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The Initial Analysis Of Infectious Adverse Events In Pediatric Ventricular Assist Devices Reported To The Action Registry

Author Block: N. Bansal[1], S. R. Auerbach[2], M. F. Shezad[3], A. B. Patel[4], A. Reichhold[5], A. Lorts[6], D. N. Rosenthal[7], A. Shiu[7], L. Danziger-Isakov[8].
[1]Children's Hospital at Montefiore, Bronx, NY, [2]University of Colorado Denver, Anschutz Medical Campus and Children's Hospital Colorado, Denver, CO, [3]Division of Cardiothoracic Surgery, Cincinnati Children's Hospital Medical Center, Cincinnati, OH, [4]Division of Infectious Diseases, Ann & Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, [5]Ann and Robert H. Lurie Children's Hospital of Chicago, Chicago, IL, [6]Cincinnati Children's Hospital Medical Center, Cincinnati, OH, [7]Stanford University School of Medicine, Palo Alto, CA, [8]Division of Infectious Diseases, Cincinnati Children's Hospital Medical Center, Cincinnati, OH,

Abstract:
Purpose Infection adverse events (IAE) are frequent in pediatric ventricular assist device (VAD) patients. In this study we aim to describe IAE in pediatric VAD patients from the Advanced Cardiac Therapy Improving Outcome Network (ACTION) multi-center registry.
Methods VAD data from the ACTION registry (9/2018 to 8/2021) were analyzed. Cohort was divided by device type as paracorporeal (PC) (Berlin EXCOR, Pedimag, Centrimag, Rotaflow) and intracorporeal (IC) (Heartware (HVAD), Heartmate3 (HM3), Heartmate2, Syncardia). IAE rates and incidence per 100 patient months were described with descriptive statistics and compared between groups by chi-square test.
Results Of the 506 patients, 139 patients (27.5%) experienced at least one IAE. Majority were sepsis (77, 34.5%) or localized non device related (77, 34.5%), 51 (22.9%) being IAE of percutaneous site and only 4 (1.8%) were pump related. Median time to first device related IAE was 40 days [6 - 1648]. Infections were bacterial in 121 (46.5%), fungal in 10 (3.86%) and unknown in 119 (46%). Upon comparison, patients on PC devices were significantly younger (0.81 vs 15.2 years), smaller (0.39 vs 1.46 m^2), and sicker (INTERMACS profile1 and 2, ECMO at implant and ventilator support; all p values <0.05) than patients on IC. There was no difference in gender, diagnosis, and dialysis frequency between devices. PC devices had a significantly higher IAE rate and had significantly more sepsis IAE (Table). Device related IAE were significantly higher in HM3 than HVAD [17 (47.2%) vs 7 (17.9%); p= 0.019; IAE/100 patient months= 2.58 vs 1.02; p= 0.007], which seem to be driven by driveline infections (IAE/100 patient months= 2.28 vs 1.02; p =0.028)
Conclusion A significant proportion of children on VAD experienced IAE, the majority of which are not device related. PC VAD had a higher risk of IAE than IC VAD. Within IC devices, there was a significantly higher rate of driveline site infections in HM3 patients.

Infection Adverse Events (IAE) in pediatric VAD

	Intracorporeal (IC)*(n = 206)*		**Paracorporeal (PC)*(n = 361)***		*p* value
Infection Rate					
Number of IAE	76		151		
Subjects with at least 1 IAE	49		90		
IAE/patient	23.8		24.9		0.79
IAE/100 patient months	5.62		14.72		0.001*
Type of major infection	n (%)	IAE/100 patient months	n (%)	IAE/100 patient months	
Device related	24 (31.5%)	1.77	31 (20.5%)	3.02	0.073
Non device related	52 (68.5%)	3.84	120(79.5%)	11.69	
Location of Major Infection					
Mediastinitis	2 (2.6%)	0.14	9 (5.9%)	0.87	0.28
Sepsis	20 (26.3%)	1.48	60 (39.7%)	5.84	0.04*
Internal pump component	2 (2.6%)	0.14	2 (1.3%)	0.19	0.52
Localized non-device	26 (34.2%)	1.92	41 (27.1%)	3.99	0.28
Percutaneous site and/or pocket	22 (28.9%)	1.62	29 (19.2%)	2.82	0.10
Other	4 (5.2%)	0.29	10 (6.6%)	0.97	0.71

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