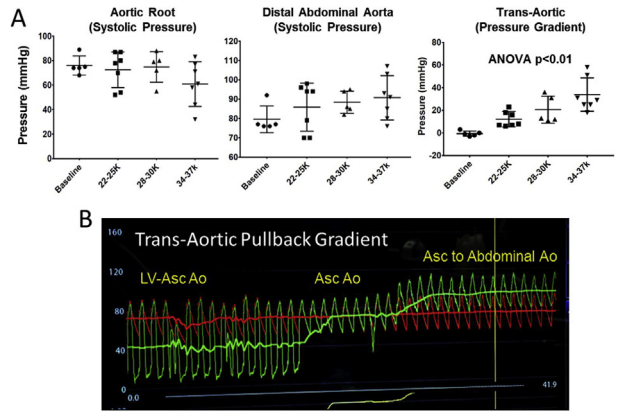

OTHER

CRT-600.13

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

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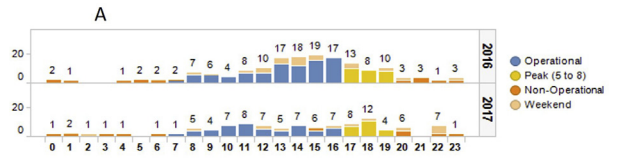
BACKGROUND Acute mechanical circulatory support (AMCS) implantation is often performed urgently off scheduled operating hours. There is no available analysis comparing outcomes between off- vs. on-hours implantation of AMCS.

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.

Figure 1. A) 2016 and 2017 AMCS inserts by hour of day. B) Distribution of AMCS implantation Off vs. On-hours.



B

AMCS Implantation Off- vs. On-Hours

	Off % (n)	On % (n)
IABP	30 (46)	70 (109)
Impella	22 (16)	78 (58)
VA-ECMO	48 (12)	52 (13)
All Devices	29 (74)	71 (180)

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 chance in systolic blood pressure during stimulation. All patients were followed up to 3 months.

RESULTS Mean age of the patiens included was 58±12 years, 11/20 patients were female. Mean office blood pressure was 156±23mmHg and GFR was 78±13mL/min/1.73m^2. 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.

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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BACKGROUND Medicare's Post-Acute Transfer (PACT) policy costs hospitals nationwide penalties following transcatheter aortic valve replacement. While discharging home without home services avoids PACT policy activation, its impact on 30-day outcomes following transcatheter aortic valve replacement (TAVR) is not well known. We aimed to evaluate the impact of discharging home without services on 30-day outcomes in adults undergoing TAVR with contemporary valves.

METHODS The study population included 177 consecutive patients who underwent TAVR with a contemporary valve [Sapien 3 valve (Edwards Life Sciences, Irvine, CA) or Corevalve Evolut R or Evolut Pro (Medtronic, Minneapolis, MN) from December 2015-October 2017 at an academic tertiary medical center. Baseline and clinical characteristics, procedural data, and clinical outcomes were recorded.

RESULTS Of the 177 patients, 49 (27.7%) were discharged home without services while 128 (72.3%) were not. Of these 128 patients, 35 (27.3%) were discharged to a skilled nursing facility and 93 (72.7%) were discharged home with home services. Patients who were discharged home without services were younger (78 vs 81 years, p=0.017) with lower Society of Thoracic Surgeons (STS) risk score (4.9% vs 7.0%, p=0.018). They had higher hemoglobin (12.4 vs 11.5 g/dl, p=0.007), serum albumin (4.1 vs 3.8 mg/dl, p=0.002) and creatinine clearance (68 vs 57 ml/min, p=0.031). While no significant difference in medical comorbidities were noted, patients who were discharged home without home services had lower rates of right bundle branch block (2.6% vs 16.4%, p=0.028) and atrioventricular block (2.7% vs 19.5%, p=0.010) prior to TAVR. With respect to 30-day outcomes, patients who were discharged home without home services had significantly lower rates of new pacemaker (2.3% vs 13.5%, p=0.043) and a trend toward lower all-cause readmission (6.1% vs 17.3%, p=0.089). No significant difference in stroke (0% vs 1.6%, p=1.000) was noted between both groups.

