A NOVEL STANDARD OF QUALITY EVALUATION IN BRADYARRHYTHMIA PACING

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**Introduction** The annual implantation rate for bradyarrhythmia pacing devices continues to increase, due to the aging population fulfilling the indication criteria defined in national guidelines. Morbidity and mortality benefits conferred by pacemaker implantation, are well documented and evidence based. However, the complications arising from such invasive procedures are less well documented. The reported rates of complications are out of date and compounded by variation in complication definitions and the time scale of evaluation. Further confusion arises as a result of the denominator utilised to report complication rates for example, per procedure volume, or per number of leads deployed. The predominant focus on complication data has been peri-procedure and is thus insufficient to accurately represent patient morbidity.

This study presents novel complication data reporting for de novo bradyarrhythmia pacing systems implanted at a high volume centre, with all complications and any form of re-operation tracked to 1-year post implant.

**Methodology** A prospective review was performed following consecutive virgin pacemaker implants, between April 2008 and March 2011, at a tertiary cardiothoracic centre in the UK. All procedures were consultant led. Health records for each patient were reviewed independently by two clinicians, analysing the documentation pertaining to the primary procedure and all subsequent health care episodes within 1 year. Complications within this period were defined as follows; (1) radiographic evidence of a pneumothorax confirmed by a consultant radiologist, (2) pericardial effusion demonstrated on transthoracic echocardiogram indicated on clinical grounds and (3) any return to theatre within one calendar year post implant.

**Results** Between April 2008 and March 2011, 1224 new bradyarrhythmia devices were implanted. Within 1 year of the index implant, 53 patients (4.3%) had one or more complications or re-operations. Cumulatively, 58 complications and re-operations were encountered (4.7%), with 5 patients sustaining two events. 6 pneumothoraces (0.5%) were identified, 1 haematoma mandating surgical evacuation (0.1%) and 1 pericardial effusion (0.1%). Regarding re-operation within the first year, 6 device extractions (0.5%) were performed, 30 procedures for either lead displacement or to refine pacing parameters (2.5%), 9 upgrades to cardiac resynchronisation therapy or implantable cardioverter defibrillator (0.7%) and 2 pocket revisions (0.2%).

**Conclusions** For primary bradyarrhythmia pacemaker implantation at a high volume tertiary cardiothoracic centre, we report an overall 4.7% complication rate to 1 year post implant.