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Research Article

Comparative Outcomes of iVAC2L and IABP Support in High-Risk PCI: Six-Month Survival and Complication Analysis

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Aims: This study aimed to compare 6-month survival and complication rates of patients undergoing high-risk percutaneous coronary intervention (PCI) supported by either iVAC2L mechanical circulatory support (MCS) or intra-aortic balloon pump (IABP).

Methods and Results: In this retrospective cohort analysis, we included 54 patients who underwent a high-risk PCI for an unprotected left main, 3-vessel disease or a last remaining vessel stenosis with temporary MCS. Patients received either iVAC2L ($n = 24$) or IABP ($n = 30$) during PCI. The primary endpoint was 6-month all-cause mortality. Secondary endpoints included vascular complications, repeat revascularization, and stroke. The groups had similar baseline characteristics, with the ejection fraction being $34.4 \pm 9.5\%$ in the iVAC2L group and $37.9 \pm 9.4\%$ in the IABP group ($p = 0.177$). The 6-month mortality rate was lower in the iVAC2L group (8.3%) compared to the IABP group (16.7%), though the difference was not statistically significant ($p = 0.365$). Access site vascular complications were numerically higher in the iVAC2L group (12.5% vs. 3.3%; $p = 0.201$). Repeat revascularization rates (iVAC2L 4.2% vs. IABP 6.7%, $p = 0.690$) and stroke rates (iVAC2L 4.2% vs. IABP 3.3%, $p = 0.872$) were similar in both groups.

Conclusion: Patients with iVAC2L MCS had higher 6-month survival compared to IABP in high-risk PCI, albeit without statistically significant differences. Both devices provided effective hemodynamic support during the intervention with no periprocedural mortality. Vascular complications were numerically more frequent with iVAC2L, highlighting the need for skilled vascular access management. Larger prospective studies are needed to confirm these findings and guide optimal MCS device selection for high-risk PCI.

Keywords: high-risk PCI; IABP; intra-aortic balloon pump; iVAC2L; left main intervention; pulsatile flow left ventricular assist device

1. Introduction

High-risk percutaneous coronary intervention (PCI) in patients with severe coronary artery disease (unprotected left main, three-vessel, last remaining vessel lesions) and compromised left ventricular function presents unique procedural challenges due to the elevated risk of hemodynamic instability and adverse outcomes. Patients in this cohort often lack alternative revascularization options, making PCI a critical, albeit high-stakes, therapeutic approach [1]. Mechanical circulatory support (MCS) devices, particularly short-term options such as intra-aortic balloon pumps (IABPs) and percutaneous assist devices inserted directly into the left ventricle such as the iVAC2L, are often utilized to maintain hemodynamic stability during these complex interventions [2].

Among the MCS devices, the IABP is a widely used support system for high-risk PCI due to its ease of use, availability, and relatively low complication rate [3].

Moreover, its cost is significantly lower compared to other MCS systems [4]. It has an indirect mechanism of action, inflating during diastole, synchronously with aortic valve closure, and deflating rapidly just before systole. This way, it reduces afterload, allows blood displacement from the aorta to the peripheral vascular district, resulting in a modest increase in cardiac output (0.5 L/min) and improved coronary perfusion through diastolic aortic pressure augmentation [4]. It is inserted via femoral access (7-8 Fr) and is available in different sizes according to body size area [5]. In a large randomized controlled trial (BCIS-1), IABP-assisted PCI did not show a reduction in mortality at 28 days compared to no support [6]. Long-term follow-up from the same trial suggested a potential mortality benefit at 51 months (HR: 0.66, 95% confidence interval [CI]: 0.44–0.98, $p = 0.039$), although the authors acknowledge that the study was primarily designed to address in-hospital major adverse cardiac and cerebrovascular events (MACCEs) capped at 28 days [7]. Recommendations from professional societies concerning the use of IABP differ. The European Association of Percutaneous Cardiovascular Interventions (EAPCI) does not recommend IABP use in high-risk PCI, while the American College of Cardiology, American Heart Association, Society for Cardiovascular Angiography and Interventions (ACC/AHA/SCAI) support its utilization for this indication in selected patients [8, 9].

