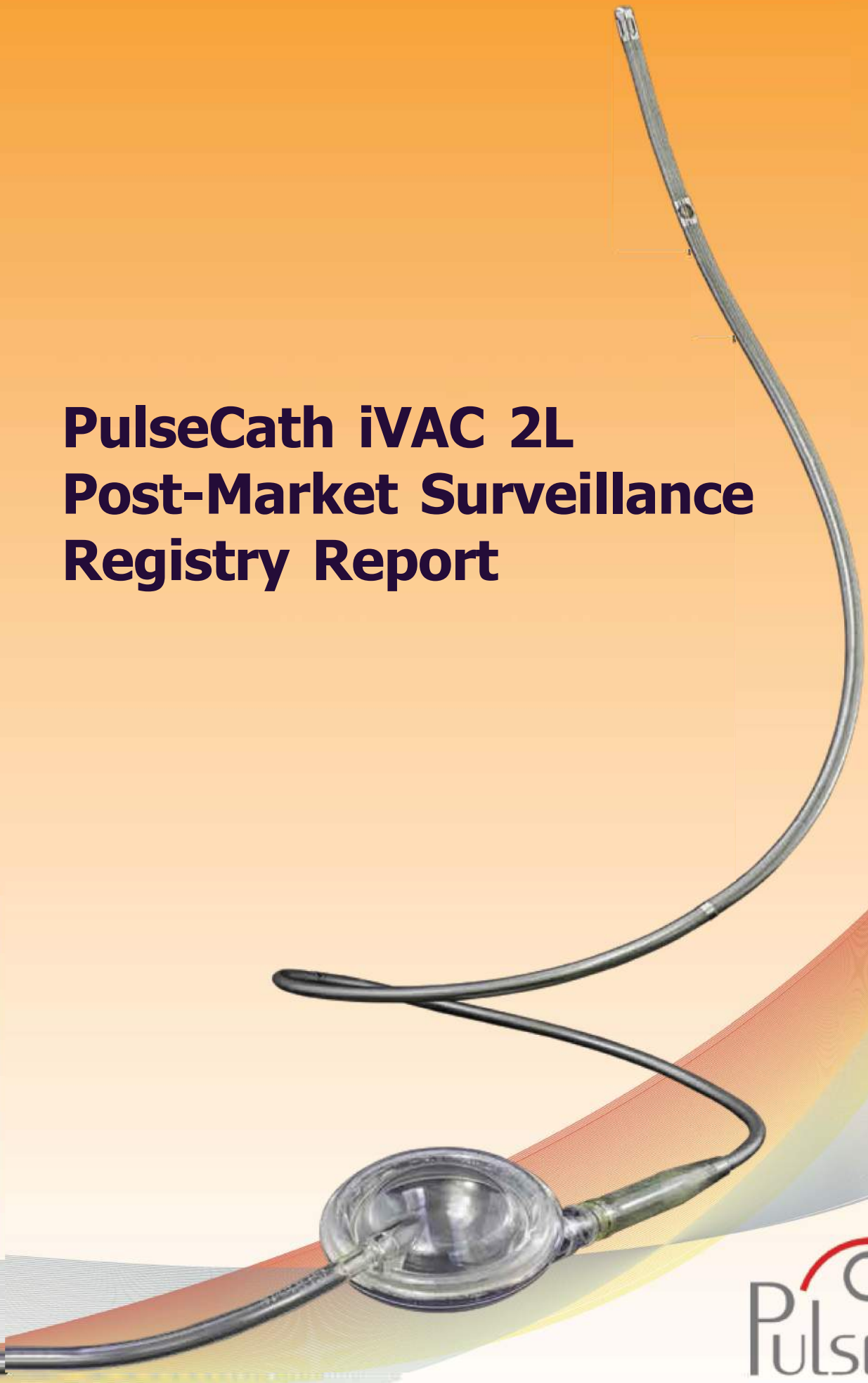
# PulseCath iVAC 2L Post-Market Surveillance Registry Report



PulseCath

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## Summary

Retrospective data on the use of PulseCath iVAC2L in the Catheterization Laboratory. Baseline data and clinical outcomes are presented and compared with previous literature on mechanically-assisted high-risk PCI.

