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REVIEW ARTICLE

The contemporary utilization of TandemHeart® in Severe Cardiogenic Shock and Acute Decompensated Heart Failure

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ABSTRACT
Severe cardiogenic shock in the setting of acute decompensated heart failure, refractory to aggressive pharmacologic intervention is synonymous with high mortality. Recent innovative advancements in mechanical circulatory system [MCS] has provided some semblance of hope, with use exponentially increasing due to the favorable outcomes. These devices serve as bridge towards definitive therapy by providing hemodynamic stability. The TandemHeart® (LivaNova Inc) has gained increased notoriety due to the increased degree of support provided in in left ventricular failure. A nationwide shock database analysis found increased mortality benefits of TandemHeart® over Impella®. However, there continues to remain scarce data and limited clinical trials demonstrating the efficacy of TandemHeart® over other devices. We present three assorted cases of cardiogenic shock refractory to Impella® successfully managed with the TandemHeart® system. We discuss the indication, utility, and the potential benefits provided by the TandemHeart® system including ability to add oxygenator in circuit, ease to convert to VA-ECMO, use in prosthetic aortic valve, and capable of offloading left atrium and left ventricle.

Keywords: Cardiogenic Shock, TandemHeart®, Impella®, Intra-aortic balloon pump, ECMO

Abbreviations

MCS	Mechanical circulator systems
AMI	Acute myocardial infarction
CABG	Cardiopulmonary bypass surgery
PCI	Percutaneous valve interactions
IABP	Intra-aortic balloon pump
ECMO	Extracorporeal circulatory mechanical system
pVAD	Percutaneous ventricular assist device
ECG	Electrocardiogram
STEMI	ST elevation myocardial infarction
NSTEMI	Non-ST elevation myocardial infarction
TEE	Transesophageal echocardiogram
EF	Ejection fraction
LAD	Left anterior descending
LCx	Left Circumflex
LM	Left Main
RCA	Right coronary artery

Introduction

Cardiogenic shock remains a significant cause for hospital morbidity and mortality, with the National Inpatient Sample accounting for greater than 100,000 cases yearly and a 30-day mortality near 50%.[1] It is defined as a state of low cardiac output, resulting in a determinantal end-organ hypoperfusion and hypoxia.[2] This state of cardiac failure is exacerbated by a self-fulfilling loop. As the body adapts with compensatory mechanisms to improve systemic perfusion, such as extensive peripheral vasoconstriction, it does so with inadvertent damage to the myocardium from increased cardiac afterload.[3] The multitude of etiologies causing cardiogenic shock are typically associated with some form of insult to the heart, with acute myocardial infarction [AMI] being the culprit in 81% of patients; other common etiologies include ventricular failure, valvular abnormalities, and post coronary bypass complications.

