Pacemaker and Implantable Cardioverter Defibrillator Implantation Without Reversal of Warfarin Therapy

MICHAEL C. GIUDICI, S. SERGE BAROLD,* DEBORAH L. PAUL, and PRAVEEN BONTU
From the Divisions of Cardiology, Genesis Medical Center, Davenport, Iowa and the *Tampa General Hospital, Tampa, Florida

GIUDICI, M., ET AL.: Pacemaker and Implantable Cardioverter Defibrillator Implantation Without Reversal of Warfarin Therapy. The study evaluated all patients undergoing permanent pacemaker and ICD implantation over a 4-year period to determine if anticoagulated patients required normalization of coagulation factors in the periprocedural period. The study included 1,025 (597 men, 428 women, age 24-100 years, mean 72 years) consecutive patients who underwent device implantation using mostly a percutaneous subclavian approach. The procedures were performed without reversal of anticoagulation in 470 patients with INRs > 1.5 at the time of the procedure (mean INR 2.6 ± 1.0, range 1.5-7.5). The complication rate in the anticoagulated group was similar to those in patients with a normal INR. Routine normalization of coagulation factors prior to pacemaker/ICD placement may not be necessary. (PACE 2004; 27:358-360)

anticoagulation, pacemaker implantation

Introduction

Many patients requiring permanent pacemaker or implantable cardioverter defibrillator (ICD) placement are anticoagulated with warfarin for a number of indications. In the present experience it approximates 45% of patients referred for pacemaker or ICD placement. The indications include atrial fibrillation, which is the most common cause, cerebrovascular disease, prosthetic heart valves, deep venous thrombosis, and severe left ventricular dysfunction. It is common practice to postpone device implantation in anticoagulated patients until the international normalized ratio (INR) has normalized by withholding warfarin (often in a hospital setting) or by the administration of coagulation factors (fresh frozen plasma) or vitamin K. This strategy increases the cost and length of hospitalization. When warfarin therapy is resumed, several days are needed to reestablish therapeutic anticoagulation. Furthermore, subtherapeutic anticoagulation exposes patients to potential embolic complications.

The authors conducted an ongoing registry of patients who remained on warfarin therapy during and after the transvenous implantation of a pacemaker or ICD. The investigation was based on their observation that a number of patients on warfarin who underwent device implantation on an emergency basis without reversing anticoagulation exhibited no untoward bleeding complications.

Methods

From November 1, 1996 to June 1, 2002, all patients undergoing permanent pacemaker/ICD placement had INRs checked before surgery. The patients were not randomized in terms of stopping or continuing warfarin therapy. The implanting physician proceeded directly to implantation without any change in therapy or would actively (coagulation factors or vitamin K) or passively (waiting) normalize the coagulation factors. Patients were followed for any procedure related complications like hematoma requiring intervention, bleeding, lead dislodgement, pneumothorax, cerebrovascular accident (CVA), and peripheral embolization. Data were collected in a registry and analyzed retrospectively.

Of the 1,025 patients studied, 117 (11%) underwent lead placement via a cephalic vein cutdown approach. Venous access was obtained by percutaneous subclavian vein puncture in the remaining patients. A total of 53 patients had device replacement alone for battery depletion. The subclavian technique used at the authors' institutions consists of placing an intravenous line in the ipsilateral arm of the subclavian vein used for cannulation. Then, a small amount of radiographic contrast material (10-15cc) is then injected to define the subclavian anatomy to facilitate the percutaneous puncture. This eliminates repeated blind subclavian punctures and also allows cannulation of the vein in a lateral position avoiding clavicle and first rib interactions and the virtual elimination of lead fractures. The initial subclavian puncture is made by a "micropuncture" technique with a 21-gauge needle and then a small introducer upsizes the initial 0.018 guidewire to a 0.035 standard introducer wire. This is intended to decrease pneumothoraces and reduce the potential for bleeding from inadvertent arterial punctures.
The authors used the smallest introducer sheaths, active-fixation leads, and careful attention was given to hemostasis in the device pocket.

The majority of patients in either group were discharged within 24 hours of the procedure. Many patients were discharged the same day as their procedure. Patients hospitalized longer than 24 hours after the procedure had concurrent medical problems such as congestive heart failure, immediate postoperative coronary bypass, valve surgery, pulmonary disease, etc. There was no difference in length of stay between groups.

**Patient Population**

A total of 1,025 patients (597 men, 428 women; age 24-100 years, mean 72 years) underwent permanent pacemaker/ICD implantation by five experienced implanting physicians. Indications for pacing were AV block (n = 116), atrial fibrillation/tachycardia (n = 303), sinus node dysfunction (n = 205), ventricular tachycardia (n = 108), congestive heart failure (n = 32), battery replacements with lead replacement or pocket revision (n = 208), and battery replacement alone (n = 53).

**Results**

At the time of the procedure, 470 patients (277 men, 193 women; mean age 72 years) had an INR > 1.5. The mean INR in this group was 2.6 ± 1.0 (range 1.5-6.9). Ten early (in hospital) complications occurred in the anticoagulated group. One atrial lead dislodgement occurred and nine pocket hematomas were seen in patients with mean INR 3.0 (2.0-6.9). Two hematomas required pocket exploration and the ether seven were treated with pressure dressings alone. These all resolved without sequelae. Six hematomas were seen at the 2-week follow-up and were treated with pressure dressings. Warfarin was temporarily stopped (1 week) in one patient but all the remaining patients remained on their usual anticoagulant therapy.

