RESEARCH
VOLUME 9 ISSUE 3
ISSN: 2639-5274, 2096-5168

Complex and High-Risk Percutaneous Intervention Assisted By Extracorporeal Membrane Oxygenation (ECMO)

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Abstract

Background: Despite improvements in percutaneous coronary artery techniques (PCI) and equipment, traditional PCI alone is still insufficient to manage complex and high-risk lesions due to increased risk of major adverse cardiac events, including myocardial infarction, cardiogenic shock, and death. In recent years, the use of extracorporeal membrane oxygenation (ECMO) during PCI has emerged as a potential solution to manage complex and high-risk lesions.

Objective: To examine the in-hospital and 1-year clinical outcomes in patients who underwent complex, high-risk PCI with VA-ECMO support**.**

Methods: This retrospective study included patients who underwent elective complex and high-risk PCI with hemodynamic support provided by VA-ECMO from 2018 to 2022. Rates of VA-ECMO related complications, complications related to PCI, death, and MACCE events during hospitalization and after one-year follow-up were analyzed.

Results: A total of 81 patients (Average age: 62.74 ±10.807 years) underwent complex and high-risk PCI assisted with ECMO. The VA-ECMO support was provided for an average of 21.0 hours (With a range of 1-312). Intra-aortic Balloon Pump IABP support was provided in 32.1% of

patients. The pre-and post-PCI SYNTAX scores of the patients were 39.92 ± (6.4) and 6.04 ± (9.25), respectively (P <0.001). Most of the patients had triple-vessel coronary disease (47%). Interoperated complications include Cardiac Tamponade (N=1,1.2%), Acute Myocardial Infarction (N=6,7.2%), Cardiogenic Shock (N=2,2.4%), Cardiac Arrest (N=2,2.4%), Arrhythmias malignant in nature which required electro cardioversion (2,2.4%), Ventricular tachycardia (N=1,1.2%), Non-infectious multiple organ failure MODS(N=1,1.2%), Aortic Dissection Type-A (N=1,1.2%). Blood hemoglobin Pre- CHIP assisted VA-ECMO PCI and Post-procedure were 136.17 ± 21.479 g/L and 106.67 ± 19.103 g/L respectively P<0.001). eGFR pre and post-PCI were 67.22 ± 26.85 and 60.09 ± 27.78 respectively (<0.002), Pre and Post PCI EF were 38.69 ± 13.65 and 43.55 ± 13.72 respectively (<0.001), During hospitalization the outcomes for the CHIP assisted by ECMO procedure include Death (N=16,19.8%), Inguinal Hematoma (N=2,2.5%), Bleeding from the punctured site (N=2,2.5%), Pseudoaneurysm (N=1,1.2%), Cerebral Infarction(N=1,1.2%), Subarachnoid hemorrhage (N=1,1.2%). Lower limb ischemia, acute renal injury, and Bacteremia were not observed in any of the hospitalized patient. Hemoglobin level (Hb) was decline in 72.8% of patients requiring blood transfusion therapy was (N=59). Survival at discharge (Healthy) was (N=65, 80.2%). In 1 year of follow-up, six patients died (6, 7.5%), including 1 patient who died of ventricular fibrillation after discharge, 1 patient died of aortic stenosis after 1 month of high-risk PCI, 1 patient died of terminal illness, 1 patient had recurrent acute myocardial infarction 6 months after PCI (stent restenosis), another died of acute heart failure after 28 days, and another died of multiple organ dysfunction syndrome (MODS).

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VOLUME 9 ISSUE 3
ISSN: 2639-5274, 2096-5168

Conclusion: ECMO-assisted support during high-risk PCI is a safe and effective strategy for achieving revascularization in complex and high-risk coronary artery lesions in patients who are not candidates for CABG. The use of VA-ECMO resulted in minimal complications and low rates of MACCE during hospitalization and one-year follow-up. Further research is needed to determine the optimal timing for VA-ECMO initiation

Introduction

According to the current guidelines, coronary artery bypass grafting (CABG) and percutaneous coronary intervention (PCI) procedures are revascularization elective strategies in complex coronary artery diseases, including multiple vessel involvement, bifurcation stenosis, unprotected left main stenosis, and chronic total occlusion CTO [1]. CABG is recommended by guidelines in complex and high-risk coronary artery disease; however, PCI is becoming more popular in patients not suitable for CABG [2, 3, 4]. In patients with complex coronary artery lesions, revascularization with PCI or CABG benefits in prognosis [5, 6].In these patients, the revascularization proportion is low [7, 8]. Revascularization in complex and high-risk coronary artery lesions is achieved via High-risk PCI (HR-PCI). Several complications can occur in HR-PCI procedures, including coronary artery dissection, no coronary artery reflow, hemodynamic insatiability, cardiac tamponade, and sudden cardiac arrest [3]. Yet, HR-PCI poses a great challenge for interventional cardiologists.

According to the published literature, mechanical circulatory assistance during revascularization can be achieved in complex and high-risk PCI [3, 4, 9]. Mechanical devices including intra-aortic balloon pump (IABP) counter-pulsation, extracorporeal membrane

oxygenation (ECMO), Impella (Abiomed, Danvers, MA, US), and Tandem Heart (LivaNova Medical Technology Co., Ltd., Pittsburgh, PA US Co., Ltd., Pittsburgh, PA, United States) can be used as circulatory assistance during HR-PCI, [4, 10]. Cardiac arrest or hemodynamic instability can ensure intraoperative HR-PCI, and ECMO can offer prevailing circulatory support and significantly enhance patient prognosis [11]. Though, Veno-arterial (VA)-ECMO support can surge the risk of complications related to ECMO, including an increased risk of infection at the site of intervention, hematoma, destruction of blood cells, and lower limb ischemia [10]. Still, there is a lack of recommended guidelines and published clinical data about the employment of VA-ECMO as mechanical assistance circulatory support in HR-PCI procedures. Therefore this study was designed to examine and analyze the outcomes of the preventive use of VA-ECMO during HR-PCI.

