Prolonged duration of Impella 5.5 does not impact clinical outcomes

Zachary W. Sollie MD[1], Tobi Kamoru BS[2], Lefan Xuan BS[1], Bipul Mainali BS[3], Brady Gunn DO[1], Jingwen Zhang MS[1], Brett A Welch MBA MHA[1], Lucas Witer MD[1], Brian A. Houston MD[1], Anthony Carnicelli MD[1], Arman Kilic MD[1]

1.Medical University of South Carolina, Charleston, SC
2. Virginia Commonwealth University School of Medicine, Richmond, VA
3. University of Alabama Heersink School of Medicine, Birmingham Alabama

INTRODUCTION

- The Impella 5.5 (Abiomed, Danvers, MA) is an effective temporary ventricular assist device in cardiogenic shock patients
- Device is currently only FDA-approved for 14 days of use
- Prior studies show similar safety and efficacy in use > 14 days
- This study seeks to further explore the clinical outcomes in prolonged usage of this device

METHODS

- All Impella 5.5 devices implanted at our institution between Jan 2021 and Jan 2024 in adults ≥ 18 years old were retrospectively reviewed
- Patients were stratified into groups of ≤ 14 days with device and > 14 days with device
- The primary outcome was survival to device explant and reason for explant
- Secondary outcomes included incidence of major complications

RESULTS

Table 1: Baseline Cohort Characteristics of Groups for ≤ 14 days vs > 14 days of support

Variable	≤ 14 days	> 14 days	P value
N	50	44	
Age (Years)- mean (SD)	53 (15.6)	54.2 (14)	0.6963
Race – N (%)			0.8451
White	24 (48%)	20 (45.5%)	
Black	24 (48%)	23 (52.3%)	
Hispanic	2 (4%)	1 (2.3%)	
Male – N (%)	40 (80%)	29 (65.9%)	0.1229
BMI – mean (SD)	28.1 (4.9)	30.6 (4.9)	0.0156
Blood Type – N (%)			0.9527
A	14 (28%)	14 (31.8%)	
B	5 (10%)	5 (11.4%)	
AB	3 (6%)	3 (6.8%)	
O	28 (56%)	22 (50%)	
HF Etiology- N (%)			0. 8377
NICM	32 (64%)	29 (65.9%)	
ICM	15 (30%)	12 (27.3%)	
Congenital	0 (0%)	1 (2.3%)	
Restrictive	1 (2%)	1 (2.3%)	
Other	2 (4%)	1 (2.3%)	
History of Diabetes	12 (24%)	15 (34.1%)	0.2806
History of PVD	5 (10%)	4 (9.1%)	0.8812
History of Stroke	4 (8%)	6 (13.6%)	0.3765
ICD	29 (60.4%)	28 (63.6%)	0.7507
Prior Cardiac Surgery	11 (22%)	4 (9.1%)	0.0881
Baseline Labs			
Creatinine	1.7 (0.8)	1.8 (0.8)	0.8951
Total Bilirubin	1.7 (1.6)	1.7 (1.4)	0.9590
INR	1.5 (1.0)	3.4 (13.6)	0.3500
Ptt	51.9 (25.7)	43.7 (21.7)	0.1116
Lactate	1.8 (1.4)	1.5 (0.9)	0.2382
Cardiac Function			
Ejection Fraction	18.6 (7.1)	19.3 (8.7)	0.6897
CO	3.7 (1.1)	3.3 (1.1)	0.1098
CI	1.8 (0.4)	1.6 (0.5)	0.0551
PCWB	23.9 (8)	25.7 (9)	0.3246
Mean PAP	36.2 (11.1)	37.9 (12.9)	0.5058
RA	11 (7.2)	13 (7.8)	0.2331
Other pre-op MCS			0.4101
None	36 (73.5%)	36 (81.8%)	
IABP	9 (18.4%)	3 (6.8%)	
Impella CP	3 (6.1%)	4 (9.1%)	
RVAD			
ECMO	1 (2%)	1 (2.3%)	
Operative Variables			
Insertion site			0. 0681
R axillary	48 (96%)	38 (86.4%)	
L axillary	1 (2%)	6 (13.6%)	
Innominate	1 (2%)	0 (0%)	
Placement during different operation	6 (12.2%)	3 (7%)	0.3961