PulseCath iVAC2L consists of a membrane pump connected to a bidirectional flow catheter driven by an IABP console. The catheter is inserted through the femoral artery through an 18 Fr sheet. The inlet tip of the 17F catheter is positioned inside the left ventricle, where it operates in synchrony with the cardiac cycle. During diastole, the helium chamber receives helium from the IABP driver, resulting in the ejection of blood into the ascending aorta with a stroke volume of circa 21 mL. During systole, the helium chamber undergoes a deflation, which is accompanied by a refill of the blood chamber. The pump produces an additional pulsatile flow of up to 2 L/min [10]. To date, there are no large randomized controlled trials examining the iVAC2L device. There are, however, hemodynamic data [11] and outcomes from multiple observational studies and registries [12, 13], which provide encouraging results documenting its use.

In this study, we aim to assess and compare the clinical outcomes associated with the use of iVAC2L and IABP in patients undergoing high-risk PCI. By examining mortality, vascular complications, repeat revascularization, and stroke, this study seeks to elucidate the potential benefits and limitations of iVAC2L versus IABP in this high-risk population. This comparison will contribute to a growing body of evidence that can help guide the selection of MCS devices for patients requiring advanced hemodynamic support during high-risk coronary interventions.

2. Methods

2.1. Inclusion Criteria. This retrospective cohort study was conducted at University Hospital Martin, Slovakia, where we analyzed patients undergoing nonemergent high-risk PCI with temporary MCS between October of 2020 and April of 2024. Included patients had complex coronary artery disease, such as unprotected left main coronary artery disease, three-vessel disease, and last remaining vessel disease, with or without significant left ventricular dysfunction. Patients with the use of MCS for an emergent PCI (STEMI and cardiogenic shock) or its use for a mechanical complication were excluded from this study. The decision for an interventional approach with MCS was made in all cases by a multidisciplinary heart team including cardiologists and cardiac surgeons on the basis of very high or prohibitive operative risk, as determined by comorbidities, frailty, and risk for hemodynamic instability. Patients with active malignancy were excluded only if their life expectancy was less than 1 year. Preexisting moderate or severe anemia was corrected preprocedure. The study was conducted in accordance with the Declaration of Helsinki and approved by the Ethics Committee of Jessenius Faculty of Medicine, Comenius University in Bratislava, Slovakia.

2.2. Procedural Details. Two MCS devices were used for support: the IABP and the iVAC2L. Patient allocation to each device was determined by operator discretion. Femoral artery puncture was performed under ultrasound guidance. The balloon size selection (for the IABP), insertion, and operation of both devices were conducted according to manufacturer recommendations. The femoral access closure was performed using the Angio-Seal Vascular Closure Device (Terumo Interventional Systems, Somerset, NJ, USA) for IABP and the MANTA Vascular Closure Device (Teleflex Incorporated, Wayne, PA, USA) for iVAC2L.

2.3. Data Collection. Baseline demographic, clinical, and procedural characteristics were collected from electronic medical records. Data for primary and secondary outcomes were collected at scheduled visits up to 6 months post-PCI, through the electronic medical record system, and the National Healthcare Surveillance Administration database.

2.4. Study Endpoints. The primary endpoint was 6-month all-cause mortality. Secondary endpoints included access site vascular complications requiring surgical or interventional treatment, repeat revascularization of a target vessel, and stroke within the 6-month follow-up period.

2.5. Statistical Analysis. Continuous variables are presented as mean ± standard deviation and compared using the independent *t*-test. Normality of the data distribution was assessed using the Shapiro–Wilk test. Categorical variables are presented as frequencies and percentages, with comparisons made using the chi-square test. A p value of < 0.05 was considered statistically significant. Odds ratios (ORs) and 95% CIs were calculated for categorical variables. For continuous variables, group means were compared using *t*-tests with 95% CIs for mean differences. Equivalence testing for the primary endpoint was performed using the Two One-Sided Tests (TOST) procedure with an equivalence margin of ±10%. The 90% CI for the difference in proportions was

assessed using the Agresti–Caffo method. Statistical analysis was conducted using STATISTICA V 13.3 (StatSoft, Tulsa, USA).