MATERIALS AND METHODS

Study Population and Design

This single-centre retrospective observational study included 81 patients who underwent an elective complex and high-risk PCI with hemodynamic support provided by VA-ECMO from 2018 to 2022 and a follow-up of one-year post-PCI. The patient's age range was 18 years or older, with a diagnosis of complex and high-risk coronary artery disease. VA-ECMO support was provided in patients having the following criteria I) Having a Left ventricle Ejection Fraction LVEF of ≤30%; (ii) LVEF ≥30% along with the following conditions; (a) LM coronary artery Unprotected, (b) Chronic total occlusions (CTOs) in one or two coronary arteries, in addition, one severe stenosis, (c) Calcified coronary artery lesions requiring rotational grinding and

maneuverings for the severity and diagnostics purpose. New onset and older myocardial infarction, clinically unstable angina pectoris, cardiogenic shock, and acute and chronic Heart Failure were among the indicators in these patients. Intraoperative or Pre-PCI ECMO was established in each patient, and the Veno-Arterial-ECMO mode was selected. In all patients, the common femoral artery and vein were used for the ECMO intubation. Arterial cannulas at 15–17 (Fr) and venous cannulas at 19–21 (Fr) were selected for ECMO intubation since their diameters were 1-2 mm smaller than the inner diameter of the intubated vessel. Intubation for VA-ECMO was achieved with the guidance of fluoroscopy. Heparin 100 U/kg was an anticoagulation stratagem used before the Veno-arterial ECMO insertion. The activated clotting time (ACT) during VA-ECMO was set at ≥250 seconds, then 250–350 seconds during PCI. All patients received 300 mg of aspirin, 180 mg of Ticagrelor, or 300 mg of Clopidogrel PO before and after PCI. Preliminary VA-ECMO blood flow was established at 1.5-2.0 L/min per patient weightiness, and it was later modified in response to a patient's hemodynamic.

Patients who declined CABG were evaluated by the interventional cardiologist's team at the study center for HR-PCI assisted by VA-ECMO. Patients with coronary artery disease (CAD) needed PCI for revascularization. Raw data for this study was collected by accessing patient's medical records, inpatients records and follow-ups of the same patients, including the baseline demographic and clinical characteristics of patients, including age, sex, body mass index, medical history, and pre-procedure medications, intraoperative, and follow up of the patients for major adverse cardiac and cerebrovascular events MACCE events, as hospitalization due to heart failure, stroke, recurring MI, and all-cause mortality. The primary endpoint of this study was the

occurrence of major adverse cardiac and cerebrovascular events (MACCE) within the hospital and after the HR-PCI procedure assisted by VA-ECMO. MACCE was defined as (I) composite of death by any cerebrovascular or myocardial infarction, stroke, and either by re-PCI or CABG-targeted vessel revascularizations. Secondary endpoints included individual components of MACCE, bleeding events, the need for re-hospitalization, and long-term outcomes up to 1 year.

Patients were followed-up for 1 year Post-procedure. Clinical assessments and laboratory tests were performed at each follow-up visit to assess for the occurrence of adverse events and to evaluate the long-term outcomes of the procedure. Any adverse event that occurred during the follow-up period was recorded. The procedural details include the type of PCI and the number of stents used. In addition, pre and post-procedure laboratory data, including hemoglobin level, Kidney function test, and liver function test, were collected from the inpatient records department. Data regarding ECMO support, including the duration of ECMO support, type of ECMO cannulas, and complications related to ECMO support, such as bleeding or thrombosis, were collected. Data about additional interventions, such as decompression of LV by intra-aortic balloon pump (IABP) or surgical intervention for ECMO-related complications, was acquired from the catheterization lab.

The following were considered to be acute kidney injury (AKI): (i) Rise in serum Creatinine (SCr) of more or equal to 0.3 (mg/dl (≥26.5 μmol/L)) for 48 hours; (ii) a rise in SCr (serum creatinine) ≥1.5 that of the reference value, which known to have or assumed to have happened during the preceding week; and (iii) For six hours the amount of urine < 0.5 mL/Kg/hr [12]. Acute myocardial infarction was defined by the fourth edition of the global myocardial infarction as an upsurge or

reduction in blood plasma levels of cardiac troponin that is by at least one time more than the upper limit of the normal range and accompanied by simultaneous clinical evidence of acute myocardial ischemia, such as [13]: (A) Acute myocardial ischemic clinical manifestations, (B) Pathogenesis of the Q wave (novel), (C) Novel noticeable myocardial loss, Segmental wall motion abnormality in LV, (D) Electrocardiogram novel changes of ischemia, (E) Coronary artery angiography imaging examination results, and validation of coronary artery thrombosis were all illustrations of acute myocardial ischemia. The following criterion was used to state coronary artery diseases [14] (i) Micro vasculature dysfunction and/or coronary artery spasm that induces chest-related symptoms in patients who are exposed to stress, exercise or even at rest (Unstable Angina) (ii) ≥50% stenosis of Left main coronary artery and, (iii) ≥70% stenosis in one or more CA. Chronic Total Occlusion (CTO) was stated to be coronary artery obstruction thru positive thrombolysis having TIMI distal blood flow level 0 and ≥3 months for occlusion. Ipsilateral - collateral vessels or bridging at full occlusion is still considered even if distal blood flow TIMI level >0 in an occluded vessel [15]. The SYNTAX score for the patients was calculated online http://syntaxscore2020.com/. For the bleeding incidents, the Bleeding Academic Research Consortium (BARC) criteria were applied [16]. The need for the patient's informed consent was waived off as it is a retrospective observational study.