Table 2: Primary outcomes for groups of ≤ 14 days vs > 14 days of support

Outcome	≤ 14 days	> 14 days	P value
Days with Device	8.1 (3.8)	32.1 (18.2)	<.0001
Survival to Explant	46 (92%)	41 (93.2%)	0.8276
Explant Reason			0.7843
Recovery	5 (10%)	3 (6.8%)	
Transplant	21 (42%)	23 (52.3%)	
Durable LVAD	13 (26%)	9 (20.5%)	
Device Malfunction	4 (8%)	2 (4.5%)	
Palliation	2 (4%)	3 (6.8%)	
Death	4 (8%)	3 (6.8%)	
Infection	0 (0%)	1 (2.3%)	
Device Dislodgement	1 (2%)	0 (0%)	

Table 3: Incidence of Major Complications for groups of ≤ 14 days vs > 14 days of support

Complications	≤ 14 days	> 14 days	P value
Bleeding	4 (8%)	2 (4.5%)	0.4942
Stroke	3 (6%)	1 (2.3%)	0.3717
Limb Ischemia	1 (2%)	1 (2.3%)	0.9271
Vascular injury	3 (6%)	2 (4.5%)	0.7539
Hemolysis	7 (14%)	9 (20.5%)	0.4060
Device Malfunction	3 (6%)	4 (9.1%)	0.5690

CONCLUSIONS

- The Impella 5.5 is safe and effective for prolonged duration of support in patients with cardiogenic shock
- Incidence of complications and ultimate disposition are unchanged when comparing between <14 days vs ≥ 14 days of support
- Further exploration is needed to confirm the safety for Impella 5.5 use beyond 14 days to expand the FDA recommendations

Disclosures

Arman Kilic is a speaker and consultant for Abiomed, Abbott, 3ive, and LivaNova. Additionally, A.K. is the founder and owner of QImetrix. All additional authors have no financial relationships to disclose.

REFERENCES

1. Dumitru I, DeWolf J, Sevillano M, Schnell L, Bezerra H, Rinde-Hoffman D. Prolonged Impella 5.5 Support in Patients with Cardiogenic Shock: A Single-Center Retrospective Analysis. J Clin Med. 2025 Aug 8;14(16):5631. doi: 10.3390/jcm14165631. PMID: 40869457; PMCID: PMC12387053.
2. Kanwar MK, Uriel N, Carnicelli A, John K, Li S, Kong C, Zweck E, Sinha SS, Ton VK, Garan AR, Kataria R, Abraham J, Hernandez-Montfort J, Burkhoff D; CSWG Academic Research Consortium; Kapur NK. Outcomes of patients supported on Impella 5.5 for more than 14 days: A Cardiogenic Shock Working Group registry analysis. J Heart Lung Transplant. 2025 Oct;44(10):1583-1594. doi: 10.1016/j.healun.2025.05.017. Epub 2025 Jun 29. PMID: 40592372.
3. Valdes CA, Stinson G, Sharaf OM, Jimenez Contreras F, Bilgili A, Ahmed MM, Vilaro J, Parker AM, Al-Ani MAZ, Demos D, Aranda J, Bleiweis M, Beaver TM, Jeng EI. Reconsidering FDA Guidelines: A Single-Center Experience of Prolonged Impella 5.5 Support. Innovations (Phila). 2024 Jan-Feb;19(1):46-53. doi: 10.1177/15569845231212157. Epub 2023 Nov 27. PMID: 38013250.