3. Results

3.1. Baseline Characteristics. A total of 54 patients undergoing high-risk PCI with either iVAC2L ($n = 24$) or IABP ($n = 30$) support matched the criteria and were included in this analysis. Baseline demographics and comorbidities were generally similar between the groups, with no statistically significant differences. The mean age was 72 ± 8.6 years in the iVAC2L group and 74 ± 9.5 years in the IABP group ($p = 0.399$). The mean ejection fraction was in the reduced territory for both the iVAC2L ($34.4 \pm 9.5\%$) and IABP groups ($37.9 \pm 9.4\%$; $p = 0.177$). Overall, the studied group of patients had a high burden of comorbidities. Fifty percent of the patients had a history of prior coronary revascularization, 31.5% of stroke or transient ischemic attack (TIA), and 29.6% of symptomatic peripheral arterial disease. Diabetes mellitus was present in 53.7%, chronic kidney disease in 29.6%, and there were no patients with end-stage renal disease (ESRD). Atrial fibrillation was present in 22.2%, preexisting anemia (moderate or severe) in 7.4%, chronic obstructive pulmonary disease in 14.8%, and active malignancy was present in 3.7% of the patients. Prevalence of risk factors and a comparison between the groups are detailed in Table 1.

3.2. Procedural Characteristics. Both groups demonstrated a high degree of procedural complexity. The mean SYNTAX score was 34.3 ± 8.7 in the iVAC2L group and 31.5 ± 6.7 in the IABP group ($p = 0.179$), indicating comparable anatomical disease burden. The dominant indication was the unprotected left main lesion with 87.5% ($n = 21$) in the iVAC2L group (of those $n = 10$ complex two or more stent techniques and $n = 11$ provisional left main interventions) and 86.7% ($n = 26$; $p = 0.929$) in the IABP group (of those $n = 14$ complex two or more stent techniques and $n = 12$ provisional left main interventions). The use of IVUS was nonsignificantly higher in the iVAC2L group (95.8%, $n = 23$) compared to the IABP group (80%, $n = 24$; $p = 0.085$). In addition, preprocedure CT angiography of potential vascular access sites was more frequently performed in the iVAC2L group (91.7%, $n = 22$) versus the IABP group (13.3%, $n = 4$; $p < 0.001$). Chronic total occlusions were present in 54.3% ($n = 13$) of the patients in the iVAC2L group and 43.3% in the IABP group ($n = 13$; $p = 0.428$). Other procedural details, including stent number, stent length, use of drug-coated balloons, and use of more aggressive calcium-modifying methods such as intravascular lithotripsy and scoring balloons, did not differ significantly between the two groups (Table 2).

3.3. Clinical Outcomes. The 6-month mortality rate was higher in the IABP group (16.7%, $n = 5$) than in the iVAC2L group (8.3%, $n = 2$), though this difference did not reach statistical significance (OR: 0.45, 95% CI: 0.08–2.58; $p = 0.365$). The observed difference in 6-month mortality between the iVAC2L (8.3%) and IABP (16.7%) groups was −8.3%. Using a predefined equivalence margin of ±10%, the TOST procedure demonstrated statistical equivalence ($p = 0.032$), concluding that both devices provide similar survival outcomes. There were no instances of periprocedural mortality in either group. Access site vascular complications occurred in 12.5% ($n = 3$) of the iVAC2L group and 3.3% ($n = 1$) of the IABP group (OR: 4.14, 95% CI: 0.40–42.66; $p = 0.201$). Specifically, we identified two cases of limb ischemia in the iVAC2L group, one managed via interventional radiology and one requiring surgical intervention, as well as one severe bleeding event managed surgically. In the IABP group, there was one severe bleeding event managed by interventional radiology. There was no instance of infectious access site complications or acute kidney injury requiring renal replacement therapy in either group. Repeat revascularization of the target vessel rate was low in both groups, with 4.2% in the iVAC2L group and 6.7% in the IABP group (OR: 0.61, 95% CI: 0.05–7.15; $p = 0.690$). There were no unplanned revascularizations of nontarget vessels. Stroke occurred in 4.2% ($n = 1$) patients in the iVAC2L group and 3.3% ($n = 1$) patients in the IABP group (OR: 1.26, 95% CI: 0.07–21.27; $p = 0.872$), with both cases of the stroke occurring 1 month or later after the index procedure (Tables 3 and 4; Figures 1 and 2).

4. Discussion

This retrospective analysis provides insights into the comparative performance of iVAC2L and IABP in high-risk PCI, a setting where hemodynamic stability and complication risk are of paramount importance. Despite similar baseline characteristics and high procedural complexity in both groups, our findings suggest more favorable effects of iVAC2L in terms of 6-month survival, albeit without statistical significance. The observed higher rate of access site complications, although statistically not significant, underlines the challenges associated with the larger-caliber iVAC2L device. This finding emphasizes the need for appropriate patient selection and operator experience in managing vascular access in these cases.

