Original Article

Peri-procedural Anticoagulation and the Incidence of Haematoma Formation after Permanent Pacemaker Implantation in the Elderly

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Background: **Haematoma formation is a recognised complication after permanent pacemaker (PPM) implantation. The contribution of peri-procedural anticoagulation to the risk of haematoma formation is unclear.**

Method: **The records of 518 consecutive patients, mean age 76.9 ± 9.8 years, receiving their first PPM (2004–2007) in a single tertiary referral centre were reviewed. Follow-up was complete for 506 patients (97.7%) up to six weeks. Haematomas were diagnosed clinically, and further subdivided according to the need for evacuation.**

Results: **There were 27 instances of haematoma formation in 25 patients (4.9%) with 19 requiring drainage or evacuation. Twenty-one of the 25 patients who developed a haematoma had stopped warfarin and received bridging therapeutic anticoagulation pre- and post-PPM. The incidence of haematoma was significantly greater in those receiving peri-operative therapeutic anticoagulation (26.9% vs 0.9%, $p < 0.001$), but was unaffected by the use of anti-platelet therapy. Most haematomas developed in patients whose heparin was recommenced within 24 hours of implantation. The development of haematoma post-PPM increased median hospital stay significantly ($p < 0.001$). The main indication for anticoagulation in these patients was atrial fibrillation (79.5%) and most of these patients had a low to intermediate risk of peri-procedural thromboembolic events.**

Conclusion: **Peri-operative therapeutic anticoagulation is associated with more than 25-fold increase in haematoma formation post-pacemaker implantation. The risk-benefit ratio of therapeutic anticoagulation should be carefully considered, particularly in patients with a low risk of thromboembolic events.**

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Keywords. Pacemaker; Haematoma; Complication; Anticoagulation

Introduction

Implantation of a permanent cardiac pacemaker (PPM) is a relatively common procedure. Recently performed surveys have demonstrated that the implantation of PPMs is increasing steadily in Australia, with 590 PPM implantations per million population in 2005, a 20% increase from four years earlier [1]. Similar trends regarding PPM implantation have been reported in international studies [2].

Pocket haematoma formation is one of the most common and well-recognised complications following implantation of a PPM, with an incidence of 0.6–2.6% reported in the literature [3–7]. A recent audit of PPM implantation in New South Wales reported an overall complication rate of 11.9% with most complications resulting from lead displacements and pocket haematoma formation [7]. Relatively few contemporary studies have assessed PPM-related haematoma formation in detail or the clinical factors associated with this complication. One recent report indicated a high risk of haematoma formation with bridging therapy [8].

We conducted a single centre, retrospective analysis of the incidence and predictors of haematoma formation following PPM implantation, with a specific focus on the impact of anticoagulation and anti-platelet therapy.

Materials and methods

Study Population

We retrospectively reviewed electronic discharge records and inpatient clinical records up to six weeks after

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PPM implantation of all patients ($n = 518$) who underwent implantation of a first PPM at Concord Repatriation General Hospital (a tertiary care facility of the Sydney South West Area Health Service) between January 2004 and December 2007 inclusive. This retrospective review was approved by the hospital Human Ethics Committee. We included both acute and elective presentations for PPM insertion and patients referred from other hospitals for PPM implantation. We excluded patients with a prior PPM, those undergoing elective unit replacements (EUR) without change of pacemaker lead, and those patients receiving automated implanted cardiac defibrillators (AICD). Adverse events identified from electronic records and separation notes were confirmed by a detailed review of the hospital file. Recording of adverse events was performed using published (Choo) [9] and predefined criteria (Supplementary Table 1). Agreement by all three data collectors (IR, VC, JL) was required and disagreement was resolved by consensus.

Outcomes

The primary outcome of the study was the rate of haematoma formation within six weeks of PPM implantation. Haematoma was defined based on documented clinical and/or ultrasound diagnosis of wound haematoma by the implanting surgical team. Haematomas were sub-classified according to whether they required re-operation for surgical evacuation. Specific anticoagulation and anti-platelet regimes received by the patients and the relationship of these to haematoma formation were also investigated.

Other complications were recorded as secondary outcomes in order to determine if there was a relationship between these and haematoma formation. These included pacemaker infection, as defined by Choo et al. [9], lead displacement, pneumothorax, cardiac perforation, arrhythmia (requiring resuscitation) and death. Our definitions are consistent with the current local [7] and international literature [6].

Statistical Analysis

Data are summarised as frequencies and percentages for categorical variables. Normally distributed continuous variables are presented as mean and standard deviation. Otherwise continuous variables are presented as medians and twenty-fifth and seventy-fifth percentiles. Differences in proportions were analysed using the chi-square or Fisher's exact test as appropriate. Continuous variables were analysed by *t* tests or by using the Mann–Whitney *U* test for non-parametric data. Multivariable backward stepwise logistic regression analysis was performed to identify independent predictors of haematoma formation. We included all variables with a univariate *p* value of <0.25 in the multivariate model to ensure capture of all independent predictors of haematoma formation. Adjusted odds ratios (OR) and 95% confidence intervals (CIs) were reported for the independent predictors of haematoma formation. The adequacy of the regression model was assessed with the Hosmer–Lemeshow goodness-of-fit test.

All statistical analyses were performed using SPSS version 16 and SAS version 9.0 (SAS Institute). For all hypothesis testing a value of $p < 0.05$ was considered significant.

Standard Implantation Procedure

All pacemaker implantations at our institution were performed by experienced cardiothoracic surgeons in operating suites under fluoroscopic guidance. Local or general anaesthetic was used at the preference of the operating surgeon. All patients received routine antibiotic prophylaxis before and for 24 hours after the procedure. Venous access via the cephalic approach was usually preferred, and was followed by the subclavian approach if the cephalic vein was technically unsuitable.

Post-implantation, the electrode position was confirmed by analysing the intra-cardiac ECG, evaluating pacing thresholds and by chest X-ray. Pacemaker parameters were recorded on the day of discharge (usually the day after surgery). Once discharged from hospital, patients were followed up at a dedicated pacemaker clinic in four to six weeks time.

Results

Baseline Characteristics

A total of 518 patients received a new permanent pacemaker (PPM) at our centre between 2004 and 2007. Complete data to six weeks post-operatively was obtained in 506 patients (97.7%) with 12 patients being lost to follow-up. Our population was predominantly elderly (mean age was 76.9 ± 9.8 years) with a slight male predominance. The most common indication for pacing was high degree atrio-ventricular block (31.4%), followed by atrial fibrillation with a slow ventricular response rate (21.1%), and sick sinus syndrome (19.6%). Pacing was DDD(R) or VVI(R) in 57.7% and 40.7% of cases respectively. Over 75% of cases were acute presentations requiring urgent or semi-urgent implantation (Table 1).

Haematoma Formation

There were 27 instances of pocket haematoma formation in 25 patients (4.9% of all patients). In 21 of these events, occurring in 19 patients, surgical evacuation of the haematoma was required. Two patients had two separate instances of haematoma formation complicating PPM insertion, with each event requiring surgical evacuation.

Other Complications

In those with a haematoma complicating PPM insertion, this was usually the first complication experienced (80% of patients). In five patients (20%), haematoma followed another complication with three occurring after repositioning of a displaced PPM lead and a further two occurring after deep seated infection of the PPM site requiring intravenous antibiotics or evacuation or both. There were no cases of other serious complications (e.g. infection) following haematoma formation.