who were treated with transcatheter aortic valve (TAVI) replacement.

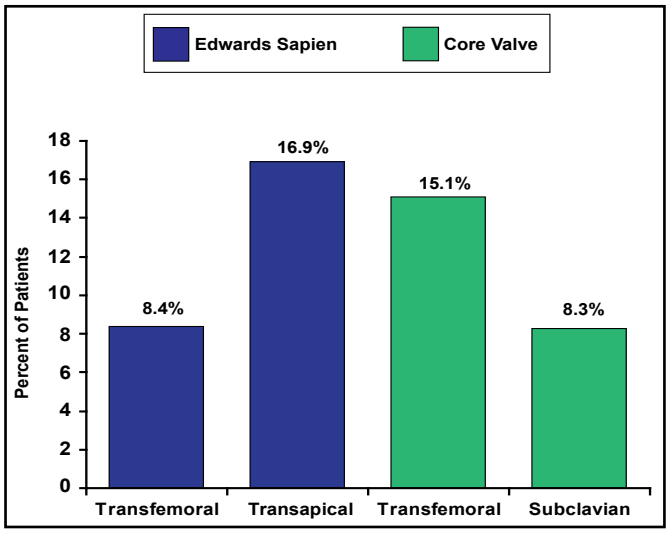
TAVI is an emerging treatment for patients with aortic stenosis who are at too high a risk to undergo conventional surgical replacement of the aortic valve. The FRANCE Registry is a multicenter prospective clinical registry that was developed to evaluate the safety and efficacy of the two aortic valve replacement devices that are currently available in France. The two valves that were used in the registry were the Edwards Sapien balloon-expandable valve (68% of patients), using either a transfemoral (39%) or transapical (29%) approach, and the CoreValve self-expandable valve (32% of patients), using a transfemoral (27%) or subclavian approach (5%).

Study patients were required to have severe aortic stenosis (effective orifice area [EOA] <1 cm^2/m^2) and severe symptoms (New York Heart Association [NYHA] Class ≥2) and be at high surgical risk (Logistics EuroScore >20%, Society of Thoracic Surgeons [STS] mortality risk score >10%), or have a contraindication to surgery). The primary endpoint of the study was 30-day mortality. Secondary endpoints (up to 3 years) included mortality, major adverse cardiac events, hemodynamics, and quality of life.

A total of 244 patients (mean age 82 years; 56% men) were recruited between February and September 2009. Diabetes was present in 27% patients; 23% had a previous myocardial infarction; 10% had a previous stroke; and ~42% had coronary artery disease. The only significant (p=0.02) difference between the four subgroups was the presence of peripheral artery disease and abdominal aortic aneurysm, which were more common in patients who were treated with a transapical or subclavian approach. The mean baseline EuroScore was 25.6%; mean STS score was 16%. The mean aortic annulus (21.9±1.8 mm) was slightly smaller in patients who received the Edwards due to the availability of the 23-mm stent and larger in the CoreValve group due to the availability of a 29-mm stent. The mean EOA was 0.68±0.16 cm^2. Mean left ventricular ejection fraction was 51% (47% [p=0.02] in patients who received the Edwards valve via the transfemoral approach). Two-thirds of the procedures were done in the cardiac catherization lab.

The devices were successfully implanted (defined as successful delivery and deployment of the valve without death on the table) in 97% of patients. Failure occurred in 7 patients; there were 4 procedural deaths. There was no difference between the groups in 30-day mortality (mean 12.7%; p=0.32; Figure 1). Hemodynamic results immediately after implantation were significant (mean increase in EOA from 0.68±0.16 cm^2 to 1.74±0.47 cm^2; p<0.001). The rate of new pacemaker implantation (overall mean 11.8%) was significantly (p<0.001) higher in the CoreValve group (25% to 27%) compared with 4% to 5% in the Edwards valve group. The transfusion rate (mean 21.3%) was higher when a transapical (27.4%) or subclavian (83.3%) approach was used.

Figure 1. 30-Day Mortality.



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Vascular complications (mean 6.5% of patients) were comparable between the four groups. Postimplantation aortic regurgitation occurred in <10% of patients. Factors that were predictive of 30-day mortality (by univariate and multivariate analysis) were prior CABG and Euroscore ≥25%.

A total of 111 patients have reached the 6-month follow-up. Survival at 6 months is 76.5%. Hemodynamic and clinical results are persistent.

