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Risk of early mortality after placement of a temporary-permanent pacemaker

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Abstract

Background: Temporary-permanent pacemakers [TPPM] are externally placed permanent generators attached to active fixation transvenous leads. TPPM can be used as an alternative to standard temporary pacing leads when placement of a permanent pacemaker is contraindicated. We sought to determine the incidence and risk factors for early (within 6 months) mortality after placement of a TPPM.

Methods: Electronic medical records were used to extract baseline characteristics for 152 patients from Wake Forest Baptist Medical Center who had a TPPM placed between the years 2007 and 2012. Multivariable adjusted Cox proportional hazard models were used to estimate hazard ratios [HR] and 95% confidence intervals [C]) for baseline characteristics [age, sex, race, hypertension, diabetes, heart failure, coronary artery disease, smoking, dyslipidemia, chronic kidney disease [CKD], and indication for pacemaker] on early mortality.

Results: Of the 152 patients [mean age 68.9 years; 57.2% female; 86.8% white], 45 [29.6%] died within the first 6 months after TPPM placement. No deaths occurred as a direct result of TPPM placement, and only 1 patient experienced documented non-fatal complications. Maximum time to PPM from the date of insertion of TPPM was 336 days. Using a backward multivariable adjusted hazard regression model, independent risk factors for early mortality were pre-existing CKD [HR (95% CI): 2.240 (1.002–5.010) for eGFR 30–59 and 7.645 (3.594–16.263) for eGFR <30 compared to eGFR >60] and history of smoking [HR (95% CI): 2.015 (1.099–3.696)]. Surprisingly, dyslipidemia was protective of early mortality [HR (95%CI): 0.470 (0.240–0.924)].

Conclusion: TPPM placement is a safe procedure with rare direct complications. CKD and smoking are predictive of increased risk for early mortality in patients undergoing TPPM placement.

Keywords: Temporary pacemaker; Heart pacing; Risk of mortality

Introduction

Temporary-permanent transvenous pacing (TPPM) via a permanent external generator attached to active fixation transvenous leads can be a lifesaving procedure in a variety of cardiac arrhythmias including sinus node and atrioventricular (AV) node dysfunction. It is a well-established method to restore normal cardiac rhythm when placement of a permanent pacemaker is contraindicated for a variety of reasons including active infection, transient conduction abnormalities, perioperative period, or prophylaxis for another procedure. The efficacy and safety of traditional temporary transvenous pacing with passive fixation and later via active fixation leads and an externalized re-usable permanent pacemaker has been previously explored [1–11]. Case reports have highlighted complications associated with temporary pacemaker and TPPM placement [6–8,12–14] and earlier studies found a low complication rate associated with the transvenous pacing [9–11].

Temporary transcutaneous pacemaker is important while bridging to permanent pacemakers in the setting of hemodynamically significant AV block, the evolving transcutaneous techniques for cardiac valves replacement due to increase in the rate of bundle branch blocks and infection [13,15,16]. Over the years, advances in cardiac pacing devices came with greatly improved pacemaker lead

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insulation and tip materials. Rastan et al. first reported utilization of active-fixation leads attached to pacemaker generators as a bridging therapy and Braun et al. compared passive vs active fixation leads [16,17] in 2005. The utilization of active fixation leads during temporary transcutaneous pacemaker insertion increased the effectiveness and reliability of temporary pacemakers by avoiding frequent loss of capture and under-sensing.

Though temporary-permanent transvenous pacing is proven to be a useful procedure, it is not without risk. Understanding which population of patients may be at an increased risk for complications may change clinical management. Given advances in cardiac pacing devices, improvements in temporary pacemaker placement, and expanding indications for temporary pacing, it would be worth revisiting the immediate complication rate and early mortality rate (within 6 months) in the general adult population presenting with contraindications to permanent pacemaker placement.

