Abstract:
Implantable cardioverter-defibrillators (ICDs) represent the treatment of choice for primary and secondary prevention of sudden cardiac death but ICD therapy is also plagued by inappropriate shocks due to supraventricular tachyarrhythmias. Dual-chamber (DC) ICDs are considered to exhibit an enhanced discrimination performance in comparison to single-chamber (SC) ICDs, which results in reduction of inappropriate detections in a short- to mid-term follow-up. Comparative data on long-term follow-up and especially on inappropriate shocks are limited. The aim of the OPTION study is to assess whether an optimized treatment with DC ICDs improves patient outcome and decreases the rate of inappropriate shocks in comparison to SC ICDs. DC ICD therapy optimization is achieved by optimal customizing of antitachycardia therapy parameters, activation of discrimination algorithms, antitachycardia pacing in the slow ventricular tachycardia zone, and avoidance of right ventricular pacing with the SafeR algorithm mode. The OPTION study, a prospective, multicenter, randomized, single-blinded, parallel study, will randomize 450 patients on a 1:1 allocation to either an SC arm with backup pacing at VVI 40 beats per minute (bpm) or to the DC arm with SafeR pacing at 60 bpm. Patients will be followed for 27 months. Primary
outcome measure is the time to first occurrence of inappropriate shock and a combined endpoint of cardiovascular morbidity and all-cause mortality. The study will evaluate the relative performance of DC in comparison to SC ICDs in terms of inappropriate shock reduction and patient outcome.