Existing therapies have multiple shortcomings and ischemic cardiomyopathy is growing at a rampant rate. We report on the early clinical use of a novel transcatheter technology which addresses the underlying problem of the disease, excessive wall tension causing ongoing ventricular dilation.

METHODS The Revivent System was developed to place permanent cardiac implants into the heart for the purpose of excluding scar from the ventricular cavity, thereby reconfiguring abnormal cardiac geometry that leads to dysfunction. This is achieved by implanting a series of micro anchors which pull the LV free wall against the septum. The procedure does not require sternotomy, ventriculotomy nor cardiopulmonary bypass. By excluding the abnormal, non-contractile, scarred portion of the ventricular wall, volume and radius are diminished easing wall tension. The Revivent components consist of a series of catheters and anchors that are deployed using fluoroscopic imaging.

RESULTS Data is presented on 70 subjects treated with the anchor implants wherein the delivery method was surgical for the first 50 patients (Cohort 1) and transcatheter on the subsequent 20 patients (Cohort 2). Patients in both Cohorts are indistinguishable clinically and statistically from the entire group. Quality of Life, 6 minute walk, NYHA class, EF and LV volume are all improved in early follow up. Procedural success of the Revivent System was high, regardless of the delivery system used. Placement of the implant using surgical delivery system was successful in all but one of the attempted cases (98.1%) but 100% successful for the transcatheter delivery system. Operative and 30 day mortality was 5.5%. Mean time to extubation was shorter for patients treated with the transcatheter system (20 hours) compared to the surgical system (34.6 hours), and had a shorter interval in the ICU (80 hours vs. 109 hours). Data are presented in Tables 1-4.

CONCLUSIONS These early clinical results suggest that the Revivent system for less invasive ventricular volume reduction and reshaping is safe and feasible when applied to appropriate subjects suffering from ischemic cardiomyopathy heart failure. The clinical and hemodynamic improvement experienced by these patients treated with this early iteration of the system was demonstrated in measurable post operative differences in NYHA, QOL, EF, 6 minute walk, and LV volume. We advocate further clinical investigations of this promising new technology which fills an important clinical need.

CATEGORIES STRUCTURAL: Heart Failure

CONGENITAL AND OTHER STRUCTURAL HEART DISEASE

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Abstract nos: 738 - 743

TCT-738

The Degree of Right-to-Left Shunt is Associated with Visual Aura Due to Migraine

Yasufumi Kijima,[1] Nicholas Miller,[1] Nabil Noureddin,[1] Rubine Gevorgyan,[1] Jonathan Tobis[1]
[1]David Geffen School of Medicine at UCLA, Los Angeles, CA

BACKGROUND Cardiac or pulmonary right-to-left shunt (RLS) is associated with aura with or without migraine headache. A quantitative relation between visual aura and degree of RLS is not completely established. The aim of this study was to assess the relationship between the degree of RLS and visual aura with migraine.

METHODS Patients referred to the UCLA Interventional Cardiology program and received a transcranial Doppler (TCD) examination for assessment of patent foramen ovale (PFO) related conditions prior to any intervention were enrolled in this study. The study population was divided into two groups according to the frequency of visual aura with their migraine headache: migraine headache with frequent (≥50%) visual aura (frequent aura group); and migraine headache with occasional (<50%) or no visual aura (occasional or no aura group). Patients who had visual aura without migraine headache were classified into the frequent aura group. The degree of RLS was quantified by TCD using the Spencer grade scale at rest and post-Valsalva. Patients who had migraine events more than one time per month and who also received PFO closure were assessed for improvement of migraine headache or visual aura symptoms at 3 months after PFO closure.

RESULTS Of 141 subjects with migraine, 81 (57%) were classified into the frequent aura group and 60 (43%) were classified into the occasional or no aura group. TCD grade in the frequent aura group was significantly greater than those in the occasional or no aura group both at rest and post-Valsalva (Table). Of 54 patients who received PFO closure, those in the frequent aura group had a significantly higher frequency of migraine improvement than those in the occasional or no aura group ($p = 0.02$).

