

### PULMONARY VEIN ISOLATION USING THE NEW 12F-HIGH INTENSITY FOCUSED ULTRASOUND BALLOON CATHETER

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**Introduction:** Balloon catheters with high-intensity focused ultrasound (HIFU) are an alternative technology for the treatment of paroxysmal atrial fibrillation (PAF). A new 12-F HIFU-balloon catheter (BC; ProRhythm Inc., USA) with a broader focus zone and with less penetrative depth has been designed. The aim of the study was to assess efficacy and safety of the new 12F HIFU-BC during pulmonary vein isolation (PVI) for the treatment of PAF with particular focus on phrenic nerve (PN) palsy and atrial-to-esophageal fistula (AEF). **Methods:** Ten patients (4 female; mean age 67±6 years) with PAF were included in the study. During PVI a double transseptal puncture was performed for left atrial insertion of a spiral catheter and the 12 F HIFU-balloon catheter. In the last 4 patients a steerable sheath was used (FlexCath, CryoCath, USA). The HIFU-BC used had a diameter of 20 and 25mm. After PV angiography PN pacing (10V, 2.9ms) was conducted. Sonication was performed for 40-60 seconds. The E temperature was monitored continuously. The study protocol allowed for RFC touch-up ablation, if the PVI was not achieved with 5 HIFU sonications. **Results:** One patient had to be excluded due to the very close proximity of the E to the left inferior PV and in one patient RIPV was not present after previous lung surgery. In total 27/35 PV were isolated in 9 patients. Nineteen PVs were isolated with 1+1 HIFU-application, 3 PVs were isolated with 2+1, 1 PV was isolated with 4+1 and 1 PV was transiently isolated with 5 HIFU-applications (median 1; range 1-5). In the remaining 9 PV (4 RSPV, 2 RIPV, 1 LSPV, 2 LIPV) the gaps were all located anterior and PVI was completed with RFC ablation. The maximal E temperature was 45.4 °C. Mean procedure time was 213±83 min including 67±34 min of HIFU-catheter in-dwelling time. No AEF or PN palsy were observed, but 1 TIA occurred at day 1 after the procedure, that completely resolved within 24 hours. **Conclusions:** Using the newly designed 12F HIFU-BC >3/4 of PVIs could be achieved with a single HIFU application. However in 4/7 patients additional RFC-touch up ablation was required. No AEF or PN palsy were observed, but 1 TIA occurred.

### SAFE AND FAST ISOLATION OF PULMONARY VEINS USING A NOVEL CIRCULAR ABLATION CATHETER

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**Background:** Ablation of atrial fibrillation (AF) is one of the most time consuming procedures in interventional electrophysiology. Currently, the selection of catheters and ablation techniques is still a matter of debate. Due to the rapidly increasing demand of ablation procedures, technical advances would be helpful to reduce complexity and procedure time in AF ablation. Therefore we investigated the feasibility of a novel decapolar ablation catheter (PVAC) combined with a duty-cycled, low-power RF generator for pulmonary vein (PV) isolation. The system does not require 3D mapping or robotic steering and is the first to enable mapping, pacing and circular as well as segmental ablation with a single catheter. **Methods:** AF mapping and ablation was performed in 9 consecutive patients with intermittent AF (mean age 64 ± 3.8 years, 4 males) using the PVAC-catheter. To visualize the pulmonary vein anatomy, CT or MRI scan was performed in addition to PV angiography before ablation procedure. Additionally all patients underwent transesophageal echocardiography to rule out left atrial (LA) thrombi. Ablation procedure was performed by introducing the PVAC to the LA via single transseptal puncture. An optimal and stable catheter position for mapping and ablation was achieved by using a steerable sheath and an over the wire technique. RF energy was typically delivered for 60s for circular as well as segmental ablations. Ablation success was defined by disappearance of PV signals and complete exit block obtained by PVAC stimulation. **Results:** Isolation of all four PVs could be achieved in 35/36 veins (97%). A very small and hypoplastic right inferior PV could not be reached. The median RF application time until all PV were isolated successfully was 22.4 ± 2.9 min. First half of ablations were performed by circular RF application, second half with segmental applications until isolation. Procedure time for ablation was 84±5 min. Total fluoroscopy time was 32.1±3.2 min. There were no procedural complications. **Conclusion:** Mapping and ablation of pulmonary veins can be performed safe and fast, with low procedure times using a single catheter without 3D navigation or assisted steering. Thus this system may be of high interest not only for high volume but all centers performing AF ablation.