## 1 Abbreviations

| | |
|---|---|
| AMI: | Acute Myocardial Infarction |
| CAD: | Coronary Artery Disease |
| ECMO: | Extra-corporeal Membrane Oxygenation |
| EF: | Ejection Fraction |
| IABP: | Intra Aortic Balloon Pump |
| IQR: | Interquartile Range |
| LM: | Left Main |
| MACCE: | Major Adverse Cardiovascular and Cerebral Events |
| MAP: | Mean Arterial Pressure |
| PCI: | Percutaneous Coronary Intervention |
| PMS: | Post-market Surveillance |
| VA-ECMO: | Veno-arterial Extra-corporeal Membrane Oxygenation |

## 2 Introduction

Recent technological developments in Interventional Cardiology have enabled PCI in patients with complex coronary artery disease. PulseCath iVAC2L aims to reduce the risk of hemodynamical deterioration during manipulation of the coronary vessels. Post-market surveillance (PMS) evaluates safety and efficacy.

## 3 Materials and Methods

**3.1 Description of iVAC2L.** iVAC2L is a percutaneously-inserted left ventricular assist device that ejects arterial blood into the ascending aorta using counterpulsation. Left ventricular blood is aspirated in systole and ejected in the arterial system in diastole, in synchrony with the coronary flow. The aortic pressure waveform during iVAC2L support demonstrates a diastolic “plateau” that partially interrupts the diastolic pressure descent.

**3.2 Data Collection.** The iVAC2L registry collects clinical data from patients undergoing PulseCath iVAC2L supported high-risk PCI and is derived from published studies, medical records and reports by PulseCath personnel who are on-site during the interventions. The current version of the registry includes cases that occurred in 67 different centers in Europe, South America and Asia.

**3.3 Clinical Endpoints.** For the analysis of clinical endpoints, only data directly available to the researcher or that has been made available in published peer-reviewed publications are used. Major Adverse Cardiac and Cerebrovascular Events (MACCE) is defined as composite of death (all-causes), acute myocardial infarction, repeat revascularization and Cerebrovascular Events. Intra-procedural Complications was defined as the composite of major bleeding, major vascular complication or respiratory failure. Hemodynamic instability was defined as any situation involving severe hypotension or shock, life-threatening arrhythmias, reported use of vasopressors an/or inotropes, or need to escalate support to another device.

**3.4 Data Analysis.** Baseline data is presented as means±SD or medians ±IQR as appropriate. Baseline characteristics and clinical outcomes were reported. Clinical outcomes found in the iVAC2L registry were compared with the same endpoints reported in the BCIS-1 and PROTECT II [1, 2] trials using the Fishers’ exact test. Support time and Device Output were compared between the iVAC2L registry and the means / medians from the same trials using Wilcoxon`s one sample test or Student`s t-test for one sample as appropriate. For better comparability with the literature, MACCE was defined as the composite endpoint of death, myocardial infarction, repeat revascularization and stroke. The analysis of clinical outcomes was performed in an intention-to-treat basis, and encompassed all patients in the study. The 2-sided α-error was set to 5% in all comparisons. All calculations were made using the R statistical package version 4.0.2.

## 4 Results

**Data composition.** The registry included a total of 174 patients from three previously published studies with iVAC2L (n = 63). Two studies were completed in the Netherlands and a third one in Germany. Another four cases were added from published results. The first described a case of severe acute myocarditis complicated with cardiogenic shock and the second described a case of acute decompensated heart failure. Other two cases described

successful PCIs for CAD [3-9]. Additional clinical data was collected onsite by PulseCath personnel (n = 108).

**Demographics.** Demographic characteristics are shown in **Table 3**. Mean age was 69±11 years. Patients tended to have multivessel disease and low ejection fraction (EF). Stenting of the left coronary and its branches was more common than stenting of the right coronary artery. The mean Left Ventricular Ejection Fraction (EF) was 34±14%, and was lower than 40% in 67% of the cases. Significant LM obstruction and three-vessel disease were present in 59% and 54% respectively.