Clinical Outcomes

The outcomes of the study are procedural success, defined as achievement of complete revascularization with a residual stenosis of less than 30%, and in-hospital mortality, including the incidence of MACCE events, bleeding events such as hematomas, Pseudoaneurysm, Fistula

(Atrio-venous, deep venous thrombosis, acute kidney injury, and or Bacteremia. The primary endpoint of this study was the occurrence of major adverse cardiac and cerebrovascular events (MACCE) within the hospital Post PCI. MACCE was defined as (I) a composite of death due to cerebrovascular or cardiovascular events, stroke, either by PCI or CABG-targeted vessel revascularization. Secondary (Safety) endpoints included individual components of MACCE, bleeding events, need for re-hospitalization, and long-term outcomes up to 1 year.

Statistical Analyses

Descriptive statistics were used to summarize patient characteristics, procedural details, and outcomes. Continuous variables were presented as mean ± standard deviation, those with normal distribution or median with interquartile range, and categorical variables were presented as frequencies and percentages. Other Statistical tests for normality are Kolmogorov-Smirnov and Shapiro-Wilk. Paired t-test was used for the relatable variables and compared their mean of Pre-Op and Post-Op. The test was two-tailed, and p-<0.05 statistically significant was set for statistical analyses done by IBM SPSS Statistics 27.0 (IBM Corp., Armonk, NY, USA).

RESULTS

Baseline Clinical Characteristics

A total of 81 patients (Average age: 62.74 ±10.807 years) who underwent complex and HR-PCI assisted with VA-ECMO were included in this retrospective study. 74.1% of the study population were males (N=60), and 25.9% were females (N=21). The majority of the patients had prior comorbidities. Pre- and post-operatively LVEF was 38.65 ± 13.576 and 43.52 ± 13.640,

respectively. All the patients were hemodynamically stable before the procedure. Among the patients, 41.7% had ST-elevated myocardial infarction, 23.5% had non-ST-elevated myocardial infarction, and 25.9% had unstable angina. More than half of the patients had heart failure (50.6%). The patient included in this study was evaluated based on New York Heart Association NYHA criteria. The most common were NYHA class IV patients (39.5%). All the patients who underwent complex and high-risk PCI assisted by VA-ECMO were elective and rejected the coronary artery bypass grafting CABG. Baseline Clinical Characteristics, comorbidities, and medications before the procedure of patients included in our study are summarized in **Table-1.**

Table-1| Baseline Clinical characteristics of the patients included in this study

Age (Years)
Gender-Male Female
Body Mass Index (Metric Units)
Hypertension
Diabetes
Chronic Kidney Disease
Pulmonary Disease
Atrial fibrillation
Smoking
Hyperlipidemia
Prior Stroke
Prior CABG
Prior PCI (Stent restenosis)
Clopidogrel
Ticagrelor
Lung Disease
NSAID
NYHA Class combined Class I Class II Class III

ISSN: 2639-5274, 2096-5168

Class IV
LVEF Pre-Op
STEMI
NSTEMI
Unstable Angina UA
Heart failure (HF)
Refused CABG
Platelets *10^9/L
Prothrombin-Time (sec)
Thrombin-Time (sec)
Antithrombin (%)
INR
Alanine Aminotransferase (ALT U/L)
Aspartate Aminotransferase AST (U/L)
Albumin (g/L)

Data are presented as N (%), mean ± SD, or Medians (Interquartile Q1-Q3). CABG, Coronary Artery bypass surgery; PCI, Percutaneous coronary intervention; NSAID, non-steroidal anti-inflammatory drug; NYHA, New York Heart Association.

Intraoperative procedural and angiographic data are summarized in **Table 2.** The patients' pre and post-PCI SYNTAX scores were 39.92 ± (6.4) and 6.04 ± (9.25), respectively (P <0.001). One patient had up to five (5) diseased vessels (N, 1 = 1.2%) at maximum. 41.5% of the patients either had a single vessel or multiple vessel CTO lesion. LAD was the most common culprit vessel (95.1%), followed by RCA (85.2%), LCX (79.0%) and LM (43.2%). Revascularization was achieved in all the diseased vessels by implantations of (an average of 3.0 (0-6) stents. No stent was deployed in one patient (1.2%) because the guide wire could not pass the lesion due to heavy calcification and high tortuosity. One patient (1.2%) did not need a stent as the thrombus was aspirated successfully, with distal TIMI III flow without obvious stenosis. One patient with stent restenosis (1.2% each) had only one stent implanted, and existing stents were re-inflated with distal TIMI III flow. ECMO was set up intraoperatively in 52 patients (64.2%) and preoperatively in 29

patients (35.6%). ECMO weaning time was 21 hours with a range (1-312 hours). The intra-aortic balloon pump IABP counterpulsation was applied to 32.1% of patients. Indications and reasons for counterpulsation include; Retaining of contrast agent in coronary sinuses, Extended VA-ECMO duration causing burden on the left side of the heart, Blood stasis seen in left ventricle on bedside cardiac ultrasound, and weaning off VA-ECMO support in patients with poor cardiac function with counterpulsation IABP. Intraoperative complications include Cardiac Tamponade (N=1,1.2%), Arrhythmias malignant required electro cardioversion (2,2.4%), Ventricular tachycardia (N=1,1.2%), MACCE events and other complications during hospital post-PCI were Acute Myocardial Infarction (N=6,7.2%), Cardiogenic Shock (N=2,2.4%), Cardiac Arrest (N=2,2.4%), Non-infectious multiple organ failure MODS (N=1,1.2%), Aortic Dissection Type-A (N=1,1.2%). No patient died during the complex and high-risk PCI procedure.

TABLE-2|Procedural & Angiographic parameters of the patients included in the study.