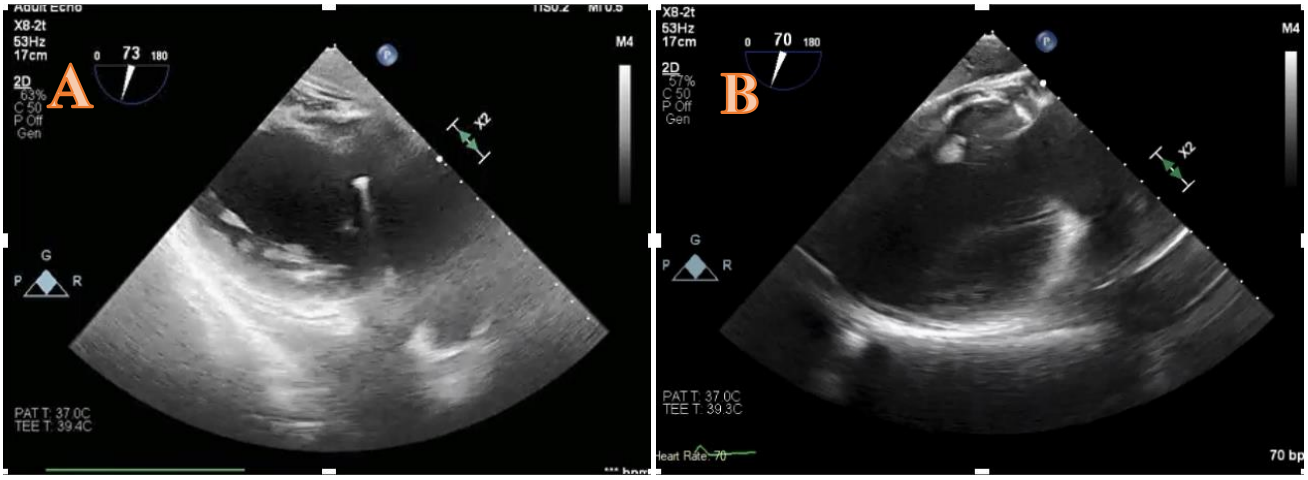
Initial therapy was limited to pharmacological support, however over the past few decades there has been remarkable strides and innovations in therapies focused on mechanical circulatory support [MCS]. [3] Mechanical circulatory support functions as bridge therapy while the underlying causality is addressed, and in doing so improves systemic blood flow, while reducing cardiac work. Indications include AMI, decompensated heart failure, acute cardiac allograft failure, post-transplant right ventricle failure, prolonged wean from cardiopulmonary bypass surgery [CABG], refractory arrhythmias, high risk percutaneous valve interactions [PCI] and prophylactic use in high-risk percutaneous intervention.[4] MCS devices include intra-aortic balloon pump [IABP], Impella®, TandemHeart®, and extracorporeal circulatory mechanical system [ECMO].[5]

TandemHeart® is a percutaneous ventricular assist device [pVAD] which utilizes an external motorized centrifugal pump connected to a drainage transeptal left atrial cannula and an arterial return cannula to off load the left heart. Compared to Impella® 2.5 and IABP, TandemHeart® provides overall improved cardiac output and hemodynamic changes.[6] Additionally, neither IABP nor Impella® can help mitigate hypoxemia for acute pulmonary edema.[7] This ability to address severe hypotension and hypoxemia from abysmal forward stroke volume has allowed TandemHeart® to gain traction as a plausible choice for MCS. We present three cases of its successful application in individuals with severe cardiogenic shock refractory standard therapies.

