Comparing Cilostazol, a selective inhibitor of phosphodiesterase 3, with placebo, on top of standard amlopidine therapy, in patients with vasospastic angina.

**Background:** Cilostazol has a potent vasodilator effect, but its impact on vasospastic angina is unknown.

**Methods:** Between October 2011 and July 2012, 50 patients with confirmed vasospastic angina who have ≥1 angina episodes/week despite amlopidine therapy (long/day) for 2 weeks were randomly assigned to receive either Cilostazol (100mg/day) or placebo for 2 weeks followed by Cilostazol (200mg/day) or placebo for 2 weeks in 10 hospitals in Korea. All patients were given diaries to record the angina episode and severity of angina (0-10 grading). Primary endpoint was percent change in weekly angina episodes defined as (number of angina at baseline week - number of angina at last week)/number of angina at baseline week×100.

**Findings:** The data of forty nine patients (25 in Cilostazol, 24 in placebo) were analysed for the study. Baseline characteristics were similar between the two groups. At 4-week follow-up, primary endpoint was significantly greater in the Cilostazol group compared with the placebo group (-66.5±88.6% vs. -17.6±140.1%, respectively, p<0.009). Secondary endpoints including change in the weekly angina episode (-3.7±0.5 vs. -1.9±0.6, respectively, p=0.029), change in angina severity scale (-2.8±0.4 vs. -1.1±0.4, respectively, p=0.003), proportion of angina free patients (76.0% vs. 33.3%, respectively, p=0.003) were in favor of Cilostazol. Headache was the most common adverse event (40.0% vs. 20.8%, respectively, p=0.2).

**Conclusion:** Cilostazol was effective in treating vasospastic angina that is unresponsive to the standard calcium antagonist. Cilostazol might be considered as an add-on therapy for patients with refractory vasospastic angina.

**Catheter Ablation of Atrial Fibrillation: Have We Met Expectations?**

3533 | **BEDSIDE** Pacing or ablation: which is better for paroxysmal atrial fibrillation related tachycardia-bradycardia syndrome?


**Purpose:** To evaluate the outcome of AF ablation in patients with paroxysmal atrial fibrillation (AF) related tachycardia-bradycardia syndrome and to compare the efficacy of catheter ablation with a strategy of permanent pacing plus antiarrhythmic drugs (AAD).

**Methods:** Forty-three consecutive patients with paroxysmal AF and prolonged symptomatic sinus pauses on termination of AF referred to our hospital for ablation were evaluated. According to current Guideline, each patient of this group (ABL group) was assigned with a "pacemaker recommendation level" before ablation and at the end of follow-up. In another 57 patients, paroxysmal AF was treated with antiarrhythmic drug and a pacemaker was implanted due to AF related tachycardia-bradycardia syndrome. These patients were used as control (PM group) in the present study.

**Results:** All the 43 patients in the ABL group fulfilled Class I indication for pacemaker implantation at baseline but they actually underwent AF ablation. Reevaluation after 20.1±9.6 months of follow-up showed that 36/43 (83.7%) patients were free from AF and no longer need a pacemaker (Class III indication) (Figure 1b). More patients in the PM group were on antiarrhythmic drugs (34.4% in PM group, 4.7% in ABL group, p<0.001) while sinus rhythm maintenance at the end of follow-up was remarkably higher in the ABL group (83.7%, vs. 21.1% in PM group, p<0.001) (Figure 1b).

**Conclusion:** In patients with paroxysmal AF related tachycardia-bradycardia syndrome, AF ablation seems to be superior to a strategy of pacing plus AAD. Pacemaker implantation can be waived in the majority of patients after a successful ablation.

3534 | **BEDSIDE** Cost-effectiveness of radiofrequency catheter ablation as first-line treatment for paroxysmal atrial fibrillation

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**Background:** Radiofrequency catheter ablation (RFA) of patients with atrial fibrillation who already failed one or more antiarrhythmic drugs (AAD) has previously been proven both clinical efficient and cost-effective. It has been suggested that RFA could take priority over antiarrhythmic drugs as first-line treatment, because of better efficacy treating atrial fibrillation and fewer serious side effects. The present study (The Medical ANtiarrhythmic Treatment or Radiofrequency Ablation in Paroxysmal Atrial Fibrillation) is the first published, large, randomized multicenter trial of the clinical effects of such implementation in patients with paroxysmal atrial fibrillation.

**Purpose:** The aim of this study was to evaluate the cost-effectiveness of treating paroxysmal atrial fibrillation with radiofrequency catheter ablation as first-line treatment.