Methods

Data were collected from the electronic medical records (EMR, Epic and Carecast) of 152 patients who received a temporary pacemaker with external generator for any indication from 2007 to 2012 at Wake Forest Baptist Medical Center. Records were reviewed for age, sex, race, pre-existing conditions (diabetes, hypertension, coronary artery disease, congestive heart failure, smoking history), temporary pacemaker indication (sinus node disease, AV node disease defined as type II second degree or third degree AV block or other high grade block), date of temporary implant, complication from implant, contraindication to permanent pacemaker placement, and time to permanent pacemaker placement (if indicated). Patients discharged were set up for follow up for device check to assess the need for PPM according to standard protocol followed by most US hospitals.

Active fixation leads (Medtronic 5076) and Medtronic external re-usable permanent pacemaker were used that were secured with sterile dressing technique. Pacing lead threshold at implantation was considered acceptable if 1.0 V at a pulse width of 0.5 ms, as were sensing amplitudes of ≥ 5 mV for the R-wave and ≥ 1 mV for the P-wave. Wound check, chest X-ray and device interrogation were performed during the first 24 h after implantation. Patients were discharged home or to a nursing care facility once clinically stable with TTPM system until PPM can be implanted.

Time to PPM if indicated or death was recorded and all-cause mortality data was collected by reviewing the EMR for date of death and cause (if documented). Mortality was only recorded if the patient died within one year of receiving a temporary pacemaker. A small subset ($n = 12$) was lost to follow up, therefore date and cause of death were not determined.

Complications related to placement of the temporary pacemaker were defined as any documented adverse outcome of the procedure including mechanical damage caused by placement of the pacing lead, or infection of the pacing system.

Contraindication to placement of a permanent pacemaker included active infection from any source, emergent placement due to hemodynamic instability, perioperative period, transient symptoms (often caused by spinal cord injury), prophylaxis for transcatheter aortic valve replacement (TAVR), or other correctable causes including electrolyte abnormalities, respiratory failure, drug overdose, or treatable diseases not expected to require permanent pacing.

Statistical analysis

Baseline characteristics of the patients were tabulated and compared by survival status within 6 months. Multivariable adjusted Cox proportional hazard regression models were used to estimate hazard ratios and 95% confidence intervals for baseline demographics and clinical factors on early all-cause mortality. Variables included in the model are age, sex, race (white vs non-white), hypertension, diabetes, congestive heart failure, coronary artery disease, smoking (current or past), dyslipidemia, chronic kidney disease, and pacing indication (SA node disease, AV node disease, others). Backward selection multivariable adjusted hazard regression model was used to identify independent risk factors for early mortality. Survival probability was estimated using Kaplan Meier method and compared by levels of the factors identified by the backward selection regression model using log-rank test. Statistical significance for all analyses was $p < 0.05$. Analyses were conducted using SAS 9.2 [SAS Institute, Cary, NC].

Results

Of the 152 total patients (mean age 68.9 years ± 16.4; 57.2% female; 86.8% white), 45 (29.6%) died within the first 6 months after TPPM placement. No deaths occurred as a direct result of pacemaker placement, and only 1 (0.7%) patient experienced documented non-fatal complication related to tamponade. Mean and median time to PPM implantation was 9.7 and 21 days respectively. Maximum time to PPM, if indicated, from the date of insertion of TPPM was 336 days. Approximately 35 patients were discharged with TPPM and 15 patients had the system in place for more than 30 days. Patients' early mortality was related to multiple conditions including cardiovascular disease (CVD), ventricular fibrillation (VF)/pulseless electrical activity (PEA) arrest, NSTEMI and abdominal aortic aneurysm (AAA) rupture (10 patients), respiratory failure (9 patient), neurological related death including stroke and subdural hematoma (5 patients), sepsis (8 patients), post bowel surgery complications (2 patients) and unknown for the remaining 11 patients.

About 30.9% of the participants had diabetes, 64.4% had hypertension, 38.2% had coronary heart disease, 24.3% had heart failure, 38.2% had dyslipidemia and 35.5% were smokers. Table 1 shows the patients characteristics stratified by occurrence of early mortality. As shown, patients with early mortality were more likely to have history of chronic kidney disease and congestive heart failure.