CONCLUSIONS In this observational study of adults undergoing TAVR with contemporary valves, discharging home without home services was not independently associated with 30-day all-cause readmission or new pacemakers. Further studies are warranted to better understand the impact of discharge services in patients undergoing TAVR in order to optimize clinical outcomes in this population.

CRT-700.05

Impact of Spironolactone on Heart Failure Readmission after Transcatheter Aortic Valve Replacement

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BACKGROUND Thirty-day readmission rates are a performance benchmark in contemporary evaluation of cardiovascular procedures. Trans-catheter aortic valve replacement (TAVR) has been widely adopted since initial Food and Drug Administration approval in 2011; however, re-admission rate following TAVR remains high. Amongst cardiac etiologies for re-admission post-TAVR, heart failure is the most common precipitant. In randomized controlled trials, spironolactone has been shown to reduce heart failure readmissions in patients with heart failure with reduced ejection fraction (HFrEF) as well as with preserved EF (HFpEF). We sought to examine the impact of spironolactone therapy on the rate of heart failure readmissions in patients discharged after TAVR at our institution.

METHODS We analyzed all TAVR patients receiving balloon-expandable Sapien (Edwards Lifesciences, Irvine, California) or self-expanding CoreValve (Medtronic, Minneapolis, Minnesota) valves from March 2012 to April 2017 at the University of Maryland Medical Center, Baltimore, MD. Patients discharged from the hospital following the TAVR procedure were grouped into two categories: those who received spironolactone (either prescribed prior to the procedure and continued upon discharge or newly initiated on spironolactone) and those who did not, based on physician discretion. The primary outcome evaluated was 30-day readmission for heart failure.

RESULTS 270 patients who underwent TAVR (132 Sapien, 138 CoreValve) were included for analysis. The mean age was 80.7 ± 9.5 years, 52% were men, 89% were Caucasian race, and 24% were on spironolactone at time of hospital discharge. A total of 52 (19%) patients were re-admitted within 30 days of discharge and among those, 21 (8%) were re-admissions for decompensated heart failure. Of those re-admitted to the hospital with heart failure, 9% were on spironolactone compared to 7% who were not (p=0.65).

CONCLUSION Our retrospective analysis did not demonstrate an impact of spironolactone on the likelihood of readmission for heart failure (both HFpEF and HFrEF sub-types) following TAVR. Further prospective studies are required in order to assess clinical benefits of adding post-procedure spironolactone.

CRT-700.06

The Association Between Contrast Dose and Renal Function in Transcatheter Aortic Valve Replacement

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BACKGROUND Transcatheter aortic valve replacement (TAVR) is recommended for high and intermediate risk severe aortic valve stenosis (AS). The impact of contrast volume reduction during TAVR on creatinine (Cr) and estimated glomerular filtration (eGFR) is not well studied.

METHODS We did a retrospective analysis of total of 570 patients with severe AS who underwent TAVR between March 2013 and March 2016. We included only patients who had Cr and eGFR values at baseline, discharge and at 3-month follow up. Our primary outcome was the impact of TAVR on RF after 3 months. We used 2-sample independent t-test.

RESULTS A total of 378 patients were included in the analysis. At baseline there was no significant difference in baseline characteristics in regards of age, race, gender, or baseline characteristics including hypertension, hyperlipidemia, diabetes or coronary artery disease. Mean contrast dose was reduced significantly between 2015 and 2016 (107.24 ml vs. 87.6 ml; P< 0.001). There was a significant reduction in the mean difference at 3 months in eGFR between 2015 and 2016 (-4.9 vs 1.8 mL/min; P<0.001) and Cr (-0.14 mg/dL vs -0.02 mg/dL; P=0.04).

CONCLUSIONS Reduction in contrast volume during TAVR achieved improvement in Cr and eGFR at 3-month follow-up. The benefits of TAVR on renal function should be further considered.