Case Presentation

Case 1

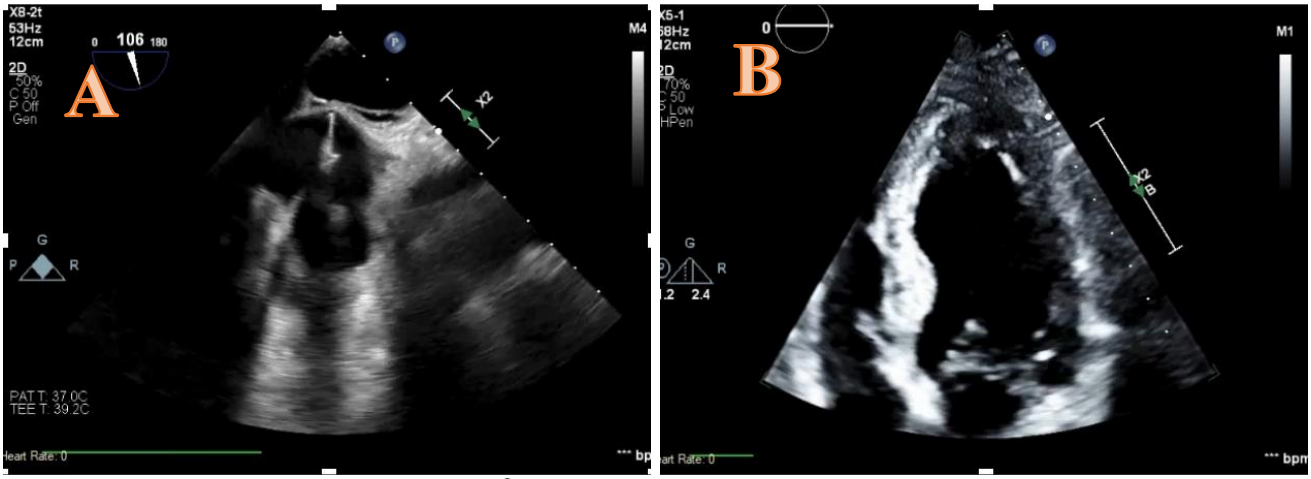
A 47-year-old male with a past medical history of diabetes and hyperlipidemia presented for shortness of breath, chest discomfort, and was found to be diabetic ketoacidosis. Serial electrocardiograms [ECGs] inevitably revealed an anterior ST elevation myocardial infarction [STEMI]. He underwent emergent catheterization, during which he sustained ventricular tachycardia arrest. A stat transesophageal echocardiogram [TEE] showed profound left ventricular failure with an estimated ejection fraction [EF] of 25%. Despite percutaneous coronary intervention [PCI] with 2 stents each to left anterior descending [LAD] and left circumflex [LCx], he inevitably developed cardiogenic shock. With cardiac power output was 0.8 and pulmonary artery pressures in 50s, he required MCS with placement of Impella CP® 3.5. Cardiac parameters were monitored with a Swan-Ganz catheter. The patient continued to demand increasing vasopressor requirements as well as had inotropic support to maintain cardiac output of ~2.1. A repeat TEE demonstrated EF of 5-10%, with severely reduced systolic function (Video 1A). The Impella® device was upgraded to a TandemHeart®. Following this, serial echocardiogram noted improving EF, with eventually recovering to 30-35% (Video 1B). The TandemHeart® was inevitably explanted, and the patient was discharged to inpatient rehab in stable condition



Video 1, Case 1: A: TEE before TandemHeart® demonstrating EF of 25%. B: TEE post TandemHeart® showing recovered EF of 30-35%.

Case 2

An 81-year-old female with no significant medical history presented for chest pain, worse with exertion and associated with diaphoresis. Initial ECG showed ST elevations in anterolateral. An emergent catheterization found LAD, LCx, distal left main [LM] and right coronary artery [RCA] stenosis. She underwent 5 stents to LM-LAD-LCx with plans for staged PCI of RCA. Post procedure she was found to be in cardiogenic shock with cardiac index 1.4 and PA saturation 44% on Swan-Ganz catheter. A transthoracic echocardiogram [TTE] demonstrated EF 10-15% with severe global hypokinesis. Despite initiation of inotropes and placement of an Impella CP® device, cardiogenic shock progressively worsened with cardiac power output 0.4-0.5, PA saturation 45-50%, and cardiac index 1.9. As a result, the patient was upgraded to TandemHeart® (Video 2 AB). Serial echocardiograms demonstrated improvement in cardiac functions, with eventual explanation of the TandemHeart® 4 days later and discharged home.