	Frequent aura group (n = 81)	Occasional or no aura group (n = 60)	p value
Age, yrs	48 ± 15	50 ± 13	0.55
TCD grade at rest, n = 140*	3.2 ± 1.5	2.1 ± 1.6	< 0.01
TCD grade post-Valsalva, n = 126*	4.3 ± 1.0	3.8 ± 1.3	0.01
Increase in TCD grade, n = 125*	1.3 ± 1.2	2.0 ± 1.3	< 0.01
PFO closed, n**	32	22	-
Migraine improved, n (%)	23 (72%)	9 (41%)	0.02
Migraine resolved, n (%)	10 (31%)	5 (23%)	0.55

PFO: patent foramen ovale; TCD: transcranial Doppler.
*There were 15 patients who had TCD only at rest and 1 patient who had TCD only post-Valsalva. **The number of patients who had migraine more than 1 time per month and also received PFO closure.

CONCLUSIONS Migraineurs who have frequent visual aura with or without headache have a greater degree of RLS than migraineurs with infrequent visual aura. Migraine with frequent visual aura (>50%) may have a greater potential to improve after PFO closure compared to migraine with infrequent visual aura.

CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Patent foramen ovale, Right-to-left shunt, TCD

TCT-739

Management of Recurrent Pulmonary Vein Stenosis

Erin A. Fender,[1] R. Jay Widmer,[1] Kristi H. Monahan,[1] Laura Peterson,[1] David R. Holmes,[2] Douglas L. Packer[1]
[1]Mayo Clinic, Rochester, MN; [2]Mayo Clinic College of Medicine, Rochester, United States

BACKGROUND One to five percent of AF ablations may be complicated by pulmonary vein stenosis (PVS). Initial management of high grade stenosis is performed with balloon angioplasty or stents. Restenosis occurs frequently. We sought to assess our center's outcomes in patients with restenosis following an initially successful intervention.

METHODS One hundred and fifty seven patients with PVS were seen between Jan. 2000 and Nov. 2014. One hundred and twelve patients had high grade stenosis (≥75% narrowing on CT imaging) and were taken for intervention. Restenosis was defined as recurrent high grade stenosis more than 1 month following the first procedure.

RESULTS One hundred and twelve patients were taken for initial intervention in 216 veins. Eighty eight veins were treated with angioplasty (41%), 81 with stenting (37%), and 47 veins (22%) received no intervention due to complete occlusion or angiographically insignificant obstruction. Stents significantly reduced recurrence relative to angioplasty (RRR 0.54, p=0.008). Despite a 94% acute success rate, 43 patients (38%) had 64 vessels which developed high grade restenosis over a median follow up of 4.6 years. Average time to restenosis was 7 months (range 1-36 months). Forty veins (62.5%) had been treated with angioplasty. Twenty four veins (37.5%) had been treated with a stent- 21 were peripheral bare metal stents (median diameter 10 mm) and 3 were drug eluting stents (median diameter 4 mm). Stents were sized to the largest achievable diameter. Forty two patients underwent a second intervention (n=59 vessels), however 2 of these veins were occluded and a wire could not be passed. One patient was asymptomatic and was monitored with CTs for progression. Stenting was used frequently to treat restenosis, with 33 veins undergoing stenting (58%) and 23 veins treated with balloon angioplasty (40%). Vessels treated with initial angioplasty followed by stenting had a

44% recurrence compared to a 53% when treated with a second angioplasty procedure (RR = 0.4, 95% CI = 0.46-1.5, p=0.48). Thirteen veins developed in-stent restenosis. Five of these veins were treated with a stent-in-stent, this was successful in four of these veins (80%). In the eight vessels where angioplasty was used for in-stent stenosis, 4 vessels developed recurrence (50%). Complications were similar; 1 patient treated with a stent had impingement of the adjacent vein requiring a second stent. In the angioplasty group 1 patient developed transient ST elevations and hypotension and 1 patient experienced PV perforation requiring intubation.

