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There is no standard method for the diagnosis of prosthetic joint infection (PJI). The contribution of 16S rRNA gene PCR sequencing on a routine basis remains to be defined. We performed a prospective multicenter study to assess the contributions of 16S rRNA gene assays in PJI diagnosis. Over a 2-year period, all patients suspected to have PJIs and a few uninfected patients undergoing primary arthroplasty (control group) were included. Five perioperative samples per patient were collected for culture and 16S rRNA gene PCR sequencing and one for histological examination. Three multicenter quality control assays were performed with both DNA extracts and crushed samples. The diagnosis of PJI was based on clinical, bacteriological, and histological criteria, according to Infectious Diseases Society of America guidelines.

A molecular diagnosis was modeled on the bacteriological criterion (≥ 1 positive sample for strict pathogens and ≥ 2 for commensal skin flora). Molecular data were analyzed according to the diagnosis of PJI. Between December 2010 and March 2012, 264 suspected cases of PJI and 35 control cases were included. PJI was confirmed in 215/264 suspected cases, 192 (89%) with a bacteriological criterion. The PJIs were monomicrobial (163 cases [85%]; staphylococci, n = 108; streptococci, n = 22; Gram-negative bacilli, n = 16; anaerobes, n = 13; others, n = 4) or polymicrobial (29 cases [15%]). The molecular diagnosis was positive in 151/215 confirmed cases of PJI (143 cases with bacteriological PJI documentation and 8 treated cases without bacteriological documentation) and in 2/49 cases without confirmed PJI (sensitivity, 73.3%; specificity, 95.5%). The 16S rRNA gene PCR assay showed a lack of sensitivity in the diagnosis of PJI on a multicenter routine basis.

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