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(443) A RANDOMIZED PROSPECTIVE EVALUATION OF NEXT-GENERATION SEQUENCING VERSUS TRADITIONAL CULTURES FOR CLINICALLY INFECTED PENILE PROSTHESES: IMPACT OF MICROBIAL IDENTIFICATION ON OUTCOMES

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Introduction: Traditional culture is the current standard-of-care to determine therapeutic antibiotics for patients suffering from penile prostheses (PP) infections. However, approximately 50% of PPs removed for infection are culture negative. Next-generation sequencing (NGS) of DNA has proven to be beneficial in its thorough analysis of biofilm composition and determination of the relative abundance of specific microbes. In this prospective, multicenter, single-blinded, randomized controlled trial, we hypothesize that the use of NGS will lead to better therapeutic strategies that will result in improved patient outcomes by determining the microbial composition of infected PP.

Objective: We present our early results from our prospective study that compares outcomes of microbial identification between NGS versus culture for clinically infected PP.

Methods: Upon institutional review board approval, adult men undergoing treatment for mild to moderate PP infection are enrolled after providing informed consent. Enrollees are randomized to one of two analytic arms – traditional culture or NGS, using Captivate by ClinCapture. Patients with severe infection requiring urgent explantation are excluded. Traditional culture and NGS samples are collected upon clinical presentation prior to initiation of antibiotics. Specimens of infected fluid were collected, stored in sterile packaging, and transported for both traditional culture at the institutional laboratory and NGS testing (MicroGenDX, Lubbock, TX). Patients are started on set empiric antibiotics and randomized to traditional culture or NGS. Patients with a positive culture or NGS result will receive treatment-specific antibiotics, while patients with negative results continue empiric antibiotics for two weeks. For patients randomized to the NGS arm, positive results will undergo central infectious disease (ID) review, and antibiotics initiated based on their recommendations. Patients will follow up within ten days of antibiotic initiation and at six months to complete a safety and compliance questionnaire which assesses symptoms, device function, and patient satisfaction.

Results: To date, two patients have been enrolled. The first patient was randomized to the culture arm and presented with mild tenderness and drainage around the scrotal pump area for five days but remained afebrile. His culture resulted as Citrobacter koseri. He started empiric treatment with amoxicillin-clavulanate which was changed to ciprofloxacin based on culture results. The second patient was randomized to the NGS arm and presented with four days of bloody and purulent drainage from the scrotal pump area. Although he was afebrile, he had moderate tenderness, swelling, and erythema in his scrotum. NGS identified multiple organisms (data remains blinded). He was started on empiric trimethoprim-sulfamethoxazole but was treated successfully with a course of cefdinir and doxycycline per ID. Both patients had primary implants and did not require device removal. On the post-treatment questionnaire, both patients reported that their devices were working and endorsed high satisfaction rates.

Conclusions: This is the first prospective, randomized controlled trial comparing the utility and outcomes of NGS and culture for the identification of microbes in clinically infected PP. Currently, recruitment is ongoing. We hope that this trial will demonstrate a clinical benefit of NGS in characterizing distinct microbiomes of infected PP to tailor antimicrobial therapy.

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