In terms of mortality, the 6-month survival rate was higher in the iVAC2L group compared to the IABP group, although this difference did not reach statistical significance. Importantly, there were no periprocedural deaths in either group, suggesting that both devices provided effective hemodynamic support during the intervention. However, deaths occurring later in the follow-up were more frequent in the IABP group, reflecting a pattern observed in the PROTECT II trial comparing IABP with Impella 2.5. Although PROTECT II found no significant short-term survival differences, the divergence in major adverse events, including mortality, became more pronounced during extended follow-up [14]. The iVAC2L, capable of delivering up to 2 L/min of pulsatile flow [10], may offer enhanced hemodynamic support that could reduce downstream complications and improve long-term outcomes compared to

Table 1: Baseline characteristics and comorbidities.

	iVAC2L ($n = 24$)	IABP ($n = 30$)	OR (95% CI)	p value
Age (years)	72 + −8.6	74 + −9.5	(−7.14–2.89)	0.399
Male sex	66.7% ($n = 16$)	76.7% ($n = 23$)	0.61 (0.18–2.02)	0.414
BMI (kg/m2)	28.5 + −4.5	26.8 + −3.1	(−0.42–3.76)	0.115
Ejection fraction (%)	34.4 + −9.5	37.9 + −9.4	(−8.69–1.64)	0.177
St. p. PCI	54.2% ($n = 13$)	40% ($n = 12$)	1.77 (0.60–5.23)	0.300
St. p. CABG	4.2% ($n = 1$)	3.3% ($n = 1$)	1.26 (0.07–21.27)	0.872
PAD	29.2% ($n = 7$)	30% ($n = 9$)	0.96 (0.30–3.12)	0.950
CKD (KDIGO 3+)	33.3% ($n = 8$)	26.7% ($n = 8$)	1.38 (0.43–4.44)	0.594
ESRD	0% ($n = 0$)	0% ($n = 0$)	—	1
Stroke/TIA	33.3% ($n = 8$)	30% ($n = 9$)	1.17 (0.37–3.70)	0.793
Atrial fibrillation	16.7% ($n = 4$)	26.7% ($n = 8$)	0.66 (0.17–2.57)	0.380
Diabetes mellitus	62.5% ($n = 15$)	46.7% ($n = 14$)	1.91 (0.64–5.69)	0.246
COPD	12.5% ($n = 3$)	16.7% ($n = 5$)	0.71 (0.15–3.35)	0.669
Anemia (moderate or severe)	4.2% ($n = 1$)	10% ($n = 3$)	0.39 (0.04–4.02)	0.416
Dyslipidemia	87.5% ($n = 21$)	66.7% ($n = 20$)	3.50 (0.84–14.60)	0.075
Arterial hypertension	87.5% ($n = 21$)	80% ($n = 24$)	1.75 (0.39–7.88)	0.462
Smoking	25% ($n = 6$)	23.3% ($n = 7$)	1.10 (0.31–3.83)	0.888
Active malignancy	4.2% ($n = 1$)	3.3% ($n = 1$)	1.26 (0.07–21.27)	0.872

Abbreviations: BMI, body mass index; CABG, coronary artery bypass grafting; CI, confidence interval; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; ESRD, end-stage renal disease; IABP, intra-aortic balloon pump; KDIGO, kidney disease improving global outcomes classification; OR, odds ratio; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; St. p., status post; TIA, transient ischemic attack.

Table 2: Procedure characteristics.

