thus, the objective of this study was to test the sensitivity and specificity of a calprotectin POC test for PJI in total knee arthroplasty (TKA) patients, using the gold standard Musculoskeletal Infection Society (MSIS) 2013 PJI diagnosis criteria.

Methods: Synovial fluid samples were prospectively collected from 73 patients who underwent revision TKA (rTKA) at two academic institutions. Patients followed the hospital standard of care for their diagnostic work-up. Data collection included demographic, clinical, and laboratory data following the MSIS 2013 PJI diagnosis criteria. Synovial fluid samples were analyzed by synovial calprotectin POC tests using manufacturer's instructions. Quantitative calprotectin read-outs were categorized into high risk (>50 mg/L), medium risk (14-50 mg/L) and low risk (<14 mg/L) for infection by the test reader system. Patients were categorized as septic or aseptic using MSIS 2013 PJI diagnosis criteria by two independent reviewers blinded to the calprotectin results. Test performance characteristics with sensitivities, specificities, and areas under the curve (AUC) were calculated for 2 thresholds for infection: 1) >50 mg/L, and 2) >14 mg/L.

Results: Following MSIS criteria, 26 rTKAs were MSIS positive and 47 rTKAs were MSIS negative. For threshold 1 (>50 mg/L), the POC performance showed a sensitivity, specificity, and AUC of 96.2%, 93.6%, and 0.949 respectively. For threshold 2 (>14 mg/L), there was a sensitivity, specificity, and AUC of 100.0%, 78.7%, and 0.894 respectively.

Conclusions: Calprotectin POC test has excellent diagnostic properties including high sensitivity and specificity for diagnosing PJI in rTKA.