

when enhanced motion occurred in mid or apical segments than when they did not ( $p=0.01, 0.005$ , respectively). d-IVV correlated with d-WMSI of the mid and apical levels ( $r=0.48, 0.42, p=0.01, 0.03$ ), while it did not for the basal level ( $r=0.21, p=0.3$ ). ROC-curve showed that d-IVV detects global viability effectively ( $AUC=0.761$ ), however, sensitivity and specificity increased for mid and apical levels ( $AUC=0.790, 0.868$ ).

**CONCLUSION** Mitral annular longitudinal motion during isovolumic contraction, represented by IVV and d-IVV, increase after LDDE in the presence of viable myocardium. Changes that occur in the mid and apical segments of the LV seem to contribute more to this effect than the basal segments.

## OTHER

### CRT-708

#### Development and Evaluation of a Smartphone Application for the Perioperative Care of Patients Undergoing Routine Cardiology Procedures.

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**BACKGROUND** Smartphone applications (apps) in healthcare are being increasingly developed with the aim of benefiting both patients and their physicians. The delivery of adequate instructions both before and after a procedure is important in ensuring the best outcome for patients. Failure to comply with instructions after a procedure can increase the risk of complications.

**STUDY** We conducted a prospective evaluation of a new smartphone app designed to provide pre- and post-operative instructions (TrackMyRecovery®). The app also permitted patients to securely send images of their wound and pain scores. The primary end points were patients' compliance with reading instructions, sending wound images and pain levels. The secondary endpoint was any post-procedural related complications.

**METHODS** The instructions were tailored according to the physician's preferences and were associated with reminders in the form of push notifications that patients would receive on their iPhones or iPads. Ten patients undergoing routine cardiac procedures were selected. Once securely registered, the patients' instructions were available on the app. Through the app, patients were prompted to read pre and post-operative instructions. Patients also received specific reminders before and after their procedure via push-notifications. The patients' progress both pre and post-procedure was sent to a newsfeed on a secured web portal, where physicians had full access. After completing use of the app, patients were asked to complete an online survey. The web portal and app were developed using a standard HIPAA compliant privacy policy.

**RESULTS** 10 patients undergoing pacemaker implantation or Left Heart Catheterization were prospectively accrued. All 10 patients successfully registered with the app, read and complied with instructions. There were no cancelled procedures or post-operative complications.

**CONCLUSION** A smartphone app developed for perioperative care was used effectively in a small cohort of 10 patients undergoing routine cardiology procedures. It ensured 100% compliance with instructions along with excellent patient satisfaction scores. The use of electronic instructions on a smartphone or tablet with built-in reminders and the ability to send secure data to physicians could improve perioperative care, ensure compliance, and reduce post-operative complications. A larger cohort of patients with long-term follow-up across various medical disciplines is necessary to corroborate these findings.

### CRT-709

#### Cardiac Output Confusion. Why Your Cardiac Catheterization Lab Computer System May Not Give You The Results You Expect And Need?

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**BACKGROUND** Accurate assessment of Cardiac Output (CO) is a critical measurement in the cardiac catheterization laboratory (CCL), especially in calculation of aortic valve area (AVA). Due to known inaccuracy of Fick assumptions, many measure Thermodilution (TD) CO as well. Most physicians assume that this more accurate measurement can be chosen to determine AVA. However, we have discovered that our popular computer system [Philips Xper Connect (XIM)] will use predetermined rules to assign one of the CO methods for the reported AVA.

**METHODS** We randomly selected one hundred consecutive patients who underwent right and left heart catheterization from 2009-2012 for assessment of aortic valve areas and had both Fick CO calculated using femoral and pulmonary arterial saturations and thermodilution CO performed for calculation of AVA. We then examined our XIMS system records for each of these procedures and documented the timing

when each CO method was performed and reviewed which CO and AVA calculation appeared on the final catheterization report.