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ISSN: 2639-5274, 2096-5168

Parameter	ECMO N (81)
Pre-PCI SYNTAX Score	39.92 ± (6.4)
Post-PCI SYNTAX Score	6.47 ± (9.25)
Number of coronary vessels having the disease One Two Three Four Five	 1 (1.2%) 6 (7.4 %) 38 (47 %) 35 (43.2 %) 1 (1.2%)
CTO	34(42.0 %)
Location of Lesion CA (Combined) Left Anterior Descending Left Circumflex Right Coronary Artery Left Main Ramus	 77 (95.1 %) 64 (79.0 %) 69 (85.2 %) 35 (43.2 %) 2 (2.46%)
OCT	14 (17.3%)
Number of Stents implanted No PCI Drug Coated Balloon Proglide Use IABP counter pulsation Canulation for distal perfusion Malfunctioning device Non-Invasive Ventilator	3.0 (0-6) 1 (1.2 %) .35 (0-4) 81 (100%) 26 (32.1%) 0(0) 0(0) 52 (64.2%)
ECMO setup **Intra-Operative** **Pre-Operative**	 52 (64.2%) 29 (35.8%)
ECMO weaning Time (Hours)	21 (1.0-312)
MACCE in CATH LAB Cardiac Tamponade Malignant Arrhythmias required electro cardioversion Ventricular Tachycardia Death	 1 (1.2%) 2 (2.4%) 1 (1.2%) 0(0)

Data are presented as N (%), mean ± SD, or Medians

(Interquartile Q1-Q3). CA, Coronary artery; PCI, Percutaneous coronary intervention; CTO, Chronic total occlusion; OCT, Optical coherence tomography; IABP, Intra-aortic balloon pump; ECMO, Extracorporeal Membrane oxygenation

Table-3 summarized the patients' blood work, renal function parameters, and echocardiography indices pre and post-complex and high-risk VA-ECMO assisted PCI. Blood haemoglobin Pre and Post-procedure were 136.17 ± 21.479 g/L and 106.67 ± 19.103 g/L respectively (P<0.001). Creatinine and blood urea nitrogen were not significantly altered before and after the procedure. Uric acid pre and post-procedure were 435.4 ± 136.5 and 362.9 ± 138.0 (p<0.001) correspondingly. eGFR pre-procedure were 67.22 ± 26.85 and post-procedure minimum 60.09 ± 27.78 (<0.002), Before PCI LVEF was 38.69 ± 13.65 and after PCI were 43.55 ± 13.72 (p<0.001)

TABLE 3| Pre and Post PCI Evaluation Laboratory, Cardiac Indices, and Renal Function parameters

Parameter	Before-PCI	After-PCI	p-Value
Hb (g/L)	136.1 ± 21.4	106.6 ± 19.1	<0.001
Cr (µmol/L)	125.7 ± 98.7	138.9 ± 101.2 (Highest)	0.052
BUN (mmol/L)	8.6 ± 4.9	14.8 ± 48.1	0.241
Uric Acid (µmol/L)	435.4 ± 136.5	362.9 ± 138.0	<0.001
Pre-Op eGFR (ml/Min)	67.2 ± 26.8	60.0 ± 27.7 (Minimum)	<0.002
Pre-Op LVEF (Percentage)	38.6 ± 13.6	43.5 ± 13.7	<0.001

Hb, Hemoglobin; Cr, Creatinine; BUN, Blood Urea Nitrogen; eGFR, Estimated Glomerulus Filtration; LVEF, Left Ventricle Ejection Fraction.

Clinical Outcomes

Table-4 Evaluation of patient's clinical outcomes for CHIP assisted by ECMO procedure includes overall Death (N=16, 19.8 %), Post-procedure infarction occurs in 7.5% (N=6), and cardiac arrest in 2.5% (N=2) of patients. Cardiogenic shock occurs in 2.5% of patients (N=2). One patient had (1.2%) NSTEMI. Aortic dissection Type-A occurs in one patient (1.2%). Inguinal Hematoma occurs in 2 patients. Bleeding from the punctured site was also observed in 2 (2.5%) patients.

ARC-Type-I was found in only one patient. A pseudoaneurysm, Cerebral Infarction, and Subarachnoid haemorrhage were each seen in one patient (n=1, 1.2%). Patients with electrolytes imbalance, contrast clearance and decompression on the left ventricle were treated with continuous renal replacement therapy (N=26, 32.1%). Lower limb ischemia, acute renal injury, or Bacteremia was not reported in any patient during the stay at the hospital post-procedure. In 72.8% of patients (N=59), Hb was declined and required blood transfusion.

TABLE-4| Clinical outcomes of the study during the stay at the hospital

Parameters	ECMO(N=81)
Survival at discharge (Healthy)	65 (80.2%)
Mortality all cause (Hospital)	16 (19.8%)
Re-infarction	6 (7.5%)
Cardiac arrest	2 (2.5 %)
Cardiogenic Shock	2 (2.5 %)
NSTEMI	1 (1.2%)
Aortic Dissection Type-A	1 (1.2%)
Inguinal Hematoma	2 (2.5%)
Bleeding from the puncture site (ECMO) ARC's-Type-I	2 (2.5 %)
Peudoaneurysm	1 (1.2%)
Cerebral Infarction Post-Op (New)	1 (1.2%)
Subarachnoid Hemorrhage	1 (1.2%)
Continuous renal replacement Therapy (CRRT)	26 (32.1%)
Blood Transfusion	59 (72.8%)

Data presented in N (%); NSTEMI, Non-ST elevated Myocardial infarction; ARC's,

Table-5 summarized the occurrence of MACCE, other significant complications, and all-cause mortality over one-year follow-up after the complex and high-risk PCI assisted by VA-ECMO. No

complications were reported in 29 patients (35.8%) at one year of follow-up and MACCE events with an average duration of 7.02 months with a range (0-34 months), zero (0) for the patients who completely lost after the procedure and thirty-four (34) is the most prolonged follow-up duration. 27 (33.3%) patients were lost to follow-up, of whom 5 (6.2%) followed up for one (1) month, whereas 22 (22.2%) never followed up post-PCI. In one year of follow-up, six patients died (6, 7.5%), including one patient who died of ventricular fibrillation after discharge, one patient died of aortic stenosis after one month of high-risk PCI, one patient died of terminal illness, one patient had recurrent acute myocardial infarction six months after PCI (stent restenosis), another died of acute heart failure after 28 days, and another died of multiple organ dysfunction syndrome (MODS). Angina occurred in two (N=2, 2.5%) seven and sixteen months postoperative, respectively. Both patients received appropriate treatment and are currently in healthy condition.

