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A Novel Therapy System for Salvage of Infected PPMs and ICDs

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Background: The currently recommended treatment for infected PPM and ICD is a complete extraction and replacement. Our objectives are to demonstrate the efficiency and safety of a novel therapy method of continuous in-situ-targeted, ultra high-dose antibiotics (CITUHA) under closed Regulated Negative Pressure Assisted Wound Therapy (RNPT) system, for infected devices limited to their pockets and proximal wiring, thereby reducing the need for explantation.
Methods: We treated 21 consecutive patients by administrating CITUHA under closed RNPT system (TANP) and, if indicated, minimal local manipulation of hardware. All procedures were performed in an operating room under strict sterile conditions applying mainly local or none anesthesia, and rarely, general anesthesia. Exposure of a generator or proximal wiring could be managed by either delayed direct closure or by coverage with minor local rotation flaps.
Results: TANP treatment lasted 6-14 days followed by a course of up to 4 weeks of oral antibiotics, as clinically indicated. Concentrations of antibiotics in the local pocket were threefold higher than normal target therapeutic plasma levels, effectively eradicating the infection. By controlling and adjusting the antibiotics concentrations in the pocket, the desired therapeutic or the low-therapeutic plasma levels were achieved, reflecting an apparent first-order pocket-to-plasma delivery. In all but 3 patients, devises were salvaged without recurrence of infection. The mean follow-up was 18.1±11.3 months (range 4-49 months).
Conclusions: Our clinical and laboratory experience demonstrates that infection of implanted device's pocket and/or subcutaneous proximal wiring can be efficiently and safely managed by TANP, markedly diminishing the need for a removal of the device. Moreover, CITUHA also provides concurrent controlled systemic antibiotic administration therapy method, adjusted to the patient's requirements and constraints.