**RESULTS** We found that whichever CO calculation was done first by the CCL computer system became the determinative output, appearing on the final report and being used to calculate the official AVA. In 32 patients the CO and AVA were calculated and displayed using the Fick calculation method, which had been performed first, and in 68.

patients TD was performed first and the AVA and CO were calculated and displayed using this CO. Although the second CO type could be selected on the computer during the case, and the computer screen would temporarily display the related AVA, this would never appear in the final report and may never be seen by the physician. Thus the CO used officially depended solely of the timing of the oxygen saturation samples. An intense effort of 11 non-intuitive computer clicks and multiple screen changes is required to make the second output the determinative value. The recommendation for surgery (AVA <1.0 cm<sup>2</sup>) was different between the CO methods in 12 cases (12% of patients).

**CONCLUSION** Our widely used computer system has an arbitrary method of selecting the determinative CO to calculate the final AVA. For the more accurate TD CO to 'trump' the Fick CO an elaborate series of computer commands needs to be performed. None of the physicians or technicians was aware of this computer selection process, which affects critical treatment decisions.

## PERCUTANEOUS VALVE INTERVENTION

### CRT-710

#### Associations Of Known Complications With Transcatheter Implantation Of First-generation Self Expandable Corevalve Aortic Valves With Peri-procedural Mortality-an Insight From Reports From The FDA Maude Database

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**BACKGROUND** Transcatheter implantations of aortic valves (TAVR) have revolutionized management of severe aortic stenosis. Specific complications have been noted with first-generation valves. Details of such were sought from the US Food and Drug Administration (FDA) maintained MAUDE database which houses medical device reports submitted to the FDA by mandatory reporters (manufacturers, importers and device user facilities) and voluntary reporters such as health care professionals, patients and consumers.

**METHODS** A detailed search was conducted in PubMed, Cochrane Library, EMBASE and CINAHL to identify adverse events reported with implantations of the first generation Medtronic CoreValve(s). Then the FDA MAUDE database was queried from January 2014 to August 31, 2014 to identify prevalence of the same complications as reported to the FDA. Individual patient reports were identified and relevant data on such complications were abstracted. Finally mortality outcomes from such patients were abstracted, and associations of same for each individual reported complication were identified in a multivariate logistic regression model.

**RESULTS** FDA MAUDE revealed 384 unique reports of complications with the first generation CoreValves. A total of 22 patients died peri-procedurally. The complications most strongly associated with peri-procedural mortality were development of peri-procedural cardiogenic shock, ventricular tachycardia, development of post-procedural atrial fibrillation, acute renal failure and the need for valve-in-valve procedure.(Table 1)

**CONCLUSIONS** Specific complications with the first-generation Medtronic CoreValves were strongly associated with mortality, and focused strategies to mitigate the same may improve outcomes with future generations of this exciting new technology.