**Methods and results:** Costs and clinical effects for the first two years were calculated directly from MANTRA-PAF data. A decision analytic Markov-model was developed to study long-term (life-long) effects and costs of RFA compared to AAD as first-line treatment. Small positive clinical effects were found in the overall population; a gain of 0.06 QALYs to an incremental cost of €3,033 resulting in an incremental cost-effectiveness ratio (ICER) of 50,570/QALY. However, the result of the subgroup analyses indicates that a major part of the positive clinical effects for the overall population were from the quartile (26%) of the youngest patient (<50 years). Older patients were also relatively costly to treat while younger patients were almost cost neutral when using a life-long perspective. The ICER of a 45 years old patient was approximately 3,434 €/QALY, while corresponding ICER of a 65 years old patient was 108,937 €/QALY. However, the result of the subgroup analyses indicates that a major part of the positive clinical effects for the overall population were from the quartile (26%) of the youngest patient (<50 years). Older patients were also relatively costly to treat while younger patients were almost cost neutral when using a life-long perspective. The ICER of a 45 years old patient was approximately 3,434 €/QALY, while corresponding ICER of a 65 years old patient was 108,937 €/QALY.

**Conclusion:** Catheter ablation seems to be a cost-effective treatment option for patients below 50 years with paroxysmal atrial fibrillation. However, the effectiveness in older patients is uncertain.

3535 | **BEDSIDE** Catheter ablation versus antiarrhythmic medication as first line therapy in paroxysmal atrial fibrillation: on treatment analysis of the MANTRA-PAF data

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**Background:** MANTRA-PAF is a large randomized multicenter trial comparing radiofrequency catheter ablation (RFA) and antiarrhythmic drug (AAD) therapy as first line treatment of paroxysmal atrial fibrillation (PAF). The present study is an intention-to-treat analysis of the MANTRA-PAF data.

**Methods:** A total of 294 AAD naïve patients with PAF were randomly assigned to RFA (146 patients) or class I/III AAD therapy (148 patients). Cumulative and percent AF burden was significantly lower in the RFA than in the AAD group. In the present on-treatment analysis we compared three groups of patients: those who received only the prescribed treatment (pure RFA and pure AAD groups) and those treated with combination of RFA and AAD (cross-over group).

**Results:** All the 43 patients in the ABL group fulfilled Class I indication for pacemaker implantation at baseline but they actually underwent AF ablation. Reevaluation after 20.1±9.6 months of follow-up showed that 36/43 (83.7%) patients were free from AF and no longer need a pacemaker (Class III indication) (Figure 1b). More patients in the PM group were on antiarrhythmic drugs (34.4% in PM group, 4.7% in ABL group, p<0.001) while sinus rhythm maintenance at the end of follow-up was remarkably higher in the ABL group (83.7%, vs. 21.1% in PM group, p<0.001) (Figure 1b).

**Conclusion:** In patients with paroxysmal AF related tachycardia-bradycardia syndrome, AF ablation seems to be superior to a strategy of pacing plus AAD. Pacemaker implantation can be waived in the majority of patients after a successful ablation.
**Results:** At 24 months, AF burden was significantly lower in the pure RFA group (n=110) than in the pure AAD (n=92) and the cross-over (n=84) groups (90th percentile 1% vs. 10%, P=0.007), and more patients in the RFA than in the other groups were free from any AF (89% vs. 73% vs. 74%, P=0.006). The cumulative AF burden was significantly lower in the pure RFA and AAD groups than in the cross-over group (90th percentile 10% vs. 6% vs. 24%, P<0.001). During the 2 year follow-up period 63%, 59% and 21% (P=0.001) of the patients in the pure RFA, pure AAD and the cross-over group had no AF episodes in any Holter recording, respectively. There was no significant difference in the number of severe complications between the groups.

**Conclusions:** These data indicate that RFA is superior to AAD as first line treatment in a large subset of patients with highly symptomatic PAF. The results are pertinent among relatively young and healthy subjects and should not be extrapolated to elderly patients or to those with comorbidities.

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**3536 | BEDSIDE**

**Very low incidence of permanent complications: report of a national multicenter registry**

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**Purpose:** Despite catheter ablation (CA) has become an accepted treatment option for symptomatic, drug-resistant atrial fibrillation (AF), safety of this procedure continues to be cause for concern. The present Italian Multicenter Registry on Procedural Safety of CA for AF aims to report incidence of permanent CA complications and detect their plausible predictors in a contemporary, unselected AF population.

**Methods:** From January 1, 2011 to December 31, 2011, data from 2,323 consecutive patients who underwent CA (median age 60 (52-67); 72.3% male) for AF in 29 Italian centers were collected. All complications occurring to the patient from admission to 30th post-procedural day were recorded.