**Procedural characteristics.** Procedural characteristics are exposed in **Table 4**.The median support time (IQR) was 71 (50-114) minutes, and the average flow produced by iVAC2L was 1.5±0.2L/min. Rotational atherectomy was applied in 11% of the cases. Intraprocedural complications (composite of major bleeding, major vascular complication or respiratory failure) occurred in 10.7% of all the available cases and resulted in the removal of the device in only two cases (1.2%). Hemodynamical instability was reported in 7.7%. Intraprocedural death and MACCE rates accounted for 0.58% and 4.9% of the cases.

**Clinical Endpoints.** Clinical endpoints are exposed in **Table 4** and put into perspective in **Figure 1**. All-causes mortality rate was 4.6% after 30 days. Acute kidney injury and cerebrovascular events were reported in 6% (each) of 66 individuals who had this information available until discharge. The rate of MACCE after 30 days was 12% out of 66 individuals and 4.9% intraprocedurally.

## 5 Discussion

This is the largest collection of clinical data on PulseCath iVAC2L to date. In this second year of data collection, this analysis suggest a better safety profile with iVAC2L as compared to other devices based on lower rates of acute myocardial infarction, major bleeding and repeat revascularization.

iVAC2L can also be used in patients receiving Veno-Arterial Extra-corporeal Membrane Oxygenation (VA-ECMO), and as a circulatory backup in severe decompensated heart failure [4, 6, 10, 11]. However, our experience indicates that the most frequent application is during high-risk PCI, being hemodynamically stable at baseline.

The data shows a 12.1% rate of MACCE after 30 days. In contrast, pooled data from two early studies performed in high-risk PCI by Briguori et al [12,13] indicate that the expected MACCE rates in high-risk PCI without MCS may be up to 17%.

With exception of the USPELLA registry, higher rates of MACCE have been reported in two of the main sources of randomized controlled data on MCS in high-risk PCI [1, 2]. The difference, however, did not reach statistical significance.

The Europella registry report, published in 2009 [14], shows a 0.7% rate of hemolysis, higher than the numbers found on the iVAC 2L. In the present analysis, no cases of hemolysis were observed and hence it is reasonable to expect that the real rates would be actually higher than that.

Despite being relatively low, the rate of MACCE with iVAC 2L may have been inflated by the number of cerebrovascular accidents, (CVE), which was proportionally higher in comparison with other studies. The observed rate (6.1%) is due to 4 events that occurred in 3 different sites, three in patients enrolled in the PULSE trial, and one at the Johannes Wesling Hospital (JWH). One patient had a stroke reported in the ICU several days after the intervention, while recovering from a period of refractory ventricular fibrillation. Other two cases consisted in one TIA and one confirmed stroke in two patients treated at the St Thomas Hospital. Both

individuals had previous history of CVE and one of them was found to have fibromuscular dysplasia of the carotid artery, an uncommon condition that works as an important determinant factor for cerebrovascular events. The fourth subject in the JWH was also reported to have a TIA (thus transitory lasting < 24h) after the intervention.

Importantly, the CVE rate should be regarded in light of the patient profile in the analyzed studies which is characterized by high-risk for cerebrovascular events. Secondly, the studied population in the present report is comparatively smaller than in other studies. A small sample size can compromise data analysis by amplifying sampling error. And thirdly, while it is reasonable to expect that the manufacturer (PulseCath) is to be promptly contacted by operators in face of adverse events that are potentially related to the marketed device, that did not happen in any of the 108 other cases recorded in the PMS registry. If only reported cases are to be considered as occurring events, that would lead to a CVE rate of less than 3% in the entire cohort.

The IMP-IT study [15], which consisted in a retrospectively collected registry of patients receiving any Impella devices for high-risk PCI (n = 117) or cardiogenic shock, provided further information on real-world mortality rates with Impella devices. The time-to-event data released allows to conclude that the mortality rate after 30 days in the high-risk PCI cohort was 9%, which is higher than in this analysis (9% vs 3% with iVAC2L, p = 0.13).