TABLE-5|Outcomes and MACCE over the 1-year follow up

Parameters	ECMO (N=81)
Healthy	29 (35.8%)
Time Duration (Months)	7.02 ± (10.0)
Lost to follow-up (Combined)	27(33.3%)
Died (Combined) Ventricular Fibrillation Aortic Stenosis Terminal illness Recurrent Acute MI Acute Heart failure Non-Infectious MODS	6 (7.5%) 1 (1.2%) 1 (1.2%) 1 (1.2%) 1 (1.2%) 1 (1.2%) 1 (1.2%)
Angina (Improved)	2 (2.5%)

Data are presented as mean ± standard deviation, N (%); MI, Myocardial Infarction; MODS, multiple organ dysfunction syndrome

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ISSN: 2639-5274, 2096-5168

Discussion

Revascularization in patients with complex and high-risk CAD has long posed challenge for interventional cardiologists due to inherent risks and potential complications associated with the procedure. CAD and its related complications make these patients vulnerable to hemodynamic instability intraoperatively. CABG is a preferred choice of treatment in patients with SYNTAX score ≥23 and left main coronary artery disease or triple vessel disease with or without diabetes. Revascularization with PCI is appropriate management in one or two coronary arteries lesions in elective revascularization strategy in complex and high-risk coronary arteries with or without stenosis of left anterior descending. [1] The findings from analyzing 81 patients in a study indicate that the utilization of VA-ECMO (veno-arterial extracorporeal membrane oxygenation) in elective high-risk percutaneous coronary intervention (HR-PCI) is safe and viable. The study reported low rates of mortality and complications. Cases involves patients with intricate and high-risk coronary artery disease, selective HR-PCI assisted by VA-ECMO could be considered as an alternative approach to coronary artery bypass grafting (CABG) for elective complex and high risk, or refusal from CABG. This study outcomes aligns with similar studies conducted at other single-center [17-23]. In patients with complex and high-risk CAD, three key clinical characteristics are frequently observed. First, presence of severe coronary artery disease, which includes conditions such as multivessel disease or involves unprotected left main trunk, chronic obstructive disease with or without calcification, and subsequent development of complications. Second, involves the coexistence of morbidities such as heart failure, diabetes, a history of previous coronary artery bypass grafting (CABG) or PCI (Stent restenosis), and advanced age. Third, manifestation of

hemodynamic changes, which may encompass hemodynamic instability, shock, or severe left ventricular dysfunction [3, 4]. The SYNTAX trial found no significant difference between PCI and CABG in all-cause mortality after 10 years of revascularization [2]. In this study HR-PCI triple vessels revascularization was successful in CABG patients, but it was limited in terms of longer survival duration and no MACCE events after HR-PCI. According to Bai et al, patients with triple vessel disease who underwent CABG had a higher survival rate than those who underwent PCI; however, patients with left main stenosis who underwent PCI and CABG did not show any significant differences in survival rates [21]. Revascularization stratagem in left main or triple vessel CAD patients were evaluated by cardiac surgeons/interventional cardiologists [2]. CABG or PCI revascularization rate in complex and high-risk CAD is low. In one group of a study' Global Registry for Acute Coronary Events Score, recruited 4,414 patients of NSTEMI (Non-ST elevated myocardial infarction) and divide them into low-risk, medium risk, and high-risk patients. In their study, they found revascularizations in high-risks group was significantly lesser compared to low and medium-risk group. Though, in such complex and high-risk CAD both CABG and PCI is progressively growing over time [7]. Another observational study evaluated revascularization in multi vessels coronary artery lesions and non-ST elevated myocardial infarction (NSTEMI) with comorbidity diabetes, including 29,769 patients. Their findings suggested of all patients who underwent revascularizations within the span of six years, half of patient went for PCI and one-third for CABG, and the proportion of total revascularization increased. Patients underwent CABG, proportion remains same but increase revascularization with PCI progressively. Revascularization with PCI or CABG in complex and high-risk CAD enhance prognosis as proposed [5, 6].

Nevertheless, HR-PCI presents several challenges in its implementation [3, 9]. Firstly, research data are scarce due to insufficient rates of revascularization and a lack of objective and reliable evidence supporting an optimal strategy for revascularization. Secondly, interventional physicians may have underestimate potential benefits of revascularization in this specific patient population. Thirdly, performing revascularization procedures in complex and high-risk CAD patients can be challenging, as intraoperative procedures and complications may significantly affect hemodynamic parameters. Lastly, operators must possess expertise in various techniques such as fractional flow reserve, intravascular ultrasound, and optical coherence tomography for better guidance. Consequently, a substantial sum of interventional physicians may lack the essential proficiency mandatory for such procedures. An increase in clinical evidence of using mechanical assistance devices for the left heart, indicates efficacy of left heart assist devices for providing circulatory support during HR-PCI. IABP is an older mechanical assistance circulatory device. The IABP-SHOCK II trial, involving mechanical circulatory assistance devices revealed that the intra-aortic balloon pump (IABP) alone does not provide adequate support to patients experiencing circulatory failure [24]. Al-Khadra et al. conducted an assessment of non-emergency PCI in patients without cardiogenic shock and acute myocardial infarction, utilizing a percutaneous ventricular assist device (PVAD) and IABP support. In their findings, they stated that mortality rate was lower in PCI assisted by PAVD than in PCI assisted by the IABP [25]. The use of ECMO can provide robust mechanical circulatory support for hemodynamic management during HR-PCI [10, 11]. Interventional cardiologist should evaluate the patient's cardiac functional condition and the severity of CAD before using VA-ECMO in complex and HR-PCI. This evaluation is crucial due to the latent occurrence of significant hemodynamic instability during PCI in patients with