Another group of 555 patients (320 men, 235 women; mean age 72 years) had an INR < 1.5 at the time of the procedure. This group included both patients whose warfarin had been discontinued or reversed and patients on no anticoagulant therapy or antiplatelet agents alone. The mean INR in this group was 1.1 ± 0.1 (range 0.9-1.4). Twenty-one complications occurred in the nonanticoagulated group: 9 early pocket hematomas were all treated with pressure dressings and discontinuation of heparin (one patient), 3 late hematomas occurred at 2-week follow-up, 5 lead dislodgements (4 atrial, 1 ventricular), 3 pneumothoraces, and 1 CVA.

Heparin was only used in four patients. One patient in the INR > 1.5 group was on heparin and had no complications. Three patients were on heparin in the INR < 1.5 group. There were no immediate complications, but one hematoma developed within 24 hours and required a pressure dressing.

Thirty-seven patients in this series underwent implantation of biventricular defibrillators (bi-v). There were no immediate complications in the 15 bi-v patients with an INR > 1.5. One patient had a hematoma requiring a pressure dressing while still in the hospital and two had small hematomas requiring no treatment. One patient developed a hematoma requiring a pressure dressing at 1 week follow-up. These all resolved without further therapy. There were three complications in the 22 patients with INK < 1.5 receiving bi-v devices. One patient developed a local abscess that resolved with oral antibiotics, one patient had a hematoma requiring a pressure dressing, and one patient had a small pneumothorax that resolved without intervention.

In the 53 patients who were having device replacements without any lead or pocket revision, 21 had an INR < 1.5 and 32 had INRs > 1.5. No complications were seen in this cohort. Results are shown in Table I.

**Discussion**

As a result of the Stroke Prevention in Atrial Fibrillation Trial (SPAF) more patients with atrial tachyarrhythmias are anticoagulated with warfarin. In addition, more patients are undergoing device procedures for atrial tachyarrhythmias because studies like the Ablate and Pace Trial (APT) demonstrated improved quality-of-life and functional capacity with pacing therapy. With more patients on anticoagulant therapy undergoing outpatient device procedures, the question of perioperative anticoagulation has become important.
There is some inherent risk to discontinuing anticoagulant therapy prior to device implantation. Likewise, there is risk, cost, and often prolonged hospital stays associated with rapid normalization of the coagulation factors with blood products and vitamin K.

Resumption of anticoagulant therapy with heparin after surgery may also lead to bleeding complications. In a recent study by Michaud et al., 49 consecutive patients with an indication for anticoagulation with heparin after pacemaker or defibrillator implantation were randomized to receive intravenous heparin 6 hours (n = 26) or 24 hours (n = 23) postoperatively. Both groups also received warfarin on a daily basis starting the evening of surgery. Twenty-eight patients who received postoperative warfarin alone and 115 patients who did not receive anticoagulation were also followed in a study registry. A pocket hematoma developed in 6 (22%) of 26 patients who were irredtud with intravenous heparin 6 hours postoperatively, as compared with 4 (17%) of 23 patients who were treated with intravenous heparin 24 hours postoperatively (P = 0.7). In total, a pocket hematoma developed in 10 (20%) of 49 patients treated with heparin, 1 (4%) of 28 patients treated with warfarin alone, and 2 (2%) of 115 patients who received no anticoagulation (P < 0.001).

Goldstein et al. previously published a retrospective study demonstrating the safety of outpatient permanent pacemaker placement in 37 patients on warfarin therapy (INR 2.5 ± 0.2) using a cephalic vein cutdown approach. Al-Khadra recently reported a series of 47 patients undergoing device implantation on warfarin therapy with a mean INR of 2.3. Using a percutaneous axillary vein approach, there were no hematomas requiring evacuation or other bleeding complications. Our prospective data, involving mainly a percutaneous subclavian approach for venous access supports these previous reports of relatively few patients that normalization of coagulation factors may not be necessary.

Our nonrandomized study may have introduced some selection bias. Some of the implanting physicians normalized the INR on all of their patients prior to procedures and other physicians continued warfarin on every patient. Small differences in techniques are certainly possible among the various implanters and could influence results in a smaller series. In view of the large number of patients in this study, it seems likely that the results would have been the same in the warfarin group had the reversal of anticoagulation been done in a random manner. The group with reversal of anticoagulation and the use of postoperative heparin would most probably have shown the same untoward bleeding complications reported by Michaud et al. and perhaps a higher incidence of stroke. The finding that patients with INRs between 1.5 and 6.9 underwent permanent pacemaker placement with no difference in bleeding complications compared to those with INR < 1.5 suggests that careful intraoperative pocket management may be more important than the presence or absence of warfarin therapy. Schwartz has suggested that the coagulation cascade plays only a minor role in hemostasis for minor surgical procedures. The primary response consists of capillary vasoconstriction with "sticky" endothelium sealing off the vessel with platelet adhesion playing an important role, neither of which are affected by warfarin anticoagulation.

References