**Results:** No procedure-related death was observed. Complications occurred in 95 patients (4.1%; 50 (2.2%) vascular access complications; 12 (0.5%) cardiac tamponades; 11 (0.5%) conservatively treated pericardial effusions; 10 (0.4%) atrial embolisms; 3 (0.1%) phrenic nerve paralysis; 3 (0.1%) pericarditis; 3 (0.1%) hematomas; and 3 (0.1%) other isolated adverse events. Seven (0.3%) patients developed permanent sequelae from their complications, 4 (0.71%) of these due to thromboembolic complications. At multivariate analysis only the use of an irrigated-tip catheter (OR 0.95, 95% CI 0.18 to 0.52, p=0.007) independently predicted a lower risk of permanent complications.

**Conclusions:** CA for AF is currently affected by a very low rate of complications leading to permanent sequelae. The use of an irrigated-tip catheter seems to further reduce this risk.

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**3537 | BEDSIDE**

**Long-term outcome of a fixed approach for persistent atrial fibrillation**

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**Objectives:** A fixed approach including bilateral circumferential pulmonary vein antrum (CPVA) isolation and left atrial roof, mitral isthmus and tricuspid isthmus linear ablations, namely “2C3L”, is our standard ablation strategy used in patients with persistent AF. The present study sought to explore whether additional complications from ablate and freeze catheters compared with conventional catheters (CFAE) ablation (stepwise approach) provided more benefits to the long-term outcome.

**Methods:** One hundred and forty six patients (age 55±11 years, 76% male) with persistent AF (≥3 months) were randomized to undergo ablation using either 2C3L (n=73) or stepwise (n=73) approach. Intra-procedural AF termination was defined as AF conversion to sinus rhythm or organized atrial tachycardia. The primary outcome was freedom from atrial tachyarrhythmia off antiarrhythmic drugs (AADs) during follow up.

**Results:** The procedural (222±42 vs. 268±43 min), fluoroscopy (41±9 vs. 55±8 min), and procedure (187±32 vs. 128±38 min) time were shorter and AF termination rate was lower (21 vs. 53%) with 2C3L strategy than with stepwise approach (all p<0.001). A repeat procedure was performed in 25 (34.2%) and 28 (38.4%) patients in 2C3L group and in stepwise group, respectively (P=0.606). At 12 month follow-up, sinus rhythm maintenance off AAD after a simple procedure was 54.8% in 2C3L group and 49.3% in stepwise group (P=0.486). After the last procedure, sinus rhythm maintenance increased to 83.6% and 79.5% over 27±7 m follow up (P=0.056), respectively (Fig 1).

**Conclusions:** The “2C3L” approach is a simplified ablation strategy and sufficient to achieve optimal long-term outcome in patients with persistent AF. CFAE ablation after 2C3L ablation is associated with prolonged ablation and fluoroscopy time but without additional benefits.

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**3538 | BEDSIDE**

**RF versus cryoballoon in atrial fibrillation ablation: outcome data from the German ablation registry I**

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**Background:** Catheter ablation is extensively used with curative intention in Atrial Fibrillation (AF). Radiofrequency ablation has long been standard of care, cryoballoon technology has emerged a feasible approach with promising results. Prospective multicenter registry data referring to both ablation technologies in AF ablation are lacking so far. We report data of the German ablation registry I with respect to efficacy and complication rates in PV ablation after the first index ablation with different energy sources for paroxysmal AF after 1 year follow-up (FU).

**Methods:** All 2556 consecutively enrolled patients with symptomatic px AF of the German ablation registry I who underwent their 1 year FU were included in this analysis. The cohort was divided into two groups according to the ablation energy source used: cryoballoon ablation (group 1, n=604 [26.8%], median age 61 years, 64.2% men) and RF ablation (group 2, n=1952 [73.2%], median age 66 years, 62.8% men).

**Results:** Procedural outcome is given in the Table. Acute success rates were similar in both groups (97.0% in cryo vs. 96.8% in RF; p=0.84). AF recurrence rate at 1 year FU was not significantly different between both groups (45.8% after cryoballoon and 45.4% after RF ablation; p=0.87). Use of antiarrhythmic therapy at 1 year follow-up was slightly more common after RF ablation (32.1% vs. 27.5% after cryoablation; p=0.03). Major complication rate was significantly higher in RF vs. cryoablation (5.1% in RF vs. 2.3% in cryo; p<0.01). Also minor bleedings (4.2% in RF vs. 2.5% in cryo; p<0.05) were more common in RF ablation. Phrenic nerve palsy was more often in cryo (2.3%) vs. RF ablation (0.1%; p<0.001).