

Natural History of Experimental Arterial Chronic Total Occlusions

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Background: Arterial chronic total occlusions (CTO) are common and associated with adverse clinical outcomes. To date, no studies have systematically assessed structural and perfusion changes occurring during CTO maturation, which may adversely affect angioplasty outcome. **Methods and Results:** Occlusions were created in 63 rabbit femoral arteries (38 rabbits) by thrombin injection. Histology, contrast (clariscan) enhanced MRI blood volume index and micro-CT imaging were analyzed at 2, 6, 12 and 18-24 weeks (n= 12-20 arteries/time point). Average T1-weighted MRI signal within the CTO was used to calculate relative blood volume (RBV). Collagen and proteoglycan content were assessed by picrosirius red and alcian blue staining, respectively. Early changes were characterized by an acute inflammatory response and negative arterial remodeling, with >70% reduction of arterial cross-section area (CSA) from 2 to 6 weeks. Intraluminal neovascularization occurred with a 2-fold increase in total microvessel CSA from 2 to 6 weeks (0.014 ± 0.002 to 0.023 ± 0.005 mm², p<0.001) and a 3-fold increase in RBV ($5.1 \pm 1.9\%$ to $16.9 \pm 2.7\%$, p<0.001). However at later time periods, there was significant reductions in both RBV ($3.5 \pm 1.1\%$, p<0.0001), and total microvessel CSA (0.017 ± 0.002 mm², p<0.02). Micro-CT imaging at 6 weeks demonstrated a corkscrew-like recanalization channel at the proximal end that regressed at later time points. Vascular changes were accompanied by marked decrease in proteoglycans and accumulation of a collagen-enriched extracellular matrix, particularly at the entrance. **Conclusions:** Vascular and matrix changes within CTO followed a specific time sequence. Regression of intraluminal neovascularization, together with collagen accumulation may underlie the high angioplasty failure rate in CTO, and could represent targets for novel therapeutic interventions.

Commissural Opening after Percutaneous Mitral Commissurotomy: Impact on Long-term Outcome

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Objectives: We sought to evaluate the prognostic value of the degree commissural opening (CO) on outcome.

Background: CO is the main mechanism by which the mitral valve area (MVA) increases after percutaneous mitral commissurotomy (PMC) but its impact on long-term outcome has never been evaluated.

Methods: 875 patients with mitral stenosis (MS) and good immediate results of PMC (MVA \geq 1.5 cm² and no regurgitation $>2/4$) were prospectively evaluated and divided into three groups: Group 1 (N=189; both commissures partially opened or not split), Group 2 (N=459; one commissure completely split) and Group 3 (N=227; both commissures completely split).

Results: Immediately after PMC, there were significant differences between Groups as regards to mean gradient (Group 1: 5.1 \pm 2.1mmHg, Group 2: 4.5 \pm 1.7mmHg, Group 3: 4.0 \pm 1.6mmHg, p<0.0001) and MVA (Group 1: 1.8 \pm 0.2cm², Group 2: 1.9 \pm 0.2cm², Group 3: 2.1 \pm 0.3cm²; p<0.0001). Ten-year rate of good functional results (survival without need for mitral surgery or repeat dilatation and NYHA functional class I or II at last follow-up) was significantly higher in Group 3 (76 \pm 5%) than in Group 1 and 2 (39 \pm 8% and 57 \pm 11% respectively; p<0.0001). In multivariate analysis, degree of CO did not emerge statistically but when MVA was excluded from the model, complete bi-commissural opening was an independent predictor of good late functional results (p<0.05).

Conclusions: Complete CO is associated with larger MVA, smaller gradients and functional improvement. Degree of CO provides important prognostic information and can be considered as a complementary measure of procedural success in addition to the MVA not always easy to assess.

Percutaneous Carotid Artery Stenting with Distal Protection Device in High- risk Patients

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Recent studies have shown conflicting results regarding the safety of percutaneous carotid artery angioplasty and stenting (CAS) as compared to surgical carotid endarterectomy (CEA). **Aim:** We evaluated the safety and feasibility of contemporary carotid artery angioplasty and stenting, with routine use of distal protection device in patients at high-risk for surgical endarterectomy. **Methods:** Between October 1999 and September 2007, a total of 190 consecutive patients with severe carotid stenosis underwent CAS with distal protection device. Of them, 90 (47%) pts had restenosis after a prior CEA and 66 (35%) were symptomatic. Patients who had high risk features, including restenosis after CEA, multivessel coronary artery disease, NYHA class III/IV heart failure or EF<30%, need for cardiac or vascular surgery within 30 days, COPD, occlusion of the contralateral carotid artery or hostile neck anatomy, were considered to be at high surgical risk, and were referred to CAS by both, the vascular surgeons and the interventional cardiologist. **Results:** The baseline clinical characteristics, outcomes up to 1-year follow-up, are presented in the table.

Clinical characteristics (N=190)		Clinical outcomes		
			at 30-days	From 30-days to 1-year
Age	70.2±9			
Male (%)	122 (64%)	Composite death/any stroke (%)	6 (3.1%)	13 (6.8%)
Diabetes mellitus (%)	70 (37%)	Death- all cause (%)	2 (1%)	10 (5.2%)
Smoking (%)	71 (37%)	TIA (%)	9 (4.7%)	
Ischemic heart disease (%)	108 (57%)	Minor stroke (%)	3 (1.5%)	2 (1%)
Hypertension (%)	160 (84%)	Major stroke (%)	1 (0.5%)	1 (0.5%)

At 1-year follow-up, the rate of restenosis (>70%) was 2.6%.

