

RENAL DENERVATION

CRT-600.15

Safety and Performance Of Diagnostic Electrical Mapping of Renal Nerves in Hypertensive Patients and/or Potential Candidates for a Renal Sympathetic Denervation (RDN) Procedure



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BACKGROUND As the exact location of renal nerves cannot be visualized, renal sympathetic denervation (RDN) remains a so-called blind procedure. The aim to the present study is to assess the safety and feasibility of renal nerve stimulation using the ConfidenHT™ mapping system. The technology could help to improve RDN procedures by providing: (1) better patient selection, and (2) intra-procedural guidance and feedback to optimize success rates.

METHODS The Confiden(HT) study is a prospective first-in-man multicenter study designed to assess the safety and feasibility of renal nerve mapping using the ConfidenHT™ system in 20 hypertensive patients with an indication for coronary angiography or a planned RDN. The Console delivers electrical energy to the catheter using a multi-channel stimulator, and a real time intra-arterial Blood Pressure (BP) monitor, which records, analyzes and displays the stimulation outcome (BP and/or heart rate changes) during the mapping phase. The flexible multi-electrode ConfidenHT™ catheter is compatible with an 8Fr guiding catheter and 0.014" guide wire. Stimulations were performed in left and right renal arteries at 3 to 4 sites per artery, including branches at 2 and 4 mA resulting in up to 8 mapped sites per patient. The primary efficacy endpoint was the change in systolic blood pressure during stimulation. All patients were followed up to 3 months.

RESULTS Mean age of the patients included was 58±12 years, 11/20 patients were female. Mean office blood pressure was 156±23mmHg and GFR was 78±13mL/min/1.73m². All procedures were performed under local anesthesia with mild conscious sedation. The use of the system appeared safe with no peri-procedural adverse events and no signs of angiographically visible spasms/thrombus or dissection post procedure. Creatinine levels remained within the normal range. Mean individual systolic BP responses varied between 3.5 and 18 mmHg while mean individual mean arterial pressure responses varied between 2.4 and 11.3 mmHg. The average time to maximal response was 45 seconds. The mean change in systolic BP response did not vary between proximal, mid, distal or branch sites when stimulating at 2mA.

CONCLUSIONS The results of the present study suggest that renal nerve mapping using the ConfidenHT™ system technology is feasible and safe and offers promising diagnostic electrical renal nerve mapping opportunities in hypertensive patients, which could help in optimizing the result of renal sympathetic denervation.

OTHER

CRT-600.13

Off- vs. On-hours Outcomes in Patients Receiving Acute Mechanical Circulatory Support



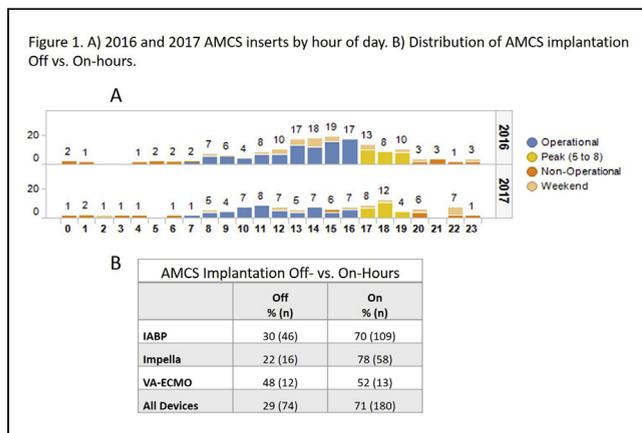
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BACKGROUND Acute mechanical circulatory support (AMCS) implantation is often performed urgently off scheduled operating hours. There is no available analysis comparing outcomes between off- vs. on-hours implantation of AMCS.

METHODS We retrospectively analyzed all patients (n=254) between 2016-2017 receiving VA-ECMO (n=25), Impella (n=74), or Intra-aortic balloon pump (IABP) (n=155) in our catheterization lab. Patients were stratified by time of implantation: on-hours (weekday operational hours: 7:30 AM to 5 PM and weekday peak hours: 5 PM to 8 PM) versus off-hours (weekends, holidays, and weeknights 8 PM to 7:30 AM). Primary outcomes were intra-procedural mortality, in-hospital mortality, and vascular complication requiring surgery. All categorical variables were analyzed using Fisher's exact test.

RESULTS A total of 180 devices were implanted during the study period (Figure 1A). 29% of devices were implanted during off-hours and 71% during on-hours (Figure 1B). There was no difference in intra-procedural mortality or vascular complications requiring surgery when comparing off- vs. on-hours implant. In-hospital mortality trended higher with IABP implantation off-hours (24% vs. 12%, p = 0.09).

CONCLUSIONS AMCS implantation occurs more frequently during regular working hours. Patients receiving AMCS during off-hours had similar outcomes to those presenting during regular hours.



VALVE & STRUCTURAL HEART

AORTIC VALVE

CRT-700.04

Impact of Discharge Home without Home Services on 30-Day Outcomes Following Transcatheter Aortic Valve Replacement with Contemporary Valves



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