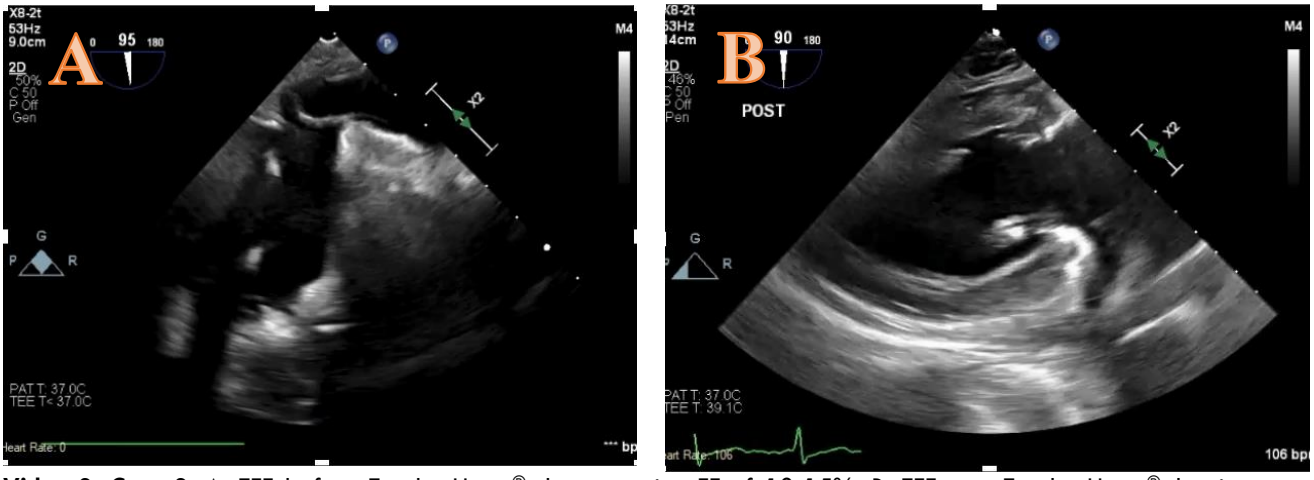


Video 2, Case 2: A: TEE before TandemHeart® demonstrating EF of 10-15% with severe global hypokinesis. B: TTE post TandemHeart® showing recovered EF of 45-50%.

Case 3

A 72-year-old male with a past medical history of hypertension, severe aortic stenosis, and diabetes presented for shortness of breath and tachycardia. ECG revealed ST depressions in anterolateral leads. Troponins were modestly elevated but equivocal. The patient was admitted for non-ST elevation myocardial infarction [NSTEMI], however later demonstrated worsening hemodynamics. A repeat ECG revealed anteroseptal STEMI with elevated troponin. Chest x-ray was concerning for flash pulmonary edema. Echo demonstrated significantly decreased cardiac function with an EF of 10-15%. The patient underwent emergent

catheterization, which showed severe diffuse disease, severe aortic stenosis, and cardiogenic shock. He received 3 stents to the LAD and placement of Impella®. Despite this, the patient continued to decline requiring multiple vasopressors and inotropic support. The Impella® was upgraded to TandemHeart®. This functioned as a bridge therapy until subsequent catheterization during which the patient received 4 stents to RCA, 1 to LCx, 1 to OM1 and 1 to OM2. Additionally, while on TandemHeart® support, the patient underwent transcatheter aortic valve replacement with Sapien-3 Ultra 26. Serial echocardiograms resulted in improving cardiac function, with resultant EF 40-45% and recovered cardiac index of 3.3 L/min/m^2 following TandemHeart® explanation. Patient fully recovered and was discharged home on day 23 after admission.



Video 3, Case 3: A: TEE before TandemHeart® demonstrating EF of 10-15%. B: TEE post TandemHeart® showing recovered EF of 30-35%.

Discussion

The TandemHeart® system is a pVAD that consists of a 21 Fr ProtekSolo transeptal cannula, 15-19 Fr arterial cannulae and an external centrifugal blood pump. The configuration involves a left atrial to femoral artery bypass. Placement of the cannulae may be done via percutaneous or surgical approach. This mechanism enables TandemHeart® to offload volume and pressure from the left atrium and left ventricle, subsequently decreases pulmonary venous pressure and congestion.[7] The centrifugal pump extracts oxygenated blood from the left atrium through an outflow cannula. This blood is then returned to the femoral artery through an inflow cannula. This system can support flow rates up to 4.0-7.0 L/min and maximum speed of 7500 RPM.[6, 9-10] In doing so, it ensures adequate peripheral and coronary perfusion is maintained while reducing cardiac work.

There are notable advantages of using TandemHeart® over its counterpart MCS devices. These include improved hemodynamic changes such as increased cardiac power output, cardiac index, and mean arterial pressure with a reduction in pulmonary capillary wedge pressure, particularly when compared to Impella 2.5 and IABP.[7,9] This was further illustrated in a meta-analysis with improved hemodynamic profiles noted in cardiogenic shock with TandemHeart® compared to IABP.[6] This being said, there has yet to be seen a mortality benefit between the two.[10] A more recent retrospective cohort analysis compared the mortality benefits in cardiogenic shock supported by Impella® versus TandemHeart® and found much higher mortality within the Impella® group.[11] Another advantage the TandemHeart® possesses is the ability for an oxygenator to be added in circuit, thereby augmenting oxygenation support in cases of severe refractory hypoxemia, functioning similarly to veno-arterial ECMO.[7] The indications and advantages are shown in figure 1.