Regarding major bleeding complications, the rate found on the iVAC 2L PMS registry compares favorably with previous data on large-bore catheterization procedures such as transcatheter aortic valve implantation (TAVI), which by default show catheter diameters lager than 7Fr, **Table 4**). The observed rates of vascular complications are most likely reflective of the level of expertise of the operators in the centers involved in the analyzed data which are mostly world-class institutions. The current rate of major vascular complications is higher than in the BCIS-1 and PROTECT II. However, when current rates are put into perspective side by side with relevant studies on MCS and large-bore catheter interventions such as TAVI **(Figure 2)**, it becomes evident that several other studies have reported higher rates with different devices, including the IABP (8Fr).

Furthermore, published data suggests that iVAC 2L may be less likely to damage the cardiac structures and to cause hemolysis than Impella. Impella results in damage to the aortic valve in 13% of the cases, while this has never been observed with iVAC 2L. In addition to that, the risk of hemolysis appears to be lower than similar devices. To date, no reports of clinically relevant hemolysis have been received by the manufacturer.

And finally, iVAC 2L apparently succeeds in creating a more stable setting for the coronary interventions to develop. Current data shows a 7.7% rate of hemodynamical instability as opposed to 12% in the BCIS-1 trial, 12.3% in the IABP arm of the PROTECT II study, and 10.2% in the Impella arm of the same study.

iVAC2L induced significant increases in MAP, SBP, DBP and CPO. HR, CO and mPCWP were unaffected. Similarly, an increase in MAP have been described both in the Dutch and in the German studies. The observed increase in CPO is interesting from the clinical perspective because a CPO < 0.6 Watts has been previously related to worse clinical outcomes [16]. Current results consistently indicate that hemolysis levels are lower than in other modalities of mechanical circulatory support [6, 10]. In line with this the present analysis shows no reports of clinically relevant hemolysis.

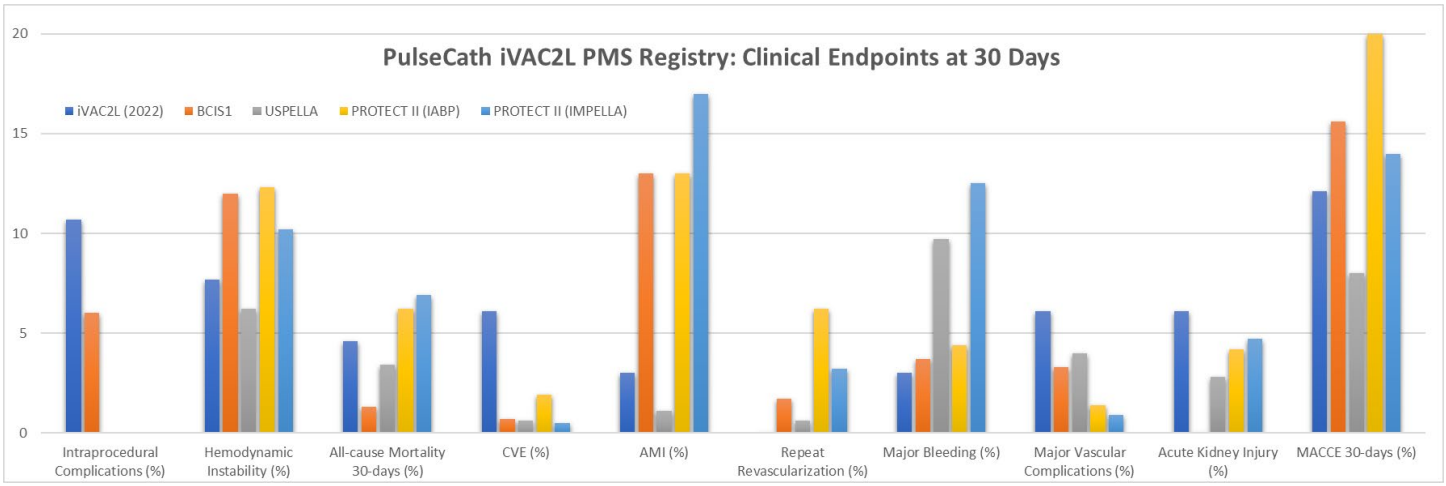


**Figure 1. Clinical Endpoints in the iVAC2L PMS Registry and previous data from major studies in Mechanical Circulatory Support.**