CONCLUSIONS The use of large stents can significantly reduce the risk of restenosis and are more effective than simple balloon angioplasty. However restenosis remains common and warrants on going surveillance after the initial procedures. This may suggest a role for novel approaches including the use of drug coated balloons.

CATEGORIES CORONARY: Complex and Higher Risk Procedures for Indicated Patients (CHIP)

KEYWORDS Restenosis, Restenosis, in-stent, Venous stenting

TCT-740

Treatment Options for the Closure of Secundum Atrial Septal Defect: A Systematic Review and Meta-Analysis

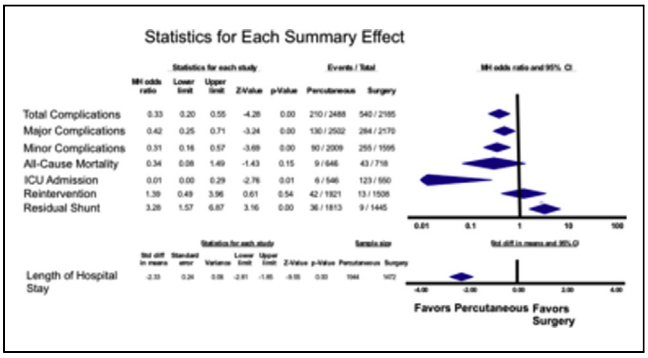
Pedro A. Villablanca Spinetto,[1] Robert Pass,[2] Giles Peek,[2] Mohammed Algodi,[1] Charanjit Rihal,[3] Jorge Alegria,[4] David Briceno,[1] Ali Zaidi[1]
[1]Montefiore Medical Center/Albert Einstein College of Medicine, New York, NY; [2]The Children's Heart Center, The Children's Hospital at Montefiore/Albert Einstein College of Medici, New York, NY; [3]Mayo Clinic, Rochester, MN; [4]Sanger Heart and Vascular Institute, Charlotte, NC

BACKGROUND Secundum atrial septal defects (ASD) are treated by surgery (SC) or transcatheter closure (TCC). There is no clear superiority of one technique and there is a scarcity of data directly comparing TCC and SC. This meta-analysis compares the clinical outcomes of the two treatment options for ASD.

METHODS A literature search was performed in MEDLINE, Embase, PubMed, Google Search, and Cochrane databases. Only studies directly comparing SC and TCC of ASDs were included. Of note, by definition and as a limitation of this work, this study compares only device-closeable ASD's (TCC) to all surgically closed ASD's. Outcomes studied were major and minor acute complications, all-cause mortality, residual shunt, reinterventions, ICU admission, and length of stay (LOS). Odds ratios (OR), standardized mean difference (SMD) and 95% confidence intervals (CI) were calculated using the Mantel-Haenszel method. A random-effect model was used to obtain summary effect. Sensitivity and cumulative analysis was performed for each outcome. All ages were included.

RESULTS 1287 manuscripts were screened. Twenty studies fulfilled the inclusion criteria: all observational studies (total n = 4,673 patients). TCC was superior to SC for the following outcomes: total complications (OR 0.33, 95% CI 0.20 to 0.75; p <0.01), major complications (OR 0.42, 95% CI 0.25 to 0.71; p <0.01), minor complications (OR 0.31, 95% CI 0.16 to 0.57; p <0.01), ICU admission (OR 0.01, 95% CI 0.01 to 0.29; p =0.01), and LOS (SMD -2.33, 95% CI -2.81 to -1.85; p <0.01). Residual shunts were more common with TCC (OR 3.28, 95% CI 1.57 to 6.87; p <0.01). No difference was observed for all-cause mortality (OR 0.34, 95% CI 0.08 to 1.49; p =0.15) or the need of reintervention (OR 1.39, 95% CI 0.49 to 3.96; p =0.61). Amongst adult patients (>18 years) a TCC was associated with shorter LOS (SMD -2.13, 95% CI -2.39 to -1.88; p <0.01).