Figure 1. Shows the advantages and indications for TandemHeart®. The inner ring exemplifies the numerous advantages TandemHeart® procures over its MCS counterparts, particularly Impella®. The outer ring demonstrates the diverse indications for TandemHeart®.

However, TandemHeart® is not without its limitations. Contraindications include aortic insufficiency or dissection, severe peripheral arterial disease, and coagulopathy. Additionally, complications may arise and primarily stem from the transeptal puncture. These includes right-to-left shunting with resultant hypoxia, strokes or perforation of adjacent structures, and tamponade.[5] Furthermore, just as other MCS devices, TandemHeart® requires use of systemic anticoagulation in lieu of pump thrombosis, thereby potentiating the risk of bleeding.[6]

The attributes and benefits of TandemHeart®, particularly over Impella® has understandably sparked a vested interest in TandemHeart® as a superior alternative MCS device. The rationale behind upgrading to TandemHeart® in our three cases stemmed from the ability to provide high blood flow rate, all-the-while offloading left atrium pressures, and decreasing pulmonary vascular congestion.

Table 1. Illustrates the patient cases with a review of the etiologies leading to severe cardiogenic shock and left ventricular failure and the resultant interventions. Impella® device was initially pursued, yet persistent cardiac failure remained as noted by EF. All patients were inevitably upgraded to TandemHeart® with steady recoverable cardiac function and successful weaned off vasopressors and inotropic support.

Pt. No.	*Age (yr)/ Sex*	*Etiology*	*Intervention*	*Prior MCS Device*	*Upgraded to TandemHeart ®*	*Duration of TH*	*Lowest EF (Prior to TH)*	*Recovered EF (Post TH)*	*Outcome/ Disposition*
1	47 M	AMI	Multiple PCI	Impella, failed	Yes	10 days	5-10 %	30-35%	Alive/home
2	81 F	AMI	Multiple PCI	Impella, failed	Yes	4 days	10-15%	45-50%	Alive/home
3	72 M	AS/AMI	Multiple PCI & TAVR	Impella, failed	Yes	7 days	10-15%	40-45%	Alive/home

Table 1 illustrates the successful outcomes and recovered cardiac function we achieved with TandemHeart® in severe cardiogenic shock and left ventricular failure refractory to Impella® and inotropic support. All three cases precipitously failed Impella®, yet demonstrated improvement with TH. This is illustrated in Graph 1, with gradual recovery, as gauged by lactic acid and SVO2 trend. By time of TandemHeart® explanation, modest EF recovery was appreciated in all patients. It is our contention, that the TandemHeart® system should be utilized more using a methodical approach for MCS management cardiogenic shock. A possible algorithm is suggested in figure 2.