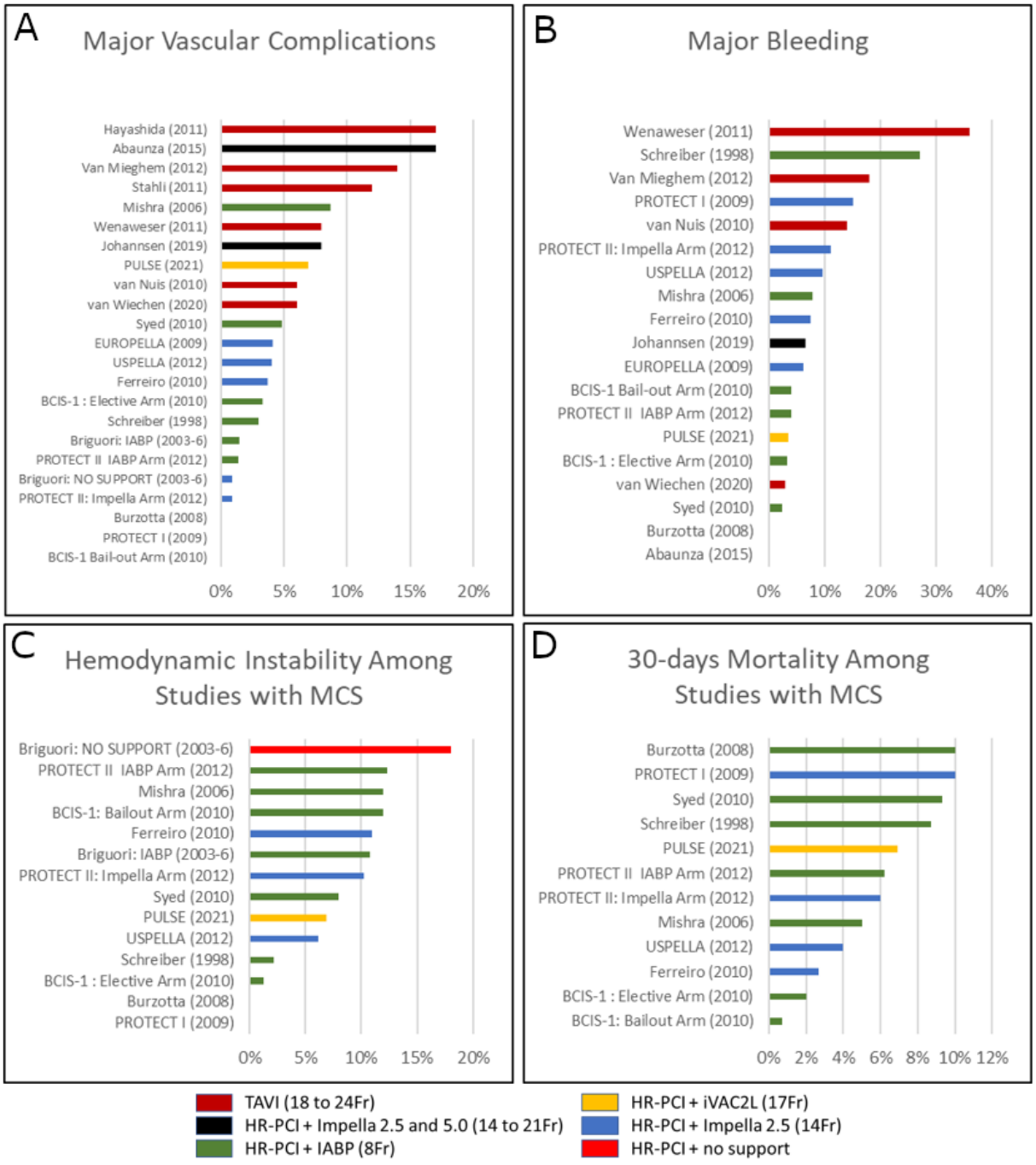


**Figure 2. Clinical Endpoints with PulseCath iVAC2L in the PULSE trial (yellow bars) and in other studies involving MCS and large-bore devices.**