	iVAC2L ($n = 24$)	IABP ($n = 30$)	OR (95% CI)	p value
Indication-acute coronary syndrome	62.5% ($n = 15$)	76.7% ($n = 23$)	0.51 (0.16–1.66)	0.257
SYNTAX score	34.3 + −8.7	31.5 + −6.7	(−1, 34–6.99)	0.179
Presence of CTO	54.2% ($n = 13$)	43.3% ($n = 13$)	1.55 (0.52–4.55)	0.428
Left main intervention	87.5% ($n = 21$)	86.7% ($n = 26$)	1.08 (0.22–5.35)	0.929
Provisional left main	45.8% ($n = 11$)	40% ($n = 12$)	1.27 (0.43–3.76)	0.666
Complex left main	41.7% ($n = 10$)	46.7% ($n = 14$)	0.82 (0.28–2.41)	0.713
Last remaining vessel intervention	4.2% ($n = 1$)	0% ($n = 0$)	3.89 (0.15–99.97)	0.259
3-vessel intervention	8.3% ($n = 2$)	13.3% ($n = 4$)	0.59 (0.10–3.54)	0.561
No. of stents (average, SD)	2.71 + −1.23	2.27 + −1.60	(−0.35–1.24)	0.270
Stent length per patient (in mm, average, SD)	65 + −29.6	58 + −40.5	(−13.28–26.40)	0.510
No. of DCB (average, SD)	0.54 + −0.72	0.43 + −0.63	(−0.26–0.48)	0.557
IVUS	95.8% ($n = 23$)	80% ($n = 24$)	5.75 (0.64–52.53)	0.085
Intravascular lithotripsy	29.2% ($n = 7$)	13.3% ($n = 4$)	2.68 (0.68–10.56)	0.151
Rotablation	4.2% ($n = 1$)	0% ($n = 0$)	3.89 (0.15–99.97)	0.259
Scoring balloon	37.5% ($n = 9$)	50% ($n = 15$)	0.60 (0.20–1.79)	0.358
Preprocedure access site CT angiography	91.7% ($n = 22$)	13.3% ($n = 4$)	71.50 (11.94–428.18)	< 0.001

Note: SYNTAX, synergy between percutaneous coronary intervention with TAXUS and cardiac surgery score.
Abbreviations: CI, confidence interval; CT, computed tomography; CTO, chronic total occlusion; DCB, drug-coated balloon; IABP, intra-aortic balloon pump; IVUS, intravascular ultrasound; OR, odds ratio; SD, standard deviation.

Table 3: Outcomes.

	iVAC2L ($n = 24$)	IABP ($n = 30$)	OR (95% CI)	p value
6-month mortality	8.3% ($n = 2$)	16.7% ($n = 5$)	0.45 (0.08–2.58)	0.365
Periprocedural mortality	0% ($n = 0$)	0% ($n = 0$)	—	1
30-Day mortality	4.2% ($n = 1$)	3.3% ($n = 1$)	1.26 (0.07–21.27)	0.872
Access site vascular complications	12.5% ($n = 3$)	3.3% ($n = 1$)	4.14 (0.40–42.66)	0.201
Repeat revascularization	4.2% ($n = 1$)	6.7% ($n = 2$)	0.61 (0.05–7.15)	0.690
Stroke	4.2% ($n = 1$)	3.3% ($n = 1$)	1.26 (0.07–21.27)	0.872
Renal replacement therapy	0% ($n = 0$)	0% ($n = 0$)	—	1
Infectious access site complications	0% ($n = 0$)	0% ($n = 0$)	—	1

Abbreviations: CI, confidence interval; IABP, intra-aortic balloon pump; OR, odds ratio.

Table 4: Number at risk.

Time (months)	iVAC2L ($n = 24$)	IABP ($n = 30$)
0	24	30
1	23	29
3	22	28
6	22	25

Abbreviation: IABP, intra-aortic balloon pump.

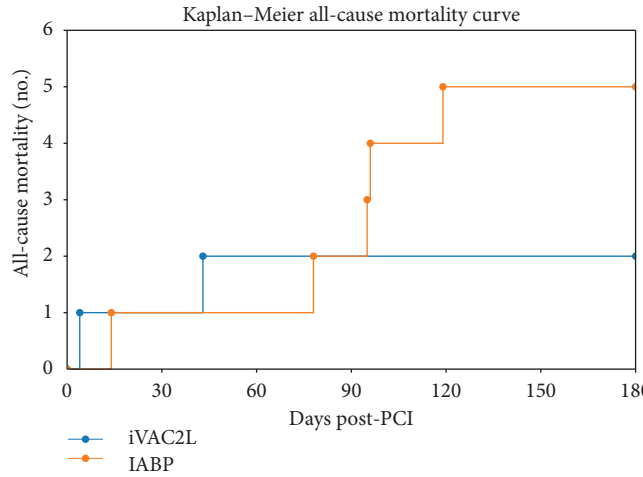

Figure 1: Kaplan-Meier all-cause mortality curve.