CONCLUSIONS We present the largest meta-analysis comparing TCC and SC for closure of secundum ASD. Though both approaches are efficacious, for TCC-appropriate ASD's, TCC is associated with shorter LOS, less morbidity and fewer ICU admissions, while SC has a lower rate of residual shunting. Of note, many surgical cases included in this meta-analysis likely could only be closed surgically suggesting that both approaches are of value in the care of patients with ASD.



CATEGORIES STRUCTURAL: Congenital and Other Structural Heart Disease

KEYWORDS Atrial septal defect, Closure device, Surgery

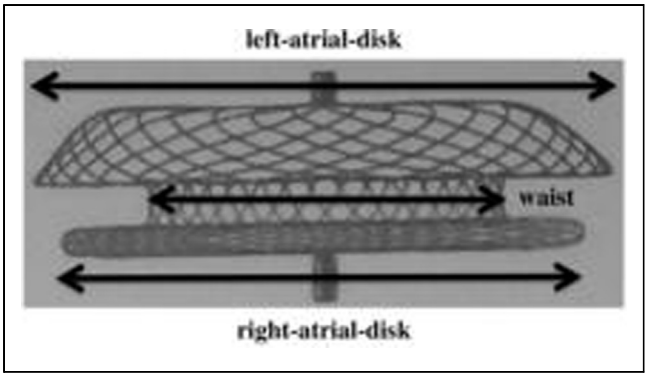
TCT-741

Atrial Septal Occlusion: Atrial Disks' Deformation Is Independent Of Waist Deformation

Manolis Vavuranakis,[1] Dimitrios A. Vrachatis,[1] Angelos-Michail Kolokathis,[1] Konstantinos Kalogeras,[1] Theodoros Papaioannou,[1] Maria Lavda,[1] Evangelia Bei,[1] Maria Kariori,[1] Carmen Moldovan,[1] Sophia Vaina,[1] Euaggelos Oikonomou,[1] Gerasimos Siasos,[1] Dimitrios Tousoulis[1]
[1]1st Dpt of Cardiology, Hippokration Hospital, National & Kapodistrian University of Athens, Athens, Greece

BACKGROUND Percutaneous closure of atrial septal defect (ASD) with a self-expandable double-disk ASD septal closure device is a well-accepted technique. Recently, concerns were raised about some rare but catastrophic long-term complications such as aortic erosion. Factors that contribute to this adverse outcome have not been recognized. Intracardiac echocardiography (ICE) can be used to guide device implantation, immediate results and to evaluate device deformation. We hypothesized that additional deformation of the disks of the implanted device may occur independently of its waist compression. The importance of such deformations and their impact on surrounding tissues is not known.

METHODS Consecutive patients undergoing percutaneous ASD closure guided by ICE were enrolled. Defect sizing was conducted with color-Doppler at "stop-flow" during balloon deployment. ICE loops were recorded and retrospectively studied. The length of the compartments of the closure device was measured at horizontal plane. Subsequently, in order to evaluate device deformation, the ratio of the measured to the nominal dimensions of the device was produced. Namely, R-waist (R-W), R-left-atrial-disk (R-LA) and R-right-atrial-disk (R-RA) were calculated.



RESULTS A total of 25 patients were included in the study. In all cases ASD was conducted uneventfully. R-W was 0.65 ± 0.13, R-LA was 0.85 ± 0.09 and R-RA was 0.84 ± 0.07. R-W differed significantly compared to the observed deformation of both disks (R-LA and R-RA), p<0.001. However, R-W was neither correlated with R-LA (r=0.175, p=0.404) nor with R-RA (r=0.123, p=0.558). This indicates that other factors besides mechanical properties of the device affect disks expansion.