PulseCath

Protected High-Risk PCI and patient selection

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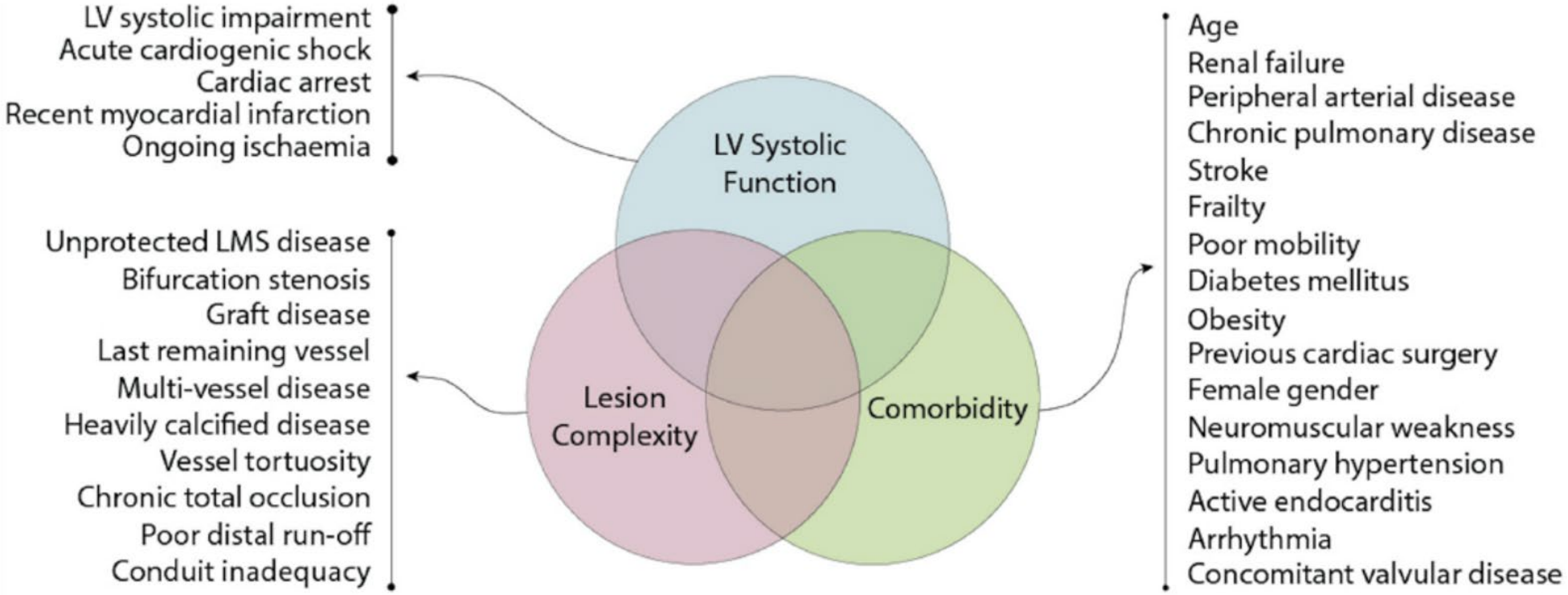
Indications Percutaneous MCS