Death	Odds Ratio	Std. Err.	Z	P>z	95% Conf. Interval
Cardiogenic Shock/ Hemodynamic Instability	48.0635	72.3063	2.57	0.01	2.519274 - 916.9706
Need for IABP	0.056092	0.147257	-1.1	0.273	0.000327 - 9.628312
Need for Circulatory Assist Device	4.75555	10.26045	0.72	0.47	0.06929 - 326.3851
Need For Emergent Cardiac Surgery	31.52746	87.71487	1.24	0.215	0.135051 - 7360.033
Pericardiocentesis Drainage	887.4621	5551.432	1.09	0.278	0.004203 - 1.87E+08
Bleeding	0.29432	1.747251	-0.21	0.837	2.60E-06 - 33269.01
Post Procedural anemia	1.05788	6.328526	0.01	0.992	8.56E-06 - 130784.4
Myocardial Injury	8.780916	13.95416	1.37	0.172	0.389813 - 197.7987
Coronary Occlusion	0.051433	0.123629	-1.23	0.217	4.63E-04 - 5.718173
Myocardial Infarction	0.481218	1.054609	-0.33	0.739	6.56E-03 - 35.30078
Heart Block Conduction Delay	2.327404	17.88211	0.11	0.912	6.71E-07 - 8070462
Need for PPM	0.002393	0.018674	-0.77	0.439	5.43E-10 - 10537.87
Vtach	216.071	403.8031	2.88	0.004	5.544123 - 8420.929
Atrial Fibrillation	37.7251	60.56209	2.26	0.024	1.622377 - 877.2209
Central AI	0.073683	0.200761	-0.96	0.338	0.000353 - 15.36769
Paravalvular AI	1.669573	1.778376	0.48	0.63	0.206982 - 13.46724
CVA/Stroke	0.899917	1.59084	-0.06	0.952	0.02815 - 28.76906
Valve Malposition	0.576193	0.706685	-0.45	0.653	0.052071 - 6.37593
Need for Valve in Valve	0.023174	0.029696	-2.94	0.003	0.00188 - 0.285616
Valve Migration	6.755297	8.962306	1.44	0.15	0.50159 - 90.97882
Need for BAV	0.389508	0.818652	-0.45	0.654	0.006331 - 23.96282
Renal Failure	416.0855	1011.941	2.48	0.013	3.540119 - 48904.33

**RENAL DENERVATION**

**CRT-711**

**Accessory Renal Arteries And Blood Pressure-lowering Effects Of Renal Denervation: Analysis From The Reduce-HTN Study**

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**BACKGROUND** The bipolar radiofrequency Vessix Renal Denervation System (Boston Scientific, Marlborough, MA) can be used in small arteries, allowing resistant hypertension patients with accessory renal arteries to be included in the REDUCE-HTN study.

**METHODS** Accessory renal arteries were identified and treated in 24 patients during study procedures. Another 19 patients had accessory arteries that were later identified in core lab angiographic analysis (ie, untreated accessory arteries). In post hoc analyses, BP changes were compared between patients with treated vs untreated accessory arteries, and between patients with accessory arteries (according to the core lab) vs without.

**RESULTS** At both 6 and 12 months, all 4 patient subgroups had significant office systolic BP reductions ( $p \leq 0.0004$ ). For patients with treated accessory arteries, mean office BP decreased from 178.0±16.1/99.1±11.2 mmHg at baseline to 157.0±26.3/86.8±14.5 mmHg at 6 months, and for patients with core lab-identified but untreated

accessory arteries, office BP decreased from 188.8±17.5/103.8±13.2 mmHg to 155.2±28.0/88.0±11.8 mmHg. None of the 6- or 12-month pairwise comparisons of systolic BP for patients with treated vs untreated accessory arteries, or for those with accessory arteries vs without, reached statistical significance (Table). In linear regression models, neither presence nor treatment of accessory arteries was significantly associated with the change in office systolic BP.

**CONCLUSION** Presence of accessory renal arteries does not prevent significant BP reductions following renal denervation treatment. Due to the small sample sizes, these unpowered post hoc analyses do not conclusively address the degree to which accessory renal artery denervation may affect BP-lowering efficacy.