This analysis has the advantage of including a relevant proportion of on-site collected data, reflecting practice in real life. In addition, it also includes data from three prospective studies leading to more standardized definitions and very low levels of missing data. Nevertheless, this comprises only 26% of the registry. Even though there is partial feed-back from operators, this has been mostly addressed by the new Data Collection Forms.

# 6 Conclusion

In conclusion, this second interim analysis of the iVAC2L PMS registry shows low rates of adverse events and significantly better hemodynamics with iVAC2L. Further research is needed to confirm that  in the long run.

# 7 References

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# 8 Tables

| Table 1. Cases by country | | |
|---|---|---|
| **Country** | Number | First Case |
| **UNKNOWN** | 1 | 01/01/2019 |
| **RUSSIA** | 1 | 01/11/2018 |
| **TURKEY** | 1 | 01/11/2019 |
| **JAPAN** | 1 | 05/12/2021 |
| **CHILE** | 1 | 18/08/2021 |
| **FRANCE** | 2 | 01/01/2019 |
| **BELGIUM** | 2 | 01/01/2020 |
| **SPAIN** | 2 | 08/02/2021 |
| **BELARUS** | 2 | 25/02/2021 |
| **FINLAND** | 4 | 01/04/2019 |
| **GREECE** | 4 | 01/11/2019 |
| **UAE** | 4 | 01/11/2019 |
| **SERBIA** | 4 | 12/01/2021 |
| **HUNGARY** | 5 | 01/01/2019 |
| **SLOVENIA** | 5 | 01/11/2019 |
| **INDIA** | 6 | 01/01/2020 |
| **ITALY** | 6 | 01/05/2019 |
| **UNITED KINGDOM** | 7 | 01/03/2018 |
| **POLAND** | 8 | 01/04/2019 |
| **CROATIA** | 8 | 01/12/2020 |
| **IRAN** | 12 | 01/12/2020 |
| **SLOVAKIA** | 21 | 01/01/2019 |
| **GERMANY** | 21 | 01/12/2019 |
| **THE NETHERLANDS** | 46 | 01/01/2017 |