RecordAF Trial Confirms No Advantage for Rate Versus Rhythm Control Strategy for in Patients with AF

The clinical outcomes that are associated with rate control versus the restoration and maintenance of normal sinus rhythm in the treatment of atrial fibrillation (AF) have been explored in a number of large-scale clinical trials [Wyse DG et al. *N Engl J Med* 2002; Van Gelder et al. *N Engl J Med* 2002]. No advantages for either treatment strategy with respect to major cardiovascular (CV) outcomes have

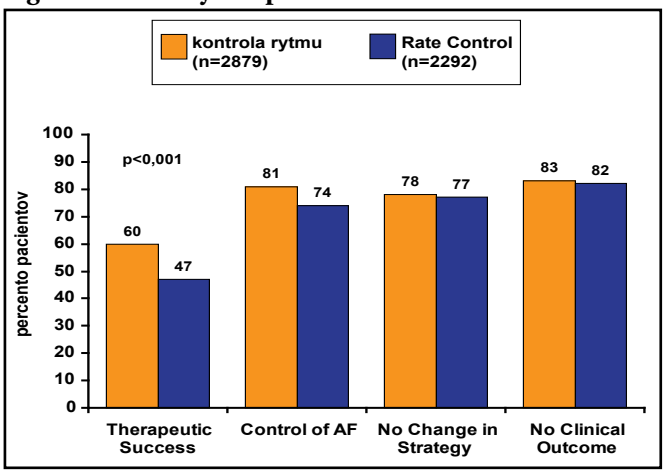
been reported. John Camm, MD, St. George's Hospital Medical School, London, UK, reported results from a real-life, international, observational, prospective, longitudinal cohort study that confirmed and complemented results from these previous controlled randomized trials.

The RecordAF (REgistry on Cardiac rhythm disORDers: an international observational prospective survey assessing the control of Atrial Fibrillation) registry was established to trace the influence of a physician's choice of a rate versus rhythm control strategy on clinical outcome for patients with first onset or recent recurrent AF. Patients (n=5604) aged 18 years and older with a <1-year history of AF were selected from 532 randomly chosen general cardiology practices in 21 countries. Patients with permanent or transient AF were not eligible. The primary study endpoint was the rate of therapeutic success of AF management (in sinus rhythm or at rate control target with no major CV event and no change in strategy) at 12 months. The co-primary endpoint was the rate of major CV events (eg, CV death, myocardial infarction, stroke, transient ischemic attack [TIA], and hospitalizations).

At baseline, 45.1% (n=2528) of patients in the registry were being treated with a rate control strategy and 54.9% (n=3076) were treated with a rhythm control strategy. Patients in the rhythm control group were an average of 3 years younger than those on rate control (64 vs 67 years; p<0.001) and had a significantly (p<0.001) lower resting heart rate (76.6 vs 80.6 beats per minute). Body mass index and systolic blood pressure were slightly but significantly (p=0.008 and p=0.02, respectively) greater in the rhythm control group.

Data for 92.3% of patients were available after 1 year of follow-up, at which time more patients in the rhythm control group were in sinus rhythm (81% vs 33%). Approximately 50% of patients had a change in pharmacological treatment and 20% had a change in therapeutic strategy in both groups. Therapeutic success was achieved significantly (p<0.001) more frequently in patients who were treated by rhythm control (60% vs 47%), which was driven by control of AF (Figure 1). For the co-primary endpoint, there was no difference (p=0.35) between the two strategies in terms of overall clinical events (18% in rate control vs 17% in rhythm control groups). Multivariate analysis showed that the occurrence of cardiovascular clinical events was more dependent on comorbidity (coronary artery disease, heart failure, age >75 years, renal disease, prior stroke/TIA) than the choice of strategy. Hospitalizations for arrhythmia were more common in the rhythm (11%) versus rate control group (7%), and hospitalizations for heart failure management were more common in the rate (5%) versus rhythm control group (2%).

Figure 1. Primary Endpoint at One Year.



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Prof. Camm concluded that although successful management of AF was achieved more often with rhythm control, this did not translate into better outcomes.

New Data from RE-DEEM and RE-LY

Results from the Phase II dose-ranging RE-DEEM trial (NCT00621855), presented by Jonas Oldgren, MD, Uppsala Clinical Research Center, Uppsala, Sweden, indicate that dabigatran up to 150 mg BID can be used in conjunction with dual antiplatelet therapy with only modestly increased bleeding risk.

RE-DEEM compared four dose regimens of dabigatran versus placebo in patients on dual antiplatelet therapy after acute coronary syndrome (ACS). The primary study endpoint was major (ISTH criteria) and clinically relevant minor bleeding. Secondary endpoints included coagulation activity and a composite of cardiovascular (CV) death, nonfatal myocardial infarction (MI), and nonhemorrhagic stroke.

Subjects (n=1878; mean age 61.8 years; 76% men) with ST or non-ST elevation ACS and ≥1 additional risk factor for CV complications who were already on dual antiplatelet therapy were randomly assigned to receive placebo or dabigatran 50 mg, 75 mg, 110 mg, or 150 mg BID for 6 months. The most common risk factors for CV complications were age ≥65 years (44%), diabetes (31%), previous MI (29%), and no revascularization for the index event (31%).