

Infants with congenital and postoperative complete heart block (CHB) that require permanent pacemakers (PMs) must receive epicardial leads and abdominal generators due to their small size. Younger age and lower weight at PM implantation have been associated with increased risk of PM complications in this population. Prior studies have failed to identify additional predictors of device-related adverse events (DRAE) due to limited sample size.

To explore associations between patient size, device characteristics, and anatomic complexity with DRAE in infants with CHB requiring permanent PM implantation.

Multicenter retrospective cohort study including patients who received a permanent epicardial PM for high-grade or CHB at <12 months between 1/1/2015-8/1/2021. The primary outcome was time to DRAE, defined as: (1) lead fracture or insulation break; (2) lead exit block; or (3) surgical site infection (SSI) requiring hospitalization for antibiotics, washout, or pocket revision. Time-to-event analysis was performed using univariate Cox regression analysis.

119 infants underwent PM implantation for CHB (81 postoperative, 38 congenital) at a median age and weight of 104 days (range 1-360) and 4.6 kg (1.9-9.7). Dual-chamber PMs were implanted in 94 patients (79%). DRAE occurred in 14 (12%) patients at a median 708.5 days (30-2673) from PM implantation: lead fracture/insulation breach in 7, SSI in 4, exit block in 2, and coronary compression in 1. Lower weight at PM implant was associated with time to DRAE, with those <3 kg at highest risk (HR 5.47, 95% CI 1.17-25.6, p=0.03). A higher ratio of generator volume/patient weight was associated with time to DRAE (HR 1.76 per 1 cc/kg, 95% CI 1.04-2.99, p=0.037). Analyzing DRAE as a binary outcome, a generator volume/patient weight ratio >4 cc/kg had a sensitivity of 21% and specificity of 95% in predicting the primary outcome. Birth weight, gestational age, presence of congenital heart disease, dual-chamber (vs single-chamber) PM, and RACHS-1 surgical risk category were not associated with time to DRAE.

Infants with lower weight and higher generator volume/patient weight ratios are at highest risk of DRAE from permanent PMs. Generator volume and patient size should be factored into pulse generator selection for infants with CHB, with caution recommended for ratios >4 cc/kg.

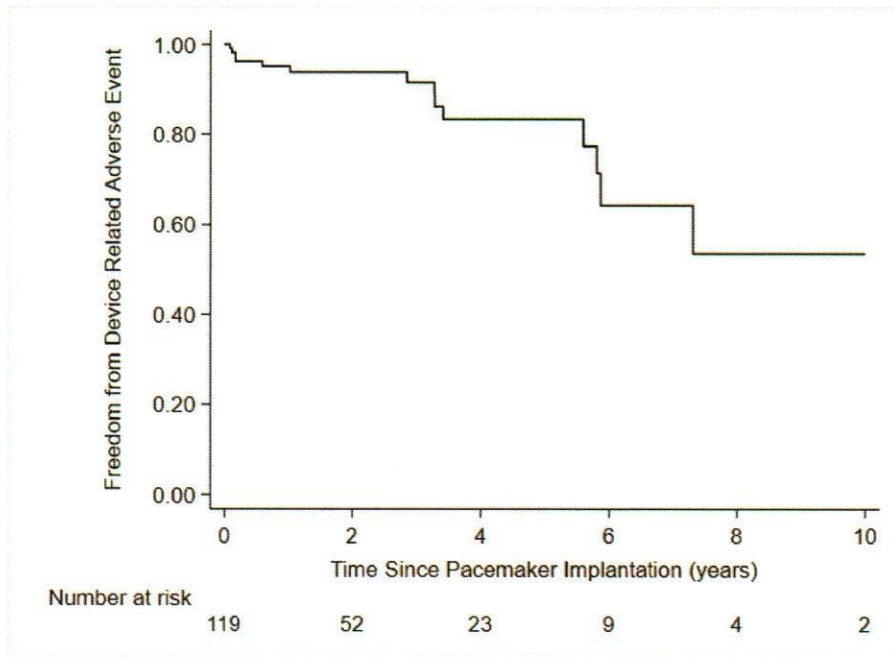


Figure: Kaplan-Meier curve for the primary composite outcome of device-related adverse event.