### MULTI-ELECTRODE CATHETERS USING LOW ENERGY PHASED RADIOFREQUENCY FOR ABLATION OF CHRONIC ATRIAL FIBRILLATION

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#### Background:

Delivery of high power standard radiofrequency (RF) energy in the left atrium has been associated with complications such as embolic events and atri-esophageal fistulas. Newly developed multi-electrode catheters can reduce RF to 3-5 W (max 10W) per electrode by delivering phased unipolar and bipolar RF delivered individually to each electrode pair by a multi-channel RF Generator.

#### Methods:

In 39 patients with persistent AF for 3.2±3.6 yrs (range 1-15), three catheters including a multi-electrode Pulmonary Vein Ablation Catheter (PVAC) for pulmonary vein isolation (PVI), a Multi-Array Septal Ablation Catheter (MASC) for ablation of complex fractionated electrograms (CFAE) at the septum and a Multi-Array Ablation Catheter (MAAC) for CFAE ablation in the left atrium were used. Follow up is 4.6 ± 1.8 months. A six month 7 day continuous ECG recording is currently available in 23 patients.

#### Results:

During a mean procedure time of 150 ± 35 min a total of 48 ± 12 min of fluoroscopy and 62 ± 15 min RFA were used. PVI was successful in 37/39 patients (95%). 2 patients needed additional standard RF applications to achieve isolation. CFAE ablation on the septum and the left atrium was successful using MASC and MAAC in all patients. Conversion to SR occurred in 4 pts and to atrial flutter in 3. One cardiac tamponade occurred after transseptal puncture, otherwise no complications were noted. After a single procedure, 19/23 patients (83%) are free of persistent AF (10/19 are in sinus rhythm on AAD therapy or have self terminating AF episodes). Long term results on all patients will be available in June, 2008.

#### Conclusion:

Multi-electrode mapping and ablation catheters using phased unipolar/bipolar RF require lower energies and are safe in routine clinical use. Procedure times are acceptable after a short learning curve. Short term results are promising.

### HIGH DENSITY MESH ABLATION : A POTENTIAL ALTERNATIVE TO POINT BY POINT ABLATION FOR PULMONARY VEIN ISOLATION

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#### Introduction:

Circumferential pulmonary vein isolation (CPVI) is traditionally performed using a point by point ablation strategy in combination with a circular mapping catheter. The High Density Mesh Ablator (HDMA, Bard Electrophysiology) is an expandable mesh electrode constructed of 36 wires and 4 thermocouples that can be used (1) to record electrograms and (2) to deliver RF energy with temperature control in a circular fashion at the ostium of the PVs. We examined the feasibility, acute efficacy, safety and short term results of CPVI with this approach.

#### Methods:

PV angiography, fluoroscopy, mesh/vessel diameter and electrograms were used to ensure proper positioning of the HDMA through a steerable transseptal sheath at LA-PV junction. 80-100 Watt of RF energy across the 36 electrodes was delivered for 300 seconds with a target temperature of 64°C maximum. The HDMA could be repositioned and the application repeated if necessary. If HDMA isolation was unsuccessful 30 sec touch up ablations were performed with a conventional ablation catheter and the HDMA as mapping catheter. During the procedure the ACT was maintained above 300 sec.

#### Results:

Sixty five PVs (100%) were targeted in 16 patients (69% male, age 57±12 years, paroxysmal AF 75%, persistent AF 25%) and could be isolated with the HDMA alone in 65% of the cases with a mean ablation time of 578±307 sec and 2.1±1.1 HDMA positions. Left sided PVs could be isolated in 57% of the cases, right sided in 71% (P=NS). All other veins could be isolated with 8±8 additional touch up RF applications of 30 seconds. Complete isolation of all PVs with the HDMA alone was only possible in 5 patients (31%). The total procedure time was 260±100 min, the fluoroscopy time 54±19 min. No major adverse events were observed. At three months follow-up, 67% of the patients were arrhythmia free.

#### Conclusions:

In combination with a steerable sheath, the HDMA can be safely positioned at LA-PV junction at the right and the left side and can be used for CPVI in the majority of cases. However, touch up ablations are necessary in a significant number of patients. Short term results of this approach are promising.