severe CAD. Therefore, for the conclusiveness in this study we includes patients with LVEF ≥15 %. Patients with left main unprotected, dual CTO with one more unembellished coronary artery stricture in which there is need aimed at maneuvering for disease severity or rotational atherectomy required in complex and high-risk PCI needed VA-ECMO support, for that reason we included a vast range (LVEF=15%-LVEF=70%) patients in our study. All patients did well at the end of the procedure without intraoperative mortality or MACCE events leading to mortality. Four cases of MACCE were reported; two had VF; a VT; and 1 had a cardiac tamponade; they were treated immediately and appropriately with electro cardioversion. Re-infarction occur in 6 (7.5%) patients, cardiac arrest occur in 2 (2.5%) patients which leads to death without any treatment option not attributable to HR-PCI or ECMO-related complication, due to the stent's thrombosis and restenosis, more the comorbidities, late the interventions ,worst ending. NSTEMI was observed in 1 patient (1.2%) with a previously discussed attributable cause as discussed earlier because these patients did very well in the procedure and ECMO was weaned off successfully after that MACCE events happened. In one patient (1.2%) Type-A aortic dissection occurs which blocks RCA leading to acute myocardial infarctions, was not the complications of HR-PCI VA-ECMO but sudden spike in blood pressure. Peudoaneurysm (N=1,1.2%) in one patient, repaired surgically without leading to in-hospital mortality, Cerebral infarction was noted in one patient (1.2%) lacking any serious complication or mortality countered by anticoagulation strategy in the patient, and subarachnoid hemorrhage occurs in (N=1,1.2%) patient, Both cerebral infarction and subarachnoid hemorrhage occurs post-procedure due to prolong durations of ECMO in these two patients which were promptly diagnosis and treated appropriately without causing any mortality in patients were healthy afterward. VA-ECMO mechanical circulatory support in severe CADand more prospective

and large-sample randomized studies are required. Several studies conducted at single centers, with small sample sizes, have examined the use of VA-ECMO as a mechanical circulatory support strategy for HR-PCI. The findings from their studies indicates that VA-ECMO is safe and effective. Furthermore, elective HR-PCI supported by VA-ECMO proves to be a viable alternative for patients who are not eligible for CABG or are deemed high-risk, offering favorable short-term and long-term prognoses. At present, existing clinical evidence regarding HR-PCI assisted by VA-ECMO is inadequate, necessitating further validation through randomized controlled trials. Successful implementation approach relies on the expertise of specialized teams comprising experienced ECMO and cardiac interventional specialists. ECMO, in comparison to alternative percutaneous mechanical support devices, possess greater operational challenges, clinical advancement and patient outcomes have been hindered by associated complications.[26] Competence in the identification, appropriate on time treatment, and management of ECMO-related complications is largely based on capability of the team in the diagnosis, treatment, and nursing care of ECMO patients. Studies have demonstrated that ECMO centers that manage the workload of more than 20 critically ill patients each year can maintain the expertise needed in ECMO treatment. [27] In addition, centers that specialize in ECMO care for adults, which treat more than 30 cases per year, have significantly lower mortality rates than centers that manage fewer than six cases per year. [28]. In center for this study expert for the ECMO are in accordance with the criterion and have excellent skills set, less VA-ECMO related complications in patients of complex and high-risk coronary artery PCI. The main complications of VA-ECMO in our study are inguinal hematoma, bleeding from the puncture site, elevated pressure on the left side of the heart (LV) counter by the IABP support successfully, blood loss in the VA-ECMO external circuit,

there was no deep venous thrombosis, lower limb ischemia, and most importantly no infection or Bacteremia was noted in any of the patient included in those with prolonged duration of ECMO in our study. For VA-ECMO intubation, all patients included in this study femoral artery and vein evaluated under the guidance of fluoroscopy by keeping cannula diameter lesser about 1-2 mm that of intubated artery and vein to avoid ipsilateral cannula and lower limb ischemia and thrombosis or DVT. [29]. Based on the experience from our study cannula was intubated under the guidance of fluoroscopy to evade arterio-venous fistula complications related to ultrasound-guided cannulation. Choice of vascular access depends on the patient's anatomy, comorbidities, and the experience of the interventional team. In addition, the management of anticoagulation during ECMO-assisted PCI is another important consideration. Anticoagulants are essential to prevent thromboembolic events during ECMO-assisted PCI, but it must be balanced against the risk of bleeding. The optimal anticoagulation strategy depends on the patient's comorbidities, the type of ECMO used, and the individual patient's response to anticoagulation. In this study, two patients (2.5%) develop a hematoma and two patients (2.5%) have bleeding from the intubation site of cannulation out of a total of 81 patients which were treated appropriately without causing mortality. In (N=59) patients (72.8%) hemoglobin Hb level drops requiring blood transfusion therapy were done primarily due to loss of blood in the VA-ECMO external circuit. In this study left ventricle overload due to prolong use of VA-ECMO support in some was decompressed with counter-pulsation with IABP in (N=26, 32.1%) patients remaining were VA-ECMO without IABP support or after the weaning of ECMO support. Impella (Abiomed) and intra-aortic balloon pump (IABP) are commonly used as primary devices for left ventricular unloading during VA-ECMO. Additional strategies include opening an atrial septum, surgical drainage of the left ventricular

apex, use of positive inotropes, use of diuretics, and use of continuous renal replacement therapy. These approaches collectively contribute to the management of left ventricular overload in the setting of VA-ECMO. [10, 11] Ventricular decompression with any of the unloading devices is better and reduced mortality in VA-ECMO-supported patients than in no loading. [30]. Among patients with cardiogenic shock undergoing VA-ECMO, no substantial disparity in hemodynamics parameters was observed by comparing effectiveness of IABP and Impella (Abiomed) for reducing left ventricular afterload. Nevertheless, concomitant utilization of IABP with ECMO may potentially contribute to a reduction in the death rate and an enhanced 180-day survival proportion reported [31]. Amongst left ventricular decompression devices used in VA-ECMO, IABP holds prominence due to its ease of percutaneous bedside implantation and straightforward operability. Combining IABP with VA-ECMO in patients experiencing cardiogenic shock yields notable benefits, including a substantial reduction in all-cause mortality rates during hospitalization and at day-28. Moreover, this approach aids in the successful weaning of patients from ECMO support, [32] in this study this approach was used in poor left ventricle function. Additional investigation is warranted to determine the optimal timing of IABP implementation as a left ventricular decompression stratagem in the context of selective complex and HR-PCI supported by VA-ECMO.