Conclusions: In correctly selected patients, with a multi-disciplinary approach, CAS is safe and durable. These results support the use of carotid artery angioplasty and stenting with a routine use of distal protection device in high surgical risk patients with significant primary or secondary carotid artery stenosis.

Percutaneous Renal Artery Angioplasty for Renal Artery Stenosis Reduces the Incidences of Flash Pulmonary Edema and Hospitalization Rate for Acute Heart Failure

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Background: Renal artery stenosis may cause uncontrolled hypertension, renal azotemia, episodes of acute heart failure and flash pulmonary edema.

Aim: to evaluate the clinical benefit of renal artery angioplasty with stenting for the control of recurrent, refractory congestive heart failure.

Methods: Renal artery angiography was performed in 470 patients having coronary angiography according to pre-selected criteria, 98 patients from these cohort (21%) had a recurrent episodes of flash pulmonary edema requiring hospitalization and treatment.

Results: Significant renal artery stenosis (luminal narrowing > 70%) was found in 46 patients, 21 patients (46%) of them had recurrent episodes of flash pulmonary edema before performing the procedure. The rate of hospitalizations for acute heart failure after performing renal artery angioplasty was reduced significantly from 2.31+ 1.25 hospitalizations per year to 0.5+0.5 per year after the procedure, (p=0.002), a reduction that was not observed in the remaining group of patients not having a significant renal artery stenosis. The reduction of hospitalizations was observed not only among those with preserved left ventricular ejection fraction (LVEF), but also among patients with moderate and moderate to severe reduced LVEF.

Conclusions and implications: Renal artery angioplasty for significant renal artery stenosis reduces hospitalizations for flash pulmonary edema and events of congestive heart failure exacerbation independently of the LVEF rate. Screening, diagnosis and treatment of significant renal artery stenosis is an important factor for reduction of morbidity and mortality among patients suffering from recurrent episodes of heart failure.

Impact of Percutaneous Closure of Inter-atrial Shunts on Future Pregnancies: Successful Single Center 10-year Experience

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Introduction

Over the last decade percutaneous closure of inter-atrial shunts has become the standard of care. Closure of most secundum atrial septal defects, whenever amenable to percutaneous treatment, is no longer performed surgically. Moreover, in young patients who underwent cryptogenic strokes believed to be secondary to paradoxical embolism, percutaneous closure of patent foramen ovale in order to prevent recurrent neurological events is also rapidly gaining popularity. Since young girls and women constitute the majority in these two target populations one of the most important measures of long term success would be normal future fertility and uncomplicated pregnancies.

Patients and Methods

124 and 78, out of 218 ASD and 130 PFO consecutive percutaneous closures, respectively, were girls or women. In the ASD group: 64 girls were younger than 18 years old (7.5 ± 4.2), 29 women were younger than 45 years (33.6 ± 6.2); In the PFO group: 33 women (36.6 ± 6.9) were in childbearing age.

Results

All inter-atrial shunts were closed successfully on first attempt by Amplatzer ASD or PFO occluding devices. The size of the implanted devices was 15.8 ± 4.9 , 24.6 ± 7.4 and 29 ± 6.2 cm for the young ASD, older ASD and PFO, respectively. Only two negligible residual shunts were recorded over a long follow-up period (70 ± 20 months). None of the PFO cases had a recurrent stroke. During follow-up 16 healthy babies were borne altogether. In the PFO group two women gave birth to two children each and two more gave birth to a single child. In the young ASD group two girls got married and gave birth to a single baby. In the older ASD group two women gave birth to two children, two had a single baby and one had a triplet following IVF. All pregnancies were normal and uneventful. Three cesarean sections were performed due to previous sections.

Conclusions

Percutaneous ASD closure yields comparable results to surgical intervention and does not hamper future fertility prospects. Normal pregnancies and deliveries are similarly possible following percutaneous PFO closure. Cardiologists, gynecologists and obstetricians should get familiar with this novel therapy and its favorable ramifications.

"Solysafe" Atrial Septal Occluder Device - The First Israeli Experience

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Introduction

We report our early experience with the Solysafe[®] atrial septal occluder device (Carag AG, Baar, Switzerland). The device is self-centering flat-profile device with two foldable patches which are attached to eight metal wires. It fits into a 10 F introducer. Once placed in the defect, the two wire-holders are moved towards each other until the wires snap into a stable position and form a flower-like shape. By snapping like this, the wires stretch the patches that are attached to them and the defect gets covered therewith. A clicking mechanism keeps the wire-holders together. It is the only guidewire based septal occluder which is deployed without the necessity of a long transseptal sheath.

Patients and Methods

Eight patients, average age 48.5 ± 13.5 (29-61) years old, underwent percutaneous closure of PFO due to recurrent CVA. The average unstretched diameter of the PFO was 4.5 (2-10) mm, the average stretched diameter measured in 5 patients was 9 (8-18.5) mm. The largest defect was encountered in a patient who had two distinct 5 mm holes that merged into one when stretched by a balloon. The size of the implanted devices was 18 ± 4.6 (15-25) mm.

Results

All PFOs were closed successfully on first attempt. Procedure length and x-ray exposure were comparable to other devices. There were no immediate or late complications during 3-months follow up. Device visibility on TEE and user-friendliness were acceptable. There were no residual shunts except for a negligible one recorded soon after closing the fenestrated inter-atrial septum. That small shunt resolved spontaneously on TTE after a month. All patients will undergo TCD 6-months after the procedure.

Conclusions

PFO closure utilizing Solysafe is safe, feasible and effective. Solysafe has several theoretical advantages that make it a good alternative to other devices. More patients and long-term follow up data are obviously still required.