**Table.** Office and 24-hours Ambulatory Systolic Blood Pressures and Accessory Renal

	Treated Accessory (n=24)	Untreated Accessory (n=19)	Difference	Visualized Accessory (n=43)	No Visualized Accessory (n=103)	Difference
<b>Office (mmHg)</b>						
Baseline	178.0±16.1	188.8±17.5	-10.8; p=0.0421	182.8±17.4	182.2±18.8	0.5; p=0.8782
6 months	157.0±26.3	155.2±28.0	1.8; p=0.8325	156.2±26.7	158.1±22.1	-1.9; p=0.6893
Δ	-21.0±21.4 (n=24)	-33.1±17.2 (n=17)	12.1; p=0.0599	-26.0±20.4 (n=41)	-23.9±22.8 (n=102)	-2.1; p=0.6026
12 months	155.5±26.3	157.6±34.3	-2.1; p=0.8289	156.4±29.4	160.2±24.3	-3.8; p=0.4332
Δ	-22.7±26.2 (n=23)	-31.5±22.6 (n=16)	8.8; p=0.2818	-26.3±24.9 (n=39)	-22.1±21.9 (n=99)	-4.2; p=0.3317
<b>24-hour Ambulatory (mmHg)</b>						
Baseline	153.0±15.3	151.1±13.5	1.9; p=0.7529	152.4±14.6	153.1±15.6	-0.7; p=0.8284
6 months	148.3±14.0	147.4±29.3	0.9; p=0.9124	148.1±18.3	146.7±15.0	1.4; p=0.6921
Δ	-8.0±13.1 (n=17)	-7.5±22.5 (n=4)	-0.5; p=0.9527	-7.9±14.6 (n=49)	-8.1±14.8 (n=49)	0.2; p=0.9634
12 months	148.2±12.7	147.3±23.0	1.0; p=0.8952	147.9±16.5	144.9±14.0	3.0; p=0.4063
Δ	-7.5±11.8 (n=14)	-2.2±12.8 (n=5)	-5.3; p=0.4120	-6.1±11.9 (n=19)	-9.5±13.5 (n=50)	3.4; p=0.3390

**CRT-712**

**Preclinical Safety And Efficacy Of A Novel Multielectrode Bipolar/unipolar Over-the-wire Renal Denervation Rf Catheter**

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**BACKGROUND** Clinical and preclinical studies suggest that the efficacy of RF renal denervation (RDN) increases with increasing number of treatments. We evaluated efficacy and safety of the 9-electrode, 5-Fr, over-the-wire, RF 'basket' catheter, along with simultaneous bipolar/unipolar therapy algorithm ReDy system (Renal Dynamics, NJ) in pigs. Two catheter configurations were contrasted, with and without a 'basket'-covering membrane designed to minimize blood flow at the electrode/tissue interface thus minimizing shunting of RF power through blood.

**METHODS** Seven juvenile Yorkshire swine underwent bilateral temperature-controlled RDN using the ReDy system. A single catheter size was used on all arteries as the ReDy device accommodates artery diameters up to 6.5mm. Pigs were sacrificed 7-30d post treatment. Arteries were harvested for histopathology and kidneys processed for norepinephrine (NEPI) quantification.

**RESULTS** There was no angiographic evidence of acute dissection, perforation, or occlusion at the time of the procedure. Macroscopic inspections of catheters post-removal showed no adherent thrombus. Angiographic assessments showed the lumens of all arteries were patent. Histologically, zones of treatment within arterial walls and surrounding adventitia were well-demarcated at 7d with resolution of tissue response over time. There was no evidence of any adverse effects on arteries or surrounding tissue, and all treated arterial sections exhibited advanced re-endothelialization.

The use of blood isolation membranes allowed for lower treatment powers (1.2±0.8 vs 1.4±0.2 W) and temperatures (63.6±6.3 vs 68±2.3 °C) while increasing ablation depth (5.0±2.6 vs 2.8±0.8 mm,  $p=0.025$ ) and percentage of affected nerves (37 vs 21%,  $P=NS$ ) at 7d, as estimated by histology and confirmed by a significant 60% reduction in NEPI (256±250 vs 634±250 ng/g,  $p=0.007$ ). Tissue response was noted in all quadrants and ~65% of the artery length. Though radial adventitial response was more compact at 30d, due to tissue repair, the percentage of affected nerves (35%) and NEPI levels (365±132 ng/g) were statistically equivalent to 7d values ( $p>0.46$ ).

**CONCLUSION** The Renal Dynamics ReDy system is safe and efficacious in a porcine RDN model. Utilization of non-occluding blood isolation membranes allowed for deep delivery of RF power into the tissue at relatively low treatment powers, at multiple axial and circumferential locations.