According to ELSO (Extracorporeal Life Support Organization) between 2014 and 2018, the infection rate midst patients undergoing VA-ECMO was documented at 7.6% [26]. Bacteremia and sepsis are frequently observed as common complications associated with VA-ECMO infections. The incidence of infection tends to rise progressively as the duration of ECMO support

extends. Notably, over 53% of patients experiencing infection-related complications encounter them within succeeding two weeks of post-ECMO intubation. [28] In this study, ECMO-related infection during or post-procedure no single case was reported of ECMO-related infection complications, This Is because ECMO intubation in our center is more than 30 per year and less time for ECMO support in total duration is less. The total VA-ECMO support in our study was an average was 21 hours (1-312) with one hour being the minimum and 312 hours being the maximum duration. Published studies suggest that ECMO should be weaned off as early as possible to avoid infection because the longer the duration for the ECMO increased the chances of infection [33]. In our study patients were in more serious state of condition pre-HR-PCI, with unprotected left main, severe coronary artery lesions with and without calcification, multi vessels disease, and depressed organ function such as advanced heart failure, atrial fibrillations, and chronic kidney disease patients, prior stroke were included. With these clinically noticeable characteristics, mechanical assistance circulatory device were given feasible opportunity to step in and assist in complex and high-risk coronary intervention. Acute renal injury (ARF) is prognosticative issue of ECMO. Studies have reported rate of severe ARF is approximately 45% in patients on ECMO requires renal replacement rehabilitation.[35].There are several factors attribute to ARF such as damaged blood cells by ECMO, Inflammatory response, ischemic reperfusion injury, Though ECMO can relieve AKI concomitantly increases the risk of ARF.[36].In 2660 single center study patients of CAD (coronary artery disease) were divided into two groups complex (1532) and noncomplex (1128), their study reported no difference contrast related AKI, no increase in contrast associated ARF in complex group[37]. It is believed ARF is not related with contrast associated. In this study Creatinine (Cr) and Blood Urea Nitrogen (BUN) were not significant pre- and post-operation.

There was not patient with acute kidney injury relates to low ARF rate. It is probably due to smaller group of patients and short duration of ECMO support. eGFR and uric acid were significantly changed before and after the procedure but were the same in patients who survived and or dead. Cr, BUN, levels indicate that the more severity of the lesion worse the results. Average survival duration post-procedure was 7.02 months, and the prolonged case follow-up of the patient is 34 months. Which is the prolonged timespan in this study and not present in previous ones. Previous studies indicate that LVEF in complex and high risk improves after the HR-PCI procedure and has fewer mortalities and hospital visits almost half of those with conventional medication therapy patients without complex and high-risk PCI procedures. [34] In comparison with our study, those who received interventional LVEF improves hence cardiac perfusion as compared to those with conventional therapy.

Thou this study give good clinical results, but still, there are certain limitations based on which we cannot generalize it to the rest of the population. Firstly, there was a single-centre retrospective study. Secondly, the sample size was small no randomization and no control group.

Strength and Limitations:

Firstly, our study addresses a critical and understudied aspect of high-risk PCI, focusing on using VA-ECMO as a mechanical circulatory support strategy. The novelty and importance of this topic make our research even more significant. We provided comprehensive and detailed data on patient characteristics, procedural details, and outcomes, enabling readers to understand our study cohort and interventions comprehensively. In our study, we include a total number of 81 patients, which is the highest so far in published studies.

Besides this, our study has some limitations. As with any retrospective study, our research might be susceptible to selection bias and confounding variables. While we have attempted to control for confounders through statistical analyses, it is essential to acknowledge these inherent limitations. We utilized data from a single centre, which may restrict the external validity of our results. Multi-centre studies are warranted to validate our findings in diverse patient populations and healthcare settings. The study's retrospective nature may introduce information bias or missing data. We have taken extensive measures to address this limitation, but it is crucial to recognize this inherent challenge.

Conclusion: ECMO-assisted HR-PCI is a valuable tool to enhance the safety and efficacy of complex PCI procedures, and observing different statistical test elective complex and high-risk PCI assisted by VA-ECMO as mechanical hemodynamic support is a safe and viable option for those patients who refuses CABG or got rejected. VA-ECMO-related complications and MACCE events within hospitalization and after one year of follow-up post-operatively are very low. The Optimum time to introduce the VA-ECMO needs further validation.

ETHICS STATEMENT

In this study, direct informed consent was waived off. But before every HR-PCI procedure, informed consent was taken from the patients or the next of kin. Human participants in this study were reviewed and sanctioned by the committee for ethics of the second affiliated Norman Bethune Hospital of Jilin University.

FUNDING

None

Conflicts of Interest

None

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Table-1 Baseline Clinical characteristics of all the patients included in this study.

