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Lead Extraction for Treatment of Cardiac **Device Infection: A 20-Year Single Centre Experience**

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Background	Infection is one of the most feared complications of cardiac implantable electronic devices. We report microbiology, antimicrobial therapy and infection recurrence in patients with cardiac device infection (CDI) treated with transvenous lead extraction (TLE) at a single centre over a 20-year period.
Methods	We identified a cohort of consecutive patients undergoing TLE for CDI by a single operator at a single high volume centre. Retrospective analysis of patient characteristics, microbiology, outcomes and infection recurrence was performed.
Results	Between May 1992 to March 2012, 348 patients underwent extraction due to localised or systemic infection. Seven hundred and twenty leads were extracted from these patients. The mean follow up was $5.5+/-4.9$ years. Staphylococcal species accounted for 81% of CDI. A difference is seen in infection onset for device revision compared with initial implants [median 10 months vs 24 months, P = 0.0001]. Duration of antibiotics therapy depended on the nature of the CDI (21 days post TLE for systemic vs. 10 days for localised infection, P < 0.0001). There was comparable mortality in the 37 (11.2%) patients who did not have a replacement device compared with a replacement (30% vs 29%, P = 0.9). Retained lead fragments are a risk factor for CDI recurrence (20.8% recurrence in retained fragments vs 4.3% in complete removal, P = 0.006).
Conclusion	Cardiac device infection can be successfully treated with a combination of TLE and antibiotic therapy. Device therapy can be safely withdrawn in some patients. Retained lead fragments are a risk factor for recurrent CDI following extraction.
Keywords	Lead extraction • Pacemaker • Internal cardioverter-defibrillator • Infection

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Introduction

Q3 Infection is one of the most feared complications of cardiac implantable electronic devices (CIEDs). While relatively uncommon, cardiac device infection (CDI) has been reported to be increasing in frequency [1-3]. A CDI can present with a

pulse-generator pocket infection or bloodstream infection 18 with or without device-related endocarditis. A CDI is associated with increased morbidity, mortality, and financial cost [4]. Recent guidelines advocate complete system removal in the event of CDI in both systemic and pocket infections [5]. 22 Transvenous lead extraction (TLE) is the preferred approach 23

Abbreviations: CIED, Cardiac implantable electronic device; CDI, Cardiac device infection; CRT, Cardiac resynchronisation therapy; ICD, Internal cardioveterdefibrillator; TLE, Transvenous lead extraction; PPM, Permanent pacemaker

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for system removal in most cases. Previous reports exist 24 25 regarding outcomes in CDI requiring TLE though reports 26 involving long-term experience are limited [6–9]. We report 27 microbiology, antimicrobial therapy and infection recurrence in patients with CDI treated with TLE at a single centre over a 28 20-year period. 29

Methods 30

We identified a cohort of consecutive patients undergoing 31 TLE by a single operator (RG) at the Eastern Heart Clinic at 32 The Prince of Wales Hospital, Sydney, Australia, between 33 34 May 1992 and March 2012. Local ethics approval was obtained. We selected patients with an indication of localised 35 36 (pacemaker site tenderness, swelling or erythema, skin erosion or discharge from the pocket) or systemic infection 37 38 (bacteraemia and/or endocarditis) from all patients under-39 going TLE during the study period. Retrospective analysis 40 of patient characteristics, microbiology, outcomes and infection recurrence was performed. Patient follow-up was 41 assessed by review of medical records for patients followed 42 up at our institution. Information on patients who did not 43 44 have subsequent follow-up at our institution was obtained from patient surveys and from the general practitioner. For 45 patients undergoing multiple TLE procedures, length of 46 follow-up and outcomes are relative to most recent proce-47 dure. Relevant data were entered into a dedicated database 48 for evaluation. 49

Statistical Methods 50

Statistical analysis was performed using Prism Graphpad 51 52 version 6, San Diego, CA, USA. Continuous variables were expressed as mean \pm SD, if they were normally distributed. 53 54 Otherwise the median was reported with first and third 55 quartiles. Continuous variables were summarised as mean \pm SD when the distributions were appropriate, and as median with interquartile range (Q1 and Q3, respectively) 57 58 if the distribution was free. We performed univariate anal-59 yses for factors that may increase the rate of recurrent CDI post TLE. Following univariate analysis we planned a step-60 wise logistic regression including all univariate analysis 61 with a P-value < 0.1. All tests of significance were two 62 sided, and P-value of < 0.05 was considered statistically 63 64 significant.