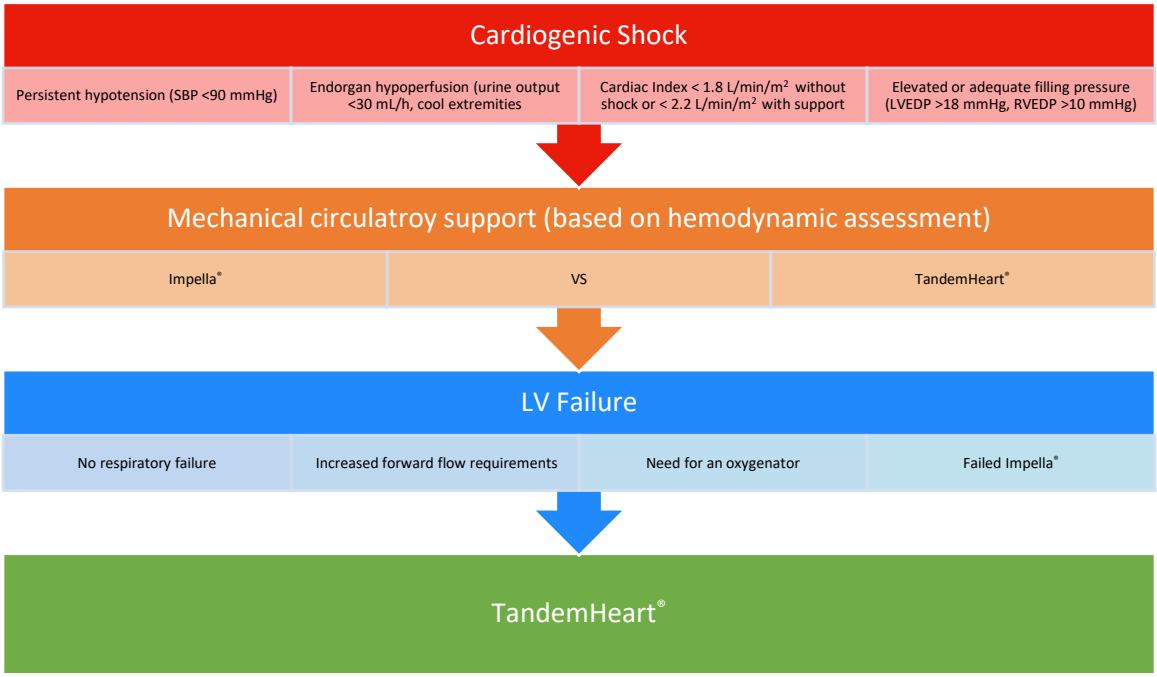
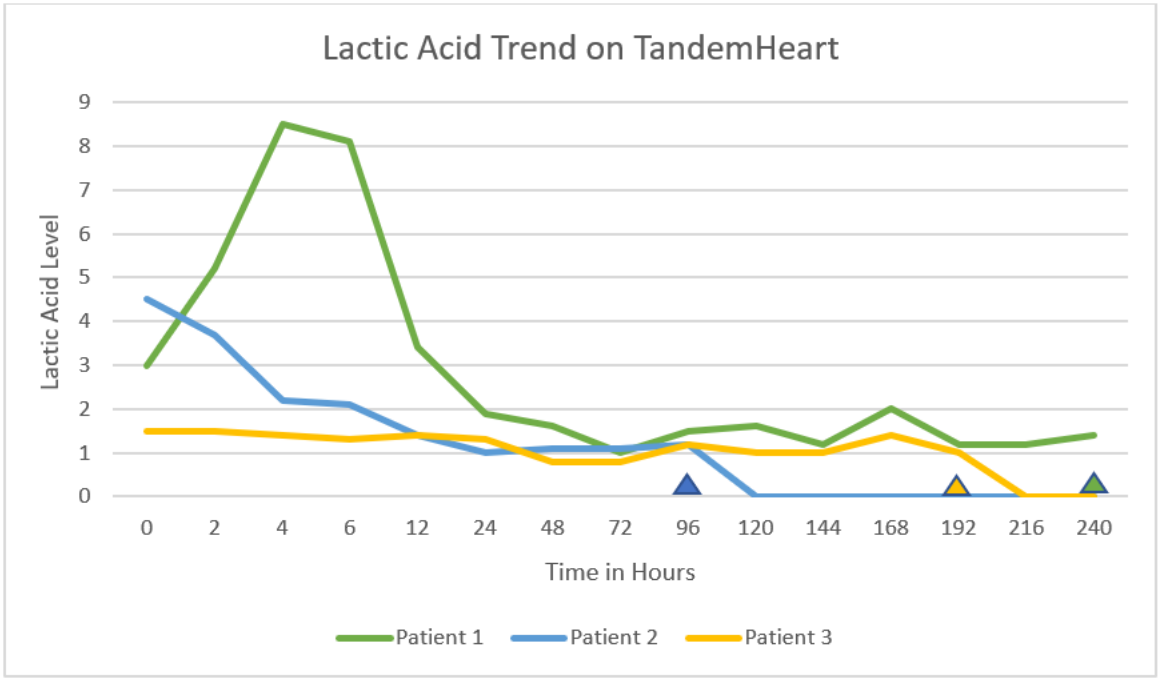


Figure 2. Approach to TandemHeart® vs Impella® in cardiogenic shock.
LVEDP, left ventricle end-diastolic pressure; RVEDP, right ventricle end-diastolic pressure.