TABLE 1 Suggested Indications for Percutaneous MCS

Indication	Comments
Complications of AMI	Ischemic mitral regurgitation is particularly well-suited to these devices as the hemodynamic disturbance is usually acute and substantial. Acutely depressed LV function from large AMI during and after primary PCI is an increasing indication for temporary MCS use. Cardiogenic shock from RV infarction can be treated with percutaneous right ventricular support.
Severe heart failure in the setting of nonischemic cardiomyopathy	Examples include severe exacerbations of chronic systolic heart failure as well as acutely reversible cardiomyopathies such as fulminant myocarditis, stress cardiomyopathy, or peripartum cardiomyopathy. In patients presenting in INTERMACS profiles 1 or 2, MCS can be used as a bridge to destination VAD placement or as a bridge to recovery if the ejection fraction rapidly improves (108).
Acute cardiac allograft failure	Primary allograft failure (adult or pediatric) may be due to acute cellular or antibody-mediated rejection, prolonged ischemic time, or inadequate organ preservation.
Post-transplant RV failure	Acute RV failure has several potential causes, including recipient pulmonary hypertension, intraoperative injury/ischemia, and excess volume/blood product resuscitation. MCS support provides time for the donor right ventricle to recover function, often with the assistance of inotropic and pulmonary vasodilator therapy (109).
Patients slow to wean from cardiopulmonary bypass following heart surgery	Although selected patients may be transitioned to a percutaneous system for additional weaning, this is rarely done.
Refractory arrhythmias	Patients can be treated with a percutaneous system that is somewhat independent of the cardiac rhythm. For recurrent, refractory, ventricular arrhythmias, ECMO may be required for biventricular failure.
Prophylactic use for high risk PCI	Particularly in patients with severe LV dysfunction (EF <20% to 30%) and complex coronary artery disease involving a large territory (sole-remaining vessel, left main or three vessel disease) (94,95,98).
High-risk or complex ablation of ventricular tachycardia	Similar to HR-PCI, complex VT ablation can be made feasible with percutaneous support. MCS use allows the patient to remain in VT longer during arrhythmia mapping without as much concern about systemic hypoperfusion.
High-risk percutaneous valve interventions	These evolving procedures may be aided with the use of MCSs.

94. Maini, B et al. Real-world use of the Impella 2.5 circulatory support system in complex high-risk percutaneous coronary intervention: the USpella Registry. Catheter Cardiovasc Interv. 2012;80:717-25.
95. O'Neill WW et al. A prospective, randomized clinical trial of hemodynamic support with Impella 2.5 versus intra-aortic balloon pump in patients undergoing high-risk PCI: The PROTECT II study. Circulation. 2012;126:1717-27.
98. Alli OO et al. Percutaneous left ventricular assist device with TandemHeart for high-risk PCI: The Mayo Clinic experience. Catheter Cardiovasc Interv. 2012;80:728-34

High-risk PCI: Definition



Factors that increase the risk of myocardial revascularization. LMS: left main stem; LV: left ventricle.
Adapted from Arri SS, et al. Heart 2018;104:166–179.

High-risk PCI: SYNTAX II

- ✓ SYNTAX ≥ 22 in PCIs for distal unprotected Left Main (LM), irrespective of the LV Ejection Fraction (EF)
- ✓ Unprotected distal LM associated with SYNTAX score ≥ 33 and severe LV dysfunction (LVEF < 35%) when surgical approach is not an option (heart team decision)
- ✓ Non-emergent PCI for unprotected distal LMCA associated with SYNTAX score > 22 and severe LV dysfunction (LVEF < 35%)

Available at: https://syntaxscore.org/calculator/start.htm

Int J Cardiol. 2019 Oct 15;293:84-90.

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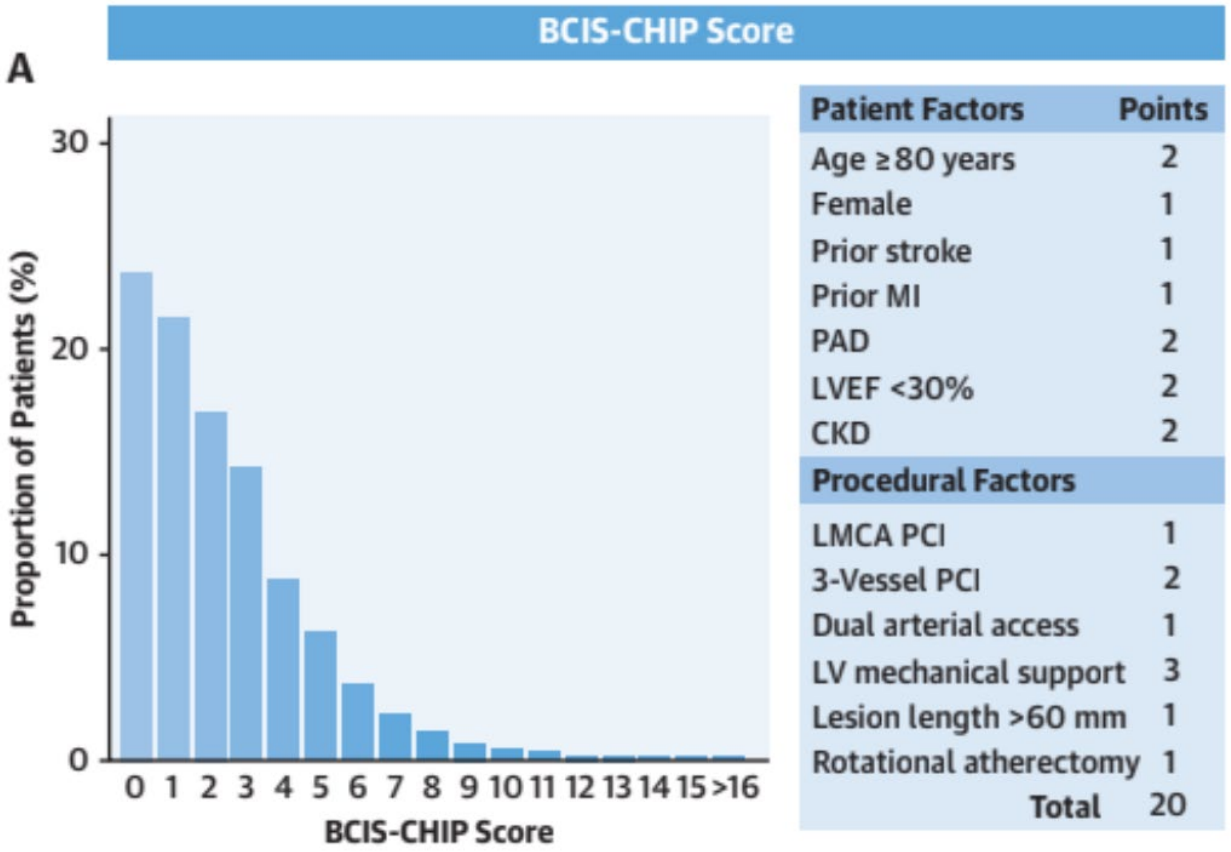
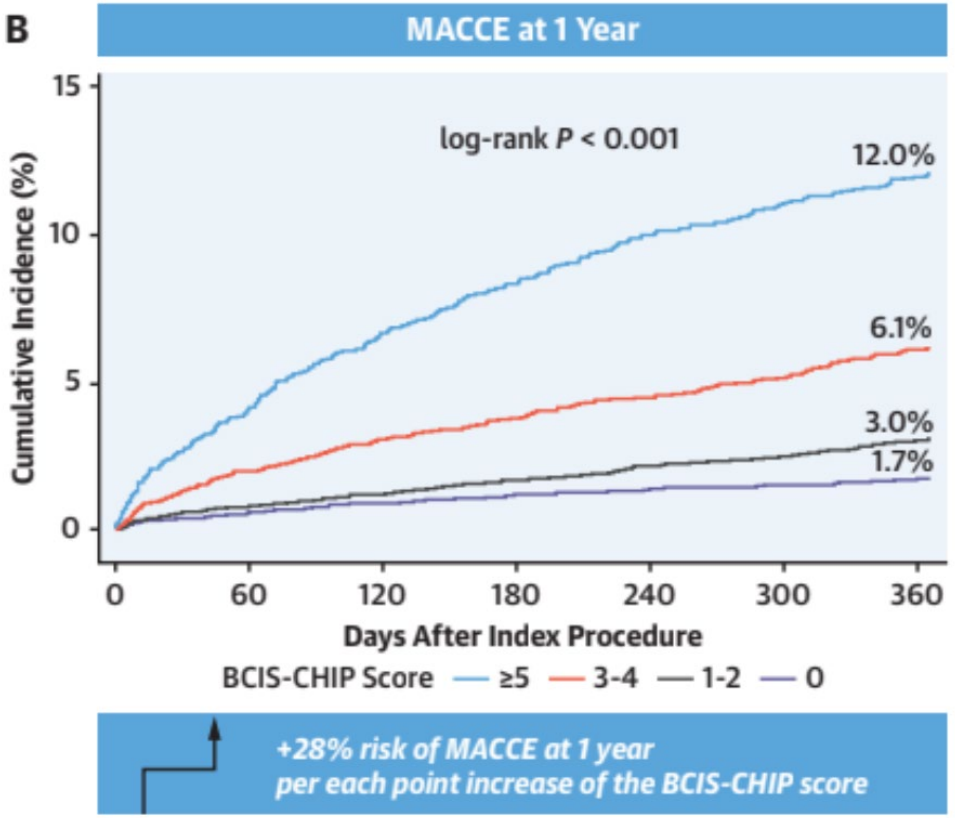
High-risk PCI: BCIS-CHIP score



Patient Factors	Points
Age ≥80 years	2
Female	1
Prior stroke	1
Prior MI	1
PAD	2
LVEF <30%	2
CKD	2
Procedural Factors	
LMCA PCI	1
3-Vessel PCI	2
Dual arterial access	1
LV mechanical support	3
Lesion length >60 mm	1
Rotational atherectomy	1
Total	20



Khandelwal G, et al. J Am Coll Cardiol Intv. 2023;16(9):1011–1020.

Protected High-risk PCI: Current recommendations

2022 ACC/AHA/SCAI : elective insertion of an appropriate haemodynamic support device as an adjunct to PCI might be reasonable in carefully selected high-risk patients (**class IIb, level of evidence B**) (1).

2014 ESC: temporary MCS (without device specification) should be considered in non-emergent, high-risk PCI procedures, such as left main coronary artery disease, single remaining patent coronary artery and complex chronic total occlusions, performed by adequately experienced operators at centres that have access to circulatory support and onsite cardiovascular surgery (2).

2018 ESC/EACTS and 2013 ACCS/AHA: there is insufficient evidence is available to support uniform use of percutaneous LV assist devices in the clinical setting of cardiogenic shock (**class IIb, level of evidence C**) (3,4).

1.Lawton, Jennifer S et al. "2021 ACC/AHA/SCAI Guideline for Coronary Artery Revascularization: Executive Summary: A Report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines." Circulation vol. 145,3 (2022): e4-e17.

2.O'Gara, P. T. et al. 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction: a report of the American College of Cardiology Foundation/ American Heart Association Task Force on Practice Guidelines. J. Am. Coll. Cardiol. 61, e78–e140 (2013).

3.Lawton, J. S. et al. 2021 ACC/AHA/SCAI guideline for coronary artery revascularization: a report of the American College of Cardiology/American Heart Association Joint Committee on Clinical Practice Guidelines. Circulation 145, e18–e114 (2022).

4.Windecker, S. et al. 2014 ESC/EACTS guidelines on myocardial revascularization: the Task Force on Myocardial Revascularization of the European Society of Cardiology (ESC) and the European Association for Cardio-Thoracic Surgery (EACTS). Developed with the special contribution of the European Association of Percutaneous Cardiovascular Interventions (EAPCI). Eur. Heart J. 35, 2541–2619 (2014).

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High-risk PCI: Current recommendations for MCS in general

2016 European Society of Cardiology Guidelines For The Diagnosis And Treatment Of Acute And Chronic Heart Failure	
Recommendation	Class and level of evidence
Bridge to transplant—An LVAD should be considered in patients who have end-stage HFrEF fraction despite optimal medical and device therapy and who are eligible for heart transplantation to improve symptoms, reduce the risk of HF hospitalization, and the risk of premature death	IIa, C
Destination therapy—An LVAD should be considered in patients who have end-stage HFrEF despite optimal medical and device therapy and who are not eligible for heart transplantation to, reduce the risk of premature death	IIa, B
2017 Canadian Cardiovascular Society Guidelines for the management of heart failure	
Recommendation	Strength and level of evidence
Bridge to transplant—MCS be considered for patients who are listed for cardiac transplantation and who deteriorate or are otherwise not likely to survive until a suitable donor organ is found, including those for whom a long wait is expected	Strong recommendation, high-quality evidence
Bridge to candidacy—MCS be considered for patients for whom there is a contraindication for cardiac transplantation but might, via MCS, be rendered transplantation-eligible.	Strong recommendation, low-quality evidence
Bridge to decision—Patients in cardiogenic shock should be considered for temporary MCS to afford an opportunity for evaluation for long-term options.	Strong recommendation, moderate-quality evidence
Destination therapy—Permanent MCS should be considered for highly selected transplantation-ineligibility patients.	Strong recommendation, low-quality evidence
2013 American College of Cardiology/American Heart Association Guidelines for the management of heart failure	
Recommendation	Class and level of evidence
MCS is beneficial in carefully selected patients with stage D HF in whom definitive management (e.g., cardiac transplantation) is anticipated or planned)	IIa, B
Nondurable MCS is reasonable as a "bridge to recovery" or "bridge to decision" for carefully selected patients with HF and acute profound disease	IIa, B
Durable MCS is reasonable to prolong survival for carefully selected patients with stage D HFrEF	IIa, B

Abbreviations: HF, heart failure; HFrEF, heart failure with reduced ejection fraction; LVAD, left ventricular assist device; MCS, mechanical circulatory support.

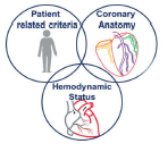
J Card Surg. 2021;36:1480–1491.

Protected High-risk PCI: how to approach

Best Practices in Protected PCI

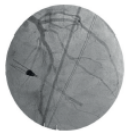
Procedural steps | Best practices

Patient Selection
- Complex anatomy (LM, MVD, long lesions, calcification...)
- HFrEF or HFmEF with hemodynamic relevant valve disease
- Co-morbidities (age, diabetes, renal failure, frailty...)
- Surgical turn-down
- Patient preference



Pre-procedural work up
- Assess and prepare femoral access site: imaging (angiography, vascular US, MRT) and imaging guided access
- Pre-closure device (suture-based devices highly recommended)
- Assess cardiac function (LV/RV contractility)
- Procedure planning (kidney function, coagulation, strategy)
- Team briefing
- Check materials and know your tool box

Antico-agulation
- Monitoring
  - Check ACT every 30 min (target: >250s)
  - Monitor total anticoagulation (heparine in purge fluid & i.v. heparine)
  - Consider bicarbonate to replace heparine in purge fluid
  - Balance bleeding risk vs. thrombotic risk in special populations (CKD, bleeding disorders)
- Haemolysis prevention (prevent interaction with papillary muscle, septal/valvular structures; check volume management)



Revascu-larization
- Aim at extensive complete revascularization
  - Residual Syntax Score (rSS) >8
- Aim at high quality of revascularization
  - Lesion preparation (imaging, debulking)
  - Stent optimization (imaging)
- Consider single vs. staged procedure (contrast volume, radiation, renal insufficiency, patient condition)

Patient handling in the cathlab
- Briefing and debriefing of staff and patient
- Plan, check, adapt interventional strategy
- Monitoring hemodynamics (RHC, LV/RV function, arterial pressure), ECG, hemoglobin, and oxygenation
- Consider weaning after procedure vs. delayed weaning
- Confirm access site closure: rule-out dissection, bleeding, fistula by angiography and confirm adequate limb perfusion (duplex sonography) before taking patient off the table

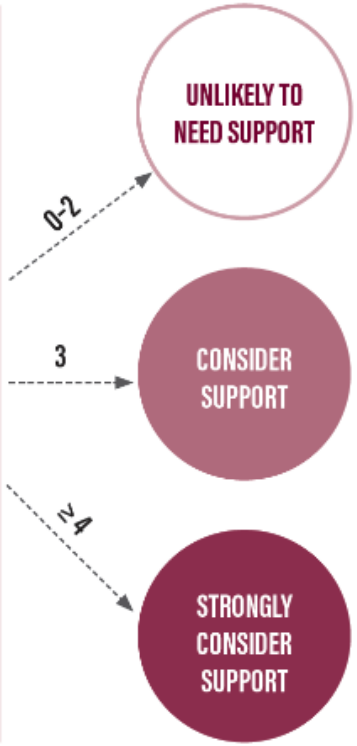
Bailout- and complication management
- Best complication management is prevention
- Standards of operations established & in place for major complications
- Be prepared for hemodynamic deterioration with cardiogenic shock despite MCS; access site complications & bleeding, non-access site bleeding, vessel perforation, vessel thrombosis, dissection

PROTECTED PCI ALGORITHM

LVEF < 50%: EVALUATE ALGORITHM

LVEF < 40%: RECOMMEND RHC PRIOR TO PCI

- +2 Cardiac index < 2.0 L/min/m² or PA sat < 55%
- +1 Syntax score ≥ 22
- +1 Ejection fraction < 25%
- +1 Systolic BP < 100 mm Hg at baseline
- +1 ACS presentation
- +1 Planned revascularization > 2 territories
- +1 Likely prolonged ischemia
  - Retrograde chronic total occlusion
  - Atherectomy
- +1 Severe mitral regurgitation
- +1 Decompensated state
  - LVEDP > 20 mm Hg
  - Significant new orthopnea
- -1 High-risk vascular injury/significant bleeding
- -1 Hemoglobin < 8 g/dL



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PulseCath Protected High-Risk PCI

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The PulseCath iVAC 2L

The iVAC 2L is a Left Ventricular Assist Device (LVAD) that is intended for short-term use up to 24h in patients with Left Ventricular (LV) dysfunction. The catheter has a diameter of 17 Fr and is introduced percutaneously through the common femoral artery using an expandable sheath. The output flow can reach values up to 2.0L/min under ideal conditions. The pump is powered by a conventional Intra-aortic Balloon Pump (IABP) console and works in synchrony with the cardiac cycle.

The iVAC 2L is most commonly deployed as a circulatory back-up in the setting of High-Risk Percutaneous Coronary Interventions (HR-PCIs). Once in place and activated, it works by assuring minimum levels of hemodynamic stability which may eventually reduce the risk of adverse events. Basically, the device unloads the LV and reduces the Myocardial Oxygen Consumption (MVO_2), while at the same time it increases the Mean Arterial Pressure (MAP). iVAC 2L has been successfully applied in elective interventions for stable coronary disease. However, anecdotal evidence suggests that is can also be used during acute myocardial infarction (AMI), acute decompensated heart failure cardiogenic shock and as a venting tool in patients receiving Extra-corporeal Membrane Oxygenation (ECMO)[1-5]

Indications

iVAC 2L is most commonly indicated in HR-PCIs, but it can also be used during other therapeutical interventions that also require circulatory back-up, such as:

- Treatment of cardiogenic shock
- Treatment of acute decompensated heart failure
- High-risk electrophysiological procedures
- High risk transcatheter valve interventions

Contra indications

iVAC 2L is inserted in the LV through the aorta and across the aortic valve. Due to its intrinsic characteristics, certain situations may result in an increased risk of complications or suboptimal assistance, and hence should be avoided. In principle, iVAC 2L should not be used in the following situations:

- Aortic disease: ascending aortic aneurism, severe aortic wall calcifications
- Aortic valve disease: aortic valve stenosis, aortic valve insufficiency
- Aortic valve prosthesis
- Femoral artery stenosis (artery diameter < 6mm)
- Thrombosis of the left ventricle and/or aorta
- Absence of residual function of left ventricle
- Severe right ventricular failure or acute pulmonary embolism

High-risk PCI and Patient Selection

An intervention is considered as high-risk according to multiple patient- and procedure-specific characteristics. The diagnosis is clinical and multifactorial. Due to the shear amount of pathophysiologies and related elements that can potentially increase procedural and post-procedural risk, this risk category still lacks a standardized definition. However, several recommendations can be taken as a guidance which include basically the amount of LV residual function and the presence comorbidities that may increase the risk of procedural complications. It also takes into account the complexity and invasiveness of the PCI that is being planned (Figure 1).

Evaluation of lesion complexity and co-morbidities

Patient selection can be facilitated by the use of validated risk scores. The SYNTAX score[6] has been extensively investigated and can accurately quantify lesion complexity. Patients can be classified as low risk (SYNTAX < 22), moderate risk (22 to 33) and high risk (≥ 33). According to recent society recommendations, mechanical circulatory support should be considered based on the SYNTAX score in the following situations[7]:

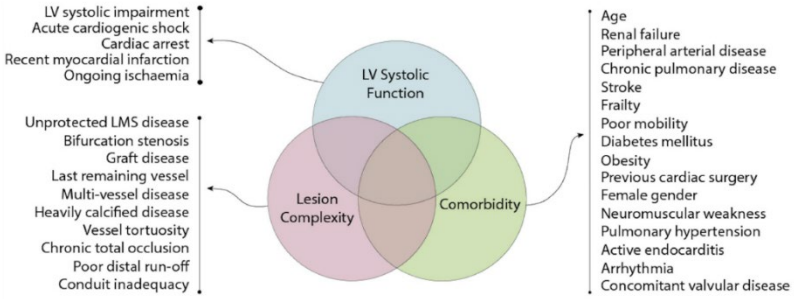

Figure 1. Factors that increase the risk of myocardial revascularization. LMS: left main stem; LV: left ventricle. Adapted from Arri SS, et al. Heart 2018;104:166–179.

- SYNTAX ≥ 22 in PCIs for distal unprotected Left Main (LM), irrespective of the LV Ejection Fraction (EF);
- Unprotected distal LM associated with SYNTAX score ≥ 33 and severe LV dysfunction (LVEF < 35%) when a surgical approach has been discouraged by a heart team;
- Non-emergent PCI for unprotected distal LM associated with SYNTAX score > 22 and LVEF < 35%.

For a more extensive evaluation, the SYNTAX II should be considered. The SYNTAX II also computes information on clinical background allowing for a more complete assessment of the risk of complications. The SYNTAX score can be calculated at https://syntaxscore.org/.

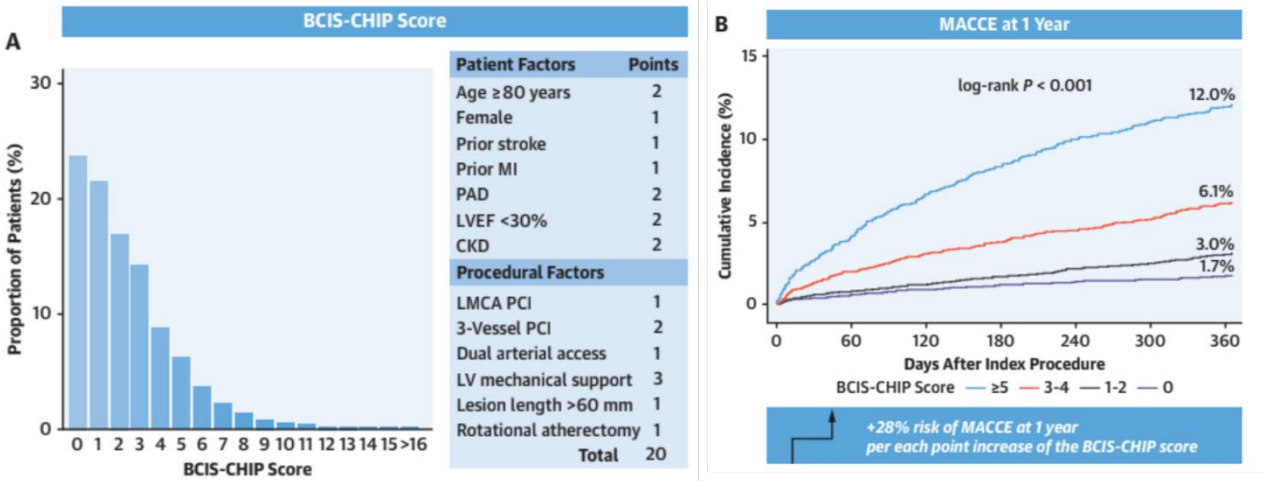

Figure 2. **(A)** Score distribution in 20,799 patients who underwent PCI and score features (range from 0 to 20 points). **(B)** Cumulative incidence of MACCE (a composite of all-cause death, MI or stroke) at 1-year in the 4 BCIS-CHIP score categories. Rates of MACCE progressively increased from the lowest to the highest BCIS-CHIP score category. For each score point increase, the risk of MACCE increased by 28 percentage.

More recently, the BCIS-CHIP[8] score has been proposed and validated in a large study that included 20,000 individuals. It aims to simplify bedside and ambulatorial screening by estimating the risk of Major Adverse Events after one year. The score is based on distinct patient and procedural factors that are summed to compute a final score. The result ranges between 0 and 20, and is considered as high-risk if higher than 5 (Figure 2). Other tools of interest include the SYNTAX II score where clinical elements are included in the calculation of the final score, and the STS Predicted Mortality (STS-PROM) score.

Defining the suitability to mechanical circulatory support

The SYNTAX and the BCIS-CHIP scores can be helpful in estimating the risk of complications but do not focus the specific question of whether a patient should receive short-term MCS or not. Recently, Kearney et al proposed a simple algorithm that uses hemodynamic and laboratorial indicators to address the issue[9].