**Table 1.** Number of cases treated with iVAC2L by country and date of the first case.

## Table2. Cases by site

| Site | Country | Cases |
|---|---|---|
| REP. CENTER OF CARDIOLOGY MINSK | BELARUS | 2 |
| CHU SART-TILMAN LIEGE | BELGIUM | 1 |
| CHU TIVOLI | BELGIUM | 1 |
| SOTERO DEL RIO | CHILE | 1 |
| CHC OSJEK | CROATIA | 1 |
| CHC RIJEKA | CROATIA | 1 |
| UHC ZAGREB | CROATIA | 3 |
| UNIVERSITY HOSPITAL CENTRE ZAGREB | CROATIA | 3 |
| LKS | FINLAND | 1 |
| MEILAHTI HOSPITAL | FINLAND | 1 |
| LAPLAND CENTRAL HOSPITAL | FINLAND | 2 |
| CLINIQUE PASTEUR | FRANCE | 2 |
| CHARITE HOSPITAL | GERMANY | 1 |
| JW UNIVERSITY HOSPITAL | GERMANY | 20 |
| ATTIKON UNIVERSITY HOSPITAL | GREECE | 1 |
| ONASSIS MEDICAL CENTER | GREECE | 1 |
| IPPOKRATEIO HOSPITAL | GREECE | 2 |
| GOKI HOSPITAL | HUNGARY | 1 |
| PECS UNIVERSITY | HUNGARY | 1 |
| SEMMELWEIS HOSPITAL | HUNGARY | 1 |
| SZEGED UNIVEERSITY | HUNGARY | 1 |
| UNKNOWN (HUNGARY) | HUNGARY | 1 |
| CHRISTIAN MEDICAL COLLEGE VELLORE | INDIA | 1 |
| CMC INDIA | INDIA | 1 |
| FORTIESCORTS HEART INSTITUTE | INDIA | 1 |
| MAX HOSPITAL SAKET | INDIA | 1 |
| MEDANTA HOSPITAL | INDIA | 2 |
| MASIH HOSPITAL | IRAN | 1 |
| MODARES HOSPITAL | IRAN | 1 |
| RAJAIE HEAR T CENTER | IRAN | 1 |
| RASHID HOSPITAL | IRAN | 1 |
| VALIASR | IRAN | 1 |
| ATIEH HOSPITAL | IRAN | 2 |
| RAJEI HEART CENTER | IRAN | 3 |
| MARIA CECILIA HOSPITAL | ITALY | 1 |
| UNKNOWN (ITALY) | ITALY | 1 |
| CLINICA MEDITERRANEA | ITALY | 4 |
| UNIVERSITY HOSPITAL KRAKOW | POLAND | 1 |
| WARSAW CLINIC | POLAND | 1 |
| WOJSKOWY HOSPITAL | POLAND | 1 |
| MSWIA WARSAW | POLAND | 2 |
| CENTRAL CLINICAL HOSPITAL | POLAND | 3 |
| NATIONAL MEDICAL RESEARCH CENTER OF SURGERY | RUSSIA | 1 |
| DEDINJE INSTITUTE | SERBIA | 1 |
| IKVB DEDINJE | SERBIA | 3 |
| KARDIOCENTRUM NITRA | SLOVAKIA | 1 |
| PRESOV FACULTY HOSPITAL | SLOVAKIA | 1 |
| VUSCH CARDIO CENTER KOSICE | SLOVAKIA | 1 |
| MEDISSIMO MEDICAL CENTER | SLOVAKIA | 2 |
| SUSCH BANSTRA BYSTRICA | SLOVAKIA | 3 |
| MARTIN UNVERSITY HOSPITAL | SLOVAKIA | 6 |
| CINRE HOSPITAL | SLOVAKIA | 7 |
| CELJE HOSPITAL | SLOVENIA | 1 |
| GH DR FRANC DERGAANC | SLOVENIA | 1 |
| GH IZOLA | SLOVENIA | 1 |
| MARIBOR | SLOVENIA | 1 |
| UMC LJUBLIJANA | SLOVENIA | 1 |

| | | |
|---|---|---|
| **GOMEZ HOSPITAL** | SPAIN | 1 |
| **HOSPITAL DE SAN JOAN DESPI** | SPAIN | 1 |
| **AMPHIA** | THE NETHERLANDS | 2 |
| **UMC UTRECHT** | THE NETHERLANDS | 2 |
| **AMPHIA BREDA** | THE NETHERLANDS | 3 |
| **ERASMUS MEDICAL CENTER** | THE NETHERLANDS | 39 |
| **MEMORIAL BAHCELIEVER HOSPITAL** | TURKEY | 1 |
| **AL QASSIMI HOSPITAL** | UAE | 4 |
| **ST THOMAS HOSPITAL** | UNITED KINGDOM | 7 |
| **UNKNOWN** | UNKNOWN | 1 |

**Table 2.** Number of cases treated with iVAC2L according to site and country.

**Table 3. Demographic Characteristics of the iVAC 2L dataset.**

| Variable | Results |
|---|---|
| **Operators** | 70 |
| **Sites** | 67 |
| **Countries** | 24 |
| **Age (years)** | 69±11 (n = 158) |
| **SYNTAX I score** | 35±12 (n = 95) |
| **Weight (Kg)** | 82±17 (n = 118) |
| **Height (cm)** | 171±15 (n = 112) |
| **Ejection fraction (%)** | 34±14 (n = 153) |
| **Gender (Male) (%)** | 79 (n = 142) |
| **EF < 40% (%)** | 67 (n = 153) |
| **Three-vessel disease (%)** | 54 (n = 152) |
| **Stented Left Main (%)** | 59 (n = 153) |
| **Unprotected Left Main (%)** | 44 (n = 98) |
| **Left Main Equivalent (%)** | 36 (n = 36) |
| **Stented LAD and branches (%)** | 70 (n = 132) |
| **Stented LCX and branches (%)** | 53 (n = 131) |
| **Stented RCA and branches (%)** | 36 (n = 133) |