Age (Years)	62.74 ± (10.807)
Gender-Male Female	60 (74.1%) 21 (25.9%)
Body Mass Index (Metric Units)	24.9 ± (3.45)
Hypertension	35 (43.2%)
Diabetes	21 (25.9%)
Chronic Kidney Disease	4 (4.9%)
Pulmonary Disease	6 (7.4%)
Atrial fibrillation	5 (6.2%)
Smoking	24 (29.6%)
Hyperlipidemia	7 (8.6%)
Prior Stroke	6 (7.4%)
Prior CABG	2(2.5%)
Prior PCI (Stent restenosis)	6 (7.4%)
Clopidogrel	66 (81.5%)
Ticagrelor	13 (16.0%)
Lung Disease	19(23.5%)
NSAID	30(37.0%)
NYHA Class combined Class I Class II	2.8 ± (1.1) 12 (14.8%) 20 (14.7%)

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Class III Class IV	17 (21.0%) 32(39.5%)
LVEF Pre-Op	38.65 ± 13.576
STEMI	33 (40.7%)
NSTEMI	19(23.5%)
Unstable Angina UA	21 (25.9%)
Heart failure (HF)	41 (50.6%)
Refused CABG	81 (100%)
Platelets *10^9/L	229.9 ± (79.9)
Prothrombin-Time (sec)	11.86 ± (7.7%)
Thrombin-Time (sec)	14.28± (4.44)
Antithrombin (%)	88.54± (18.70)
INR	1.0 ± (.74)
Alanine Aminotransferase (ALT U/L)	38.75 ± (131.34)
Aspartate Aminotransferase AST (U/L)	42.00 ± (257.8)
Albumin (g/L)	35.89 ± (5.18)

Data presented as N (%), Means ± SD, or Medians (Interquartile Q1-Q3). CABG, Coronary Artery bypass surgery; PCI, Percutaneous coronary interventions; NSAID, non-steroid anti-inflammatory drug; NYHA, New York Heart Association

TABLE 2 Procedural & Angiographic parameters of the patients included in the study.

Data presented as N (%), Means ± SD, or Medians (Interquartile Q1-Q3) CA, Coronary artery; PCI, Percutaneous coronary interventions; CTO, Chronic total occlusion; OCT, Optical coherence tomography; IABP, Intra-aortic balloon pump; ECMO, Extracorporeal Membrane oxygenation;

TABLE 3 Pre and Post PCI Evaluation Laboratory, Cardiac Indices, and Renal Function Parameters

Parameter	Before-PCI	After-PCI	p-Value
Hb (g/L)	136.1 ± 21.4	106.6 ± 19.1	<0.001
Cr (µmol/L)	125.7 ± 98.7	138.9 ± 101.2 (Highest)	0.052
BUN (mmol/L)	8.6 ± 4.9	14.8 ± 48.1	0.241
Uric Acid (µmol/L)	435.4 ± 136.5	362.9 ± 138.0	<0.001
Pre-Op eGFR (ml/Min)	67.2 ± 26.8	60.0 ± 27.7 (Minimum)	<0.002

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Parameter	ECMO N (81)
Pre-PCI SYNTAX Score	39.92 ± (6.4)
Post-PCI SYNTAX Score	6.47 ± (9.25)
Number of coronary vessels having the disease One Two Three Four Five	 1 (1.2%) 6 (7.4 %) 38 (47 %) 35 (43.2 %) 1 (1.2%)
CTO	34(42.0 %)
Location of Lesion CA (Combined) Left Anterior Descending Left Circumflex Right Coronary Artery Left Main Ramus OCT	 77 (95.1 %) 64 (79.0 %) 69 (85.2 %) 35 (43.2 %) 2 (2.46%) 14 (17.3%)
Number of Stents implanted No PCI Drug Coated Balloon Proglide Use IABP counter pulsation Canulation for distal perfusion Malfunctioning device Non-Invasive Ventilator	3.0 (0-6) 1 (1.2 %) .35 (0-4) 81 (100%) 26 (32.1%) 0(0) 0(0) 52 (64.2%)
ECMO setup **Intra-Operative** **Pre-Operative**	 52 (64.2%) 29 (35.8%)
ECMO weaning Time (Hours)	21 (1.0-312)
MACCE in CATH LAB Cardiac Tamponade Malignant Arrhythmias required electro cardioversion Ventricular Tachycardia Death	 1 (1.2%) 2 (2.4%) 1 (1.2%) 0(0)

Pre-Op LVEF (Percentage)	38.6 ± 13.6	43.5 ± 13.7	<0.001

Hb, Hemoglobin; Cr, Creatinine; BUN, Blood Urea Nitrogen; eGFR, Estimated Glomerulus Filtration; LVEF, Left Ventricle Ejection Fraction.

TABLE-4 Clinical outcomes of the study during the stay at the hospital

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Parameters	ECMO(N=81)
Survival at discharge (Healthy)	65 (80.2%)
Mortality all cause (Hospital)	16 (19.8%)
Re-infarction	6 (7.5%)
Cardiac arrest	2 (2.5 %)
Cardiogenic Shock	2 (2.5 %)
NSTEMI	1 (1.2%)
Aortic Dissection Type-A	1 (1.2%)
Inguinal Hematoma	2 (2.5%)
Bleeding from the puncture site (ECMO) ARC's-Type-I	2 (2.5 %)
Peudoaneurysm	1 (1.2%)
Cerebral Infarction Post-Op (New)	1 (1.2%)
Subarachnoid Hemorrhage	1 (1.2%)
Continuous renal replacement Therapy (CRRT)	26 (32.1%)
Blood Transfusion	59 (72.8%)

Data presented in N (%); NSTEMI, Non-ST elevated Myocardial infarction; ARC's,

TABLE-5 Outcomes and MACCE over the 1-year follow up

Parameters	ECMO (N=81)
Healthy	29 (35.8%)
Time Duration (Months)	7.02 ± (10.0)
Lost to follow-up (Combined)	27(33.3%)
Died (Combined) Ventricular Fibrillation Aortic Stenosis Terminal illness Recurrent Acute MI Acute Heart failure Non-Infectious MODS	6 (7.5%) 1 (1.2%) 1 (1.2%) 1 (1.2%) 1 (1.2%) 1 (1.2%) 1 (1.2%)
Angina (Improved)	2 (2.5%)

Data presented in mean ± standard deviation, N (%); MI, Myocardial Infarction; MODS, multiple organ dysfunction syndromes;