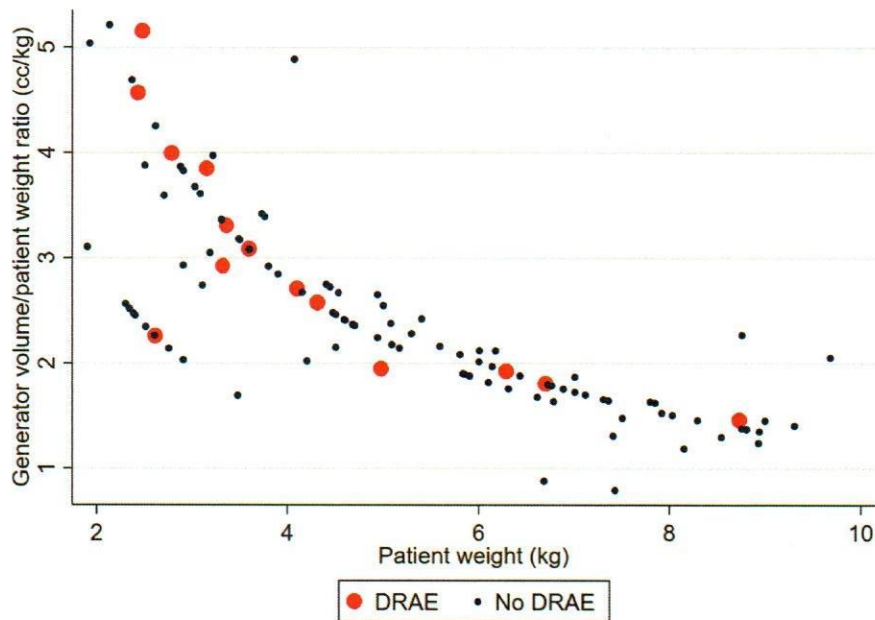


Figure: Scatter plot comparing generator volume/patient weight ratio to patient weight. DRAE = device-related adverse event.

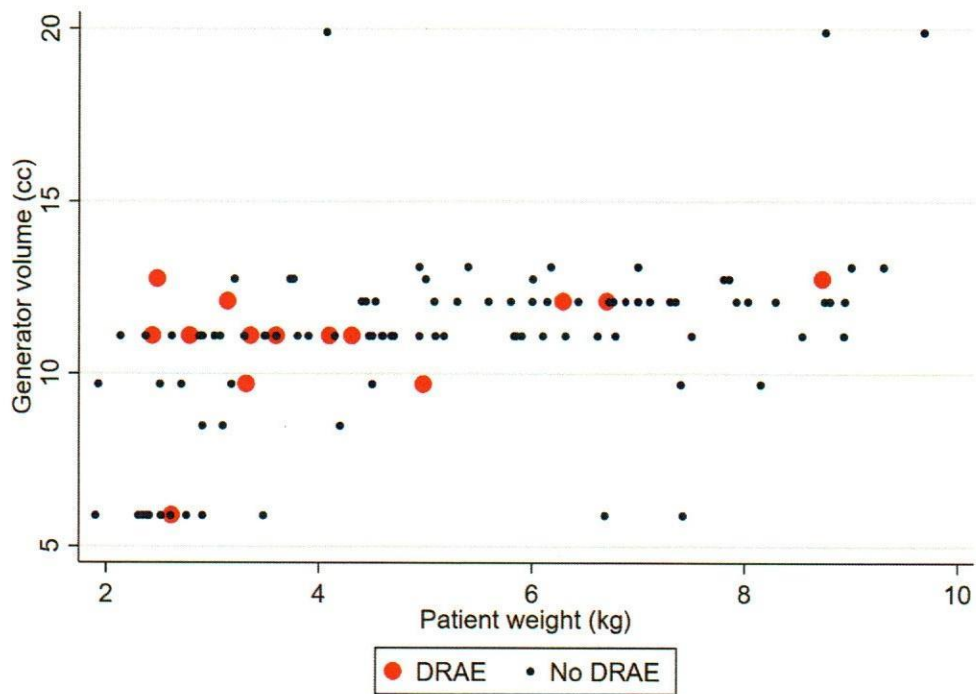


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