*Operator, site and country are described as counts. Continuous data are exposed as median (IQR) or mean±SD (n = number of observations available). Frequencies are exposed as percentages (n = number of observations available).*

| Variable | iVAC2L (2022) | BCIS1 | USPELLA | PROTECT II (IABP) | PROTECT II (IMPELLA) |
|---|---|---|---|---|---|
| **Support Time (min)** | 71 (50-114) | 516 (360-1380)*** | 60 (6–4320)*** | 504.6±1308.6*** | 112.2±161.4 |
| **Maximum flow (L/min)** | 1.5 (1.36-1.60)? | --- | 2.1±0.2*** | --- | 1.9±0.27*** |
| **Interruption of Support (%)** | 1.2 | --- | --- | --- | --- |
| **Intraprocedural Death (%)** | 0.6 | --- | --- | --- | --- |
| **Intraprocedural Complications (%)** | 10.7 | 6 | --- | --- | --- |
| **Hemodynamic Instability (%)** | 7.7 | 12 | 6.2 | 12.3 | 10.2 |
| **All-cause Mortality 30-days (%)** | 4.6 | 1.3 | 3.4 | 6.2 | 6.9 |
| **CVE (%)** | 6.1 | 0.7 | 0.6 | 1.9 | 0.5 |
| **AMI (%)** | 3 | 13* | 1.1 | 13* | 17** |
| **Repeat Revascularization (%)** | 0 | 1.7 | 0.6 | 6.2* | 3.2 |
| **Major Bleeding (%)** | 3 | 3.7 | 9.7 | 4.4 | 12.5* |
| **Major Vascular Complications (%)** | 6.1 | 3.3 | 4 | 1.4 | 0.9* |
| **Acute Kidney Injury (%)** | 6.1 | --- | 2.8 | 4.2 | 4.7 |
| **MACCE 30-days (%)** | 12.1 | 15.6 | 8 | 20 | 14 |

**Table 4.** 30-days clinical outcomes of the iVAC2L registry and two major randomized controlled trials in high-risk PCI, the BCIS-1 and PROTECT II trials. MACCE: composite endpoint of death, myocardial infarction, stroke and repeat revascularization after 30 days.

* $p < 0.05$ versus iVAC2L (2022)
** $p < 0.01$ versus iVAC2L (2022)
*** $p < 0.001$ versus iVAC2L (2022)

| Variable | Before | During | After | p.value |
|---|---|---|---|---|
| **Heart Rate (bpm)** | 74.46±14.81 | 75.22±14.46 | 73.51±12.64 | 0.63 |
| **CO (L/min)** | 4.41±1.26 | 4.84±1.31 | 4.69±1.21 | 0.28 |
| **SBP (mmHg)** | 115.24±22.76 | 122.39±24.07 | 124.48±24.82 | < 0.01 |
| **DBP (mmHg)** | 60.35±15.89 | 65.25±15.01 | 64.66±15.69 | < 0.05 |
| **MAP (mmHg)** | 78.94±16.04 | 84.46±15.71 | 84.79±16.38 | < 0.01 |
| **mPCWP (mmHg)** | 16.44±8.66 | 17.26±9.57 | 15.56±8.83 | 0.69 |
| **CPO (Watts)** | 0.72±0.25 | 0.84±0.3 | 0.86±0.29 | < 0.05 |

**Table 5.** Hemodynamic variations with the use of iVAC2L. CO: Cardiac Output. SBP: Systolic Blood Pressure. DBP: Diastolic Blood Pressure. MAP: Mean Arterial Pressure. mPCWP: Mean Pulmonary Wedge Pressure. CPO: Cardiac Power Output. P-values correspond to two-way ANOVA before, during and after support.