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Ventricular lead redundancy to prevent cardiovascular events and sudden death from fracture in pacemaker-dependent children cardiovascular events and sudden death from lead

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BACKGROUND Children requiring a permanent epicardial pacemaker (PM) traditionally have a single lead placed on the right ventricle. Lead failure in pacemaker-dependent (PMD) children, however, can result in cardiovascular events (CVEs) and death.

OBJECTIVE The purpose of this study was to determine if redundant ventricular lead systems (RVLS) can safeguard against CVE and death in PMD children.

METHODS This was a single-center study of PMD patients undergoing placement of RVLS from 2002-2013. Patients ≤21 years of age who were PMD were included. Patients with a biventricular (BiV) system placed for standard resynchronization indications were excluded. RVLS patients were compared to PMD patients with only a single pacing lead on the ventricle (SiV).

RESULTS Seven hundred sixty-nine patients underwent PM/implantable cardioverter-defibrillator placement with 76 BiV implants; 49 patients (6%) were PMD. Thirteen patients underwent implantation of an RVLS. There was no difference between the RVLS group (n = 13)and SiV PMD control group (n = 24) with regard to age (RVLS 9.5 \pm 5.8 years vs SiV 9.4 \pm 6.7 years, P = .52), weight (RVLS 38.2 \pm 32.6 kg vs SiV 35.2 \pm 29.3 kg, P = .62), indication for pacing, procedural

complications, or time to follow-up. There were 2 lead fractures (17%) in the RVLS group (mean follow-up 3.8 \pm 2.9 years), with no deaths or presentations with CVE. The SiV control group had 3 lead fractures (13%) (mean follow-up 2.8 \pm 2.9 years), with no deaths, but all 3 patients presented with CVE and required emergent PM placement.

CONCLUSION RVLS systems should be considered in children who are PMD and require permanent epicardial pacing. BiV pacing and RVLS may decrease the risk of CVE in the event of lead failure in PMD patients.

KEYWORDS Biventricular pacing; Children; Pediatrics; Pacemaker dependent; Sudden death

ABBREVIATIONS BiV = biventricular; **CHB** = complete heart block; **CRT** = cardiac resynchronization therapy; **CVE** = cardiovascular event; **ICD** = implantable cardioverter-defibrillator; **LV** = left ventricle; PM = pacemaker; PMD = pacemaker dependent; RV = right ventricle; **RVLS** = redundant ventricular lead system; **SiV** = single ventricular pacing lead system

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Introduction

Cardiac resynchronization therapy (CRT) has emerged as an important tool in the treatment and management of adult heart failure. Multiple large trials of adult heart failure patients have demonstrated that CRT devices decrease mortality and improve

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hemodynamics and quality of life. 1-3 These devices currently are considered the standard of care in adults with New York Heart Association class II-IV heart failure, left bundle branch block (ORS > 150 ms), and low ejection fraction (< 35%). More recent novel uses for CRT have emerged in patients with shorter QRS durations, less severe heart failure, and those requiring chronic pacing.^{3,5–7} The use of biventricular (BiV) pacing for CRT has also emerged as an important tool in children and patients with congenital heart disease.^{8–12}

Pacemaker-dependent (PMD) patients present another possible arena where BiV pacing may be beneficial. Historically, children requiring a permanent epicardial pacemaker (PM) 55

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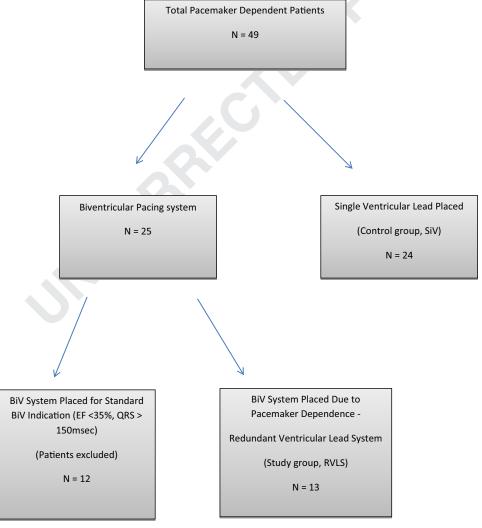
traditionally have a single lead placed on the ventricle during PM implantation. Failure of the pacing system in the event of lead fracture or failure, however, can result in cardiovascular collapse and death in PMD patients. 13,14 BiV pacing systems and redundant ventricular lead systems (RVLS) can potentially safeguard against this scenario by having a "backup" lead that would continue to function in the event of lead fracture or failure.

The purpose of this report is to describe our experience with the use of BiV pacing and ventricular lead redundancy in young patients and patients with congenital heart disease who are PMD.

Methods

The study was a single-center retrospective case-control study of pediatric PMD patients. Institutional Review Board (IRB) approval was obtained for this investigation. Patients undergoing placement of RVLS at Lucile Packard Children's Hospital-Stanford University for a primary indication of PMD from 2002-2013 were included. Patients with BiV systems placed for standard resynchronization indications

(eg., severely diminished ventricular function with ejection fraction <35% and QRS prolongation >150 ms) were excluded. Clinical characteristics and outcomes in the RVLS patients were compared to those of a control group of PMD patients who had only a single pacing lead placed on the ventricle (SiV). The control group (SiV) included all PMD patients with 1 ventricular pacing lead (Figure 1). The primary F1131 end-point was sudden death or cardiovascular events (CVEs) secondary to lead failure or fracture. For the purpose of this investigation, PMD was defined as the presence of complete heart block (CHB), with ventricular pacing for $\geq 99\%$ of the total beats and no intrinsic rhythm > 30 bpm during PM interrogation. The PM interrogation process was standard at the institution during the study period, with 1 primary person performing the majority of the interrogations. Determining pacemaker dependence involved gradual pacing rate reduction down to a rate of 30 bpm. The general practice was for patients with a PM and implantable-cardioverter-defibrillator (ICD) to have follow-up of the device every 3 months, either in the clinic or remotely via transtelephonic checks, and office visits for device interrogation at a minimum of every 6 months.



Flow diagram of pacemaker-dependent (PMD) patients. Breakdown of patients who were pacemaker dependent is shown. BiV = biventricular; EF = ejection fraction.

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