Results 65

Five hundred and twenty-three patients underwent extrac-66 tion procedures from May 1992 to March 2012. Data was 67 68 missing for 13 patients, leaving 510 patients. The characteristics, indications and procedural outcome for the whole 69 70 cohort of patients have previously been reported [10]. From 71 this cohort, 348 patients underwent extraction due to local-72 ised or systemic infection. Seven hundred and twenty leads 73 were extracted from these patients. Eighty per cent of 74 patients were male. The mean age was 71.2 ± 13.2 years

(range 19-96). The mean age for males was 71.6 ± 12.5 years and for females 69.8 ± 15.9 years.

There was a higher baseline creatinine in patients with CDI compared with other indications for extraction (mean creatinine 122.5 +/- 4.9 in infection vs 93.4 +/- 3.3 without, P = 0.0001). There was a shorter time since the most recent device procedure in patients with CDI compared with non-CDI (25.1 +/- 1.5 months compared with 32.9 +/- 1.8 months respectively, P = 0.0008). The proportion of patients with complex devices (CRT and ICD's) compared with pacemakers were similar in CDI and other indications for extraction (χ^2 for difference between groups 0,1, P = 0.8). There was no significant difference to the number of patients with an initial implant compared to a device revision or upgrade in CDI versus non-CDI (χ^2 for difference between groups 1.6, P = 0.2).

The mean time of follow-up was 5.5+/-4.9 years (range 0.2 – 18 years). While survival data was available for all 348 patients, 42 had incomplete data with respect to recurrent device infection and cause of death. Follow-up was complete for all patients who did not have a replacement device after lead extraction.

The median lead implant dwell time was 41 months (Q1-3, 14-85 months); the oldest lead had been in place for 23.9 years. The mean number of leads extracted per procedure was 1.8 \pm 0.75. A maximum of five leads were extracted from a single patient during the same procedure. Indications for extraction included pocket infection (61.2%) and systemic infection (38.8%). Systemic infection included bacteraemia (15%), bacteraemia with vegetations detected on echocardiography (21%) and vegetations without bacteraemia (2.8%).

Patients with systemic infection more commonly required mechanical extraction tools instead of simple traction (72.3% in systemic infection compared with 55.9% in pocket infection χ^2 for difference between groups 20.7, P < 0.0001). Despite this there was no difference in overall procedural time between these two groups (2.5 +/- 0.7 hours for pocket infection vs 2.4 + / - 0.1 hours for systemic infection, P = 0.3).

A CDI occurred after initial device implantation in 167 (48%) patients and after a revision (e.g., system upgrade, lead revision, generator exchange) in 181 (52%). There was a statistically significant difference in time to onset of infection for device revision compared with initial implants [median time of 10 months (Q1-3, 3-24 months) compared with 24 months (Q1-3, 8-48 months) respectively, P = 0.0001]. A statistically significant difference in time to onset of infection was also seen following initial implantation of an ICD (internal cardiac defibrillator) compared with a PPM (permanent pacemaker) [median time of 12 months (Q1-3, 6-24 months) compared with 24 months (Q1-3, 9-48 months) respectively, P = 0.049].

The majority of patients with endocarditis were cured following extraction however 14.5% of these patients had ongoing sepsis and subsequent death from multi-organ failure despite system extraction. The post-procedural mortality was significantly lower at 5.8% with bacteraemia alone and 1.9% in pocket infection.

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