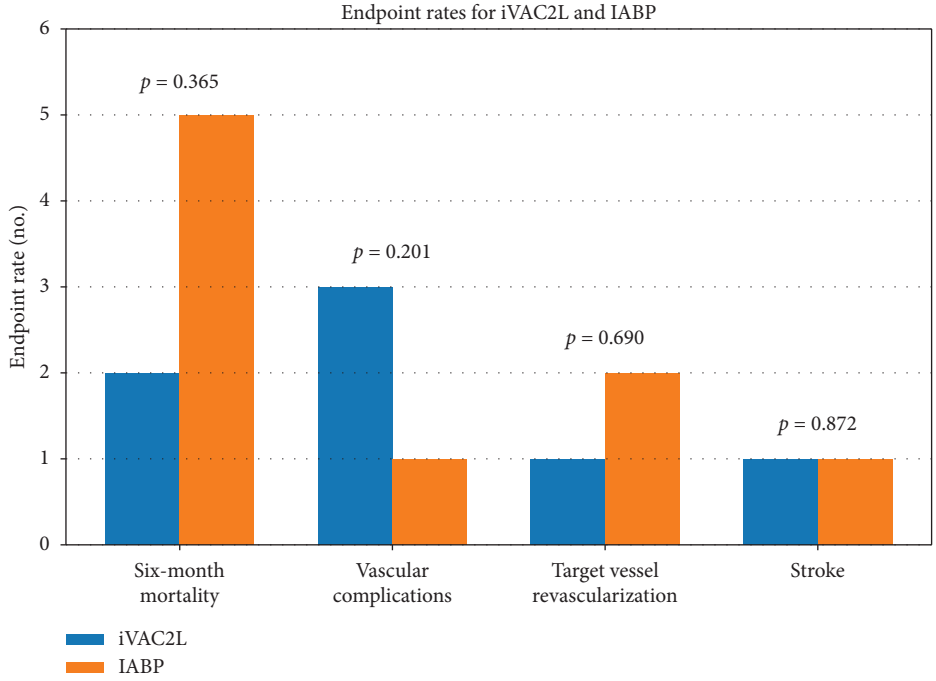

Figure 2: Endpoint rates for iVAC2L and IABP.

IABP's more modest hemodynamic effects. While these findings align with evidence suggesting benefits from other advanced MCS devices [2], larger adequately powered randomized controlled studies are needed to confirm any definitive survival advantage of iVAC2L over IABP. In addition, future studies directly comparing iVAC2L with Impella, both larger-diameter devices with high-flow, could further clarify their perspective roles in the same setting.

The complication profile observed in this study is also of interest, particularly regarding access site vascular complications, which were numerically more frequent in the iVAC2L group. This higher rate of complications aligns with prior findings that larger-caliber devices are associated with a greater risk of vascular injury and bleeding [5]. This is a key consideration in device selection, as high-risk PCI often involves patients with advanced age, peripheral arterial disease, and other comorbidities that predispose to access-related complications [15]. Effective management of access site complications remains critical, as they can contribute significantly to morbidity and may offset the hemodynamic benefits provided by iVAC2L. Interestingly, the vascular complication rate for iVAC2L in this study exceeded that reported in the largest observational registry for the device [13]. This difference may reflect variations in complication definitions, as this analysis included vascular events managed by interventional radiology and surgery, whereas prior registries reported only complications requiring a surgical approach. Given the growing role of interventional radiology in managing vascular complications [16], limiting definitions to surgical events may underestimate the true incidence. These findings highlight the importance of standardized definitions and reporting practices to accurately assess and address the vascular risks associated with MCS devices.

Lastly, repeat revascularization rates were low across groups, indicating that both devices provided comparable support enabling careful lesion treatment. Stroke rates were also not significantly different. Moreover, both stroke events occurred at least 1-month postprocedure, rather than during the periprocedural period. This delayed timing suggests that the stroke risk may not be directly attributable to the MCS device itself but rather could reflect the high-risk profile and comorbidities of the patient population.

There are several limitations to this study to consider. The modest sample size ($n = 54$) may have constrained the statistical power to detect differences in both primary and secondary outcomes. This could account for the lack of statistical significance despite clinically meaningful trends. The retrospective design inherently introduces selection biases, and although baseline characteristics were similar, unmeasured confounding factors could influence device choice and outcomes.

5. Conclusion

In this retrospective analysis, we observed higher 6-month survival in patients undergoing high-risk PCI with iVAC2L MCS compared to IABP, although the difference was not statistically significant. Both devices provided effective hemodynamic support during the intervention with no periprocedural mortality. On the other hand, there was a numerically higher frequency of vascular complications with iVAC2L. While these findings warrant further investigation, our results highlight the importance of individualized MCS selection, considering both procedural and patient-specific risks.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

Conflicts of Interest

The authors declare no conflicts of interest.

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