Graph 1. (A) Lactic acid trend on TandemHeart®. Hour 0 marks lactic acid on implantation of TandemHeart®. The triangle markers indicate TandemHeart® explanation. (B) SVO_2 trend on TH. Hour 0 is the SVO_2 percentage prior to TandemHeart® implantation.

There have been other previous studies done with TandemHeart® that support the above proposed advantages (Table 2). These randomized trials investigated the usage and efficacy of MCS vs IABP. TH was placed in patients with cardiogenic shock due to acute myocardial infarction. The results showed TandemHeart® significantly improved the hemodynamics of the patients with increase in the cardiac index (> 2.2 L/min/m²), mean arterial pressure (>70 mmHg), and decrease in pulmonary capillary wedge pressure (<24 mmHg).[12-13] Once again proving that TandemHeart® provides

adequate support for patients with refractory cardiogenic shock.

Overall, the TandemHeart® system has proven to be a safe and effective support system under the proper implantation and use. Few device-related adverse events have been noted in various studies and in different patient populations. With most studies showing possible shortening of the time period between cardiogenic shock and cardiac recovery.[14-16]

Table 2. Comparison of randomized trials in cardiogenic shock using TandemHeart® with successful outcomes.[10-11]

Author	*Number of patients*	*Etiology*	*Hemodynamic support*	*Average duration of support (days)*	*Outcome*
Thiele *et al.* 2005	41	Acute myocardial infarction	TH	3 days	35 Survived post 30 days
Burkhoff *et al.* 2006	33	Acute myocardial infarction	TH	2.5 days	30 Survived post 30 days
Kar *et al.* 2006	18	High risk PTCA (7 patients) and Cardiogenic shock (11 patients)	TH	2.7 days	11 Survived post 30 days
Bruckner *et al.* 2008	5	Acute myocardial infarction	TH	7.6 days	5 survived post 30 days

Conclusion

Although the hospital mortality rate associated with cardiogenic shock remains unacceptably high, the recent innovative measures of MCS has provided some temporizing relief to practitioners and their patients. Among these, TandemHeart® is gaining momentum as a choice for supportive care or bridge therapy in patients suffering from severe cardiogenic shock. Its functional ability to provide better hemodynamic stability, improved cardiac function with greater forward flow and potentially furnish oxygenation in setting of refractory hypoxemia has all contributed to the allure of TandemHeart®. Further investigated studies are warranted to be able to appropriately assess the full extent and degree of benefits compared to other therapeutic option.

References

1. Brener MI, Rosenblum HR, Burkhoff D. Pathophysiology and Advanced Hemodynamic Assessment of Cardiogenic Shock. *Methodist Debakey Cardiovasc J*. Jan-Mar 2020;16(1):7-15. doi:10.14797/mdcj-16-1-7

2. van Diepen S, Katz JN, Albert NM, et al. Contemporary Management of Cardiogenic Shock: A Scientific Statement From the American Heart Association. *Circulation*. Oct 17 2017;136(16):e232-e268. doi:10.1161/CIR.0000000000000525

3. Vahdatpour C, Collins D, Goldberg S. Cardiogenic Shock. *J Am Heart Assoc*. Apr 16 2019;8(8):e011991. doi:10.1161/JAHA.119.011991

4. Telukuntla KS, Estep JD. Acute Mechanical Circulatory Support for Cardiogenic Shock. *Methodist Debakey Cardiovasc J*. Jan-Mar 2020;16(1):27-35. doi:10.14797/mdcj-16-1-27

5. Wong ASK, Sin SWC. Short-term mechanical circulatory support (intra-aortic balloon pump, Impella, extracorporeal membrane oxygenation, TandemHeart): a review. Ann Transl Med. 2020 Jul;8(13):829. doi: 10.21037/atm-20-2171. PMID: 32793674; PMCID: PMC7396256.

6. Ergle K, Parto P, Krim SR. Percutaneous Ventricular Assist Devices: A Novel Approach in the Management of Patients With Acute Cardiogenic Shock. *Ochsner J*. Fall 2016;16(3):243-9.

7. DiVita M, Visveswaran GK, Makam K, et al. Emergent TandemHeart-ECMO for acute severe mitral regurgitation with cardiogenic shock and hypoxaemia: a case series. *Eur Heart J Case Rep*. Feb 2020;4(1):1-6. doi:10.1093/ehjcr/ytz234

8. Kar B, Adkins LE, Civitello AB, et al. Clinical experience with the TandemHeart percutaneous ventricular assist device. *Tex Heart Inst J*. 2006;33(2):111-5.

9. Naidu SS. Novel percutaneous cardiac assist devices: the science of and indications for hemodynamic support. *Circulation*. Feb 8 2011;123(5):533-43. doi:10.1161/CIRCULATIONAHA.110.945055

10. Burkhoff D, Cohen H, Brunckhorst C, O'Neill WW, TandemHeart Investigators G. A randomized multicenter clinical study to evaluate the safety and efficacy of the TandemHeart percutaneous ventricular assist device versus conventional therapy with intraaortic balloon pumping for treatment of cardiogenic shock. *Am Heart J*. Sep 2006;152(3):469 e1-8. doi:10.1016/j.ahj.2006.05.031

11. Khalid Y, Dasu N, Dasu K, Suga H. Impella versus TandemHeart in Cardiogenic Shock Nationwide Database Analysis 2017. *J Am Coll Cardiol*. May 2021; 77 (18_Supplement_1) 818. doi:10.1016/S0735-1097(21)02177-X

12. Holger Thiele, Alexander Jobs, Dagmar M Ouweneel, Jose P S Henriques, Melchior Seyfarth, Steffen Desch, et al. Percutaneous short-term active mechanical support devices in cardiogenic shock: a systematic review and collaborative meta-analysis of randomized trials, *European Heart Journal*, Volume 38, Issue 47, 14 December 2017, Pages 3523–3531, https://doi.org/10.1093/eurheartj/ehx363

13. Bruckner BA, Jacob LP, Gregoric ID, Loyalka P, Kar B, Cohn WE, et al. Clinical experience with the TandemHeart percutaneous ventricular assist device as a bridge to cardiac transplantation. Tex Heart Inst J. 2008;35(4):447-50. PMID: 19156239; PMCID: PMC2607106.

14. Pahuja M, Johnson A, Kabir R, Bhogal S, Wermers JP, Bernardo NL, Ben-Dor I, Hashim H, Satler LF, Sheikh FH, Waksman R. Randomized Trials of Percutaneous Microaxial Flow Pump Devices: JACC State-of-the-Art Review. J Am Coll Cardiol. 2022 Nov 22;80(21):2028-2049. doi: 10.1016/j.jacc.2022.08.807. PMID: 36396205.

15. Schwartz BG, Ludeman DJ, Mayeda GS, Kloner RA, Economides C, Burstein S. High-risk percutaneous coronary intervention with the TandemHeart and Impella devices: a single-center experience. J Invasive Cardiol. 2011 Oct;23(10):417-24. PMID: 21972160.

16. Kar B, Adkins LE, Civitello AB, Loyalka P, Palanichamy N, Gemmato CJ, Myers TJ, Gregoric ID, Delgado RM 3rd. Clinical experience with the TandemHeart percutaneous ventricular assist device. Tex Heart Inst J. 2006;33(2):111-5. PMID: 16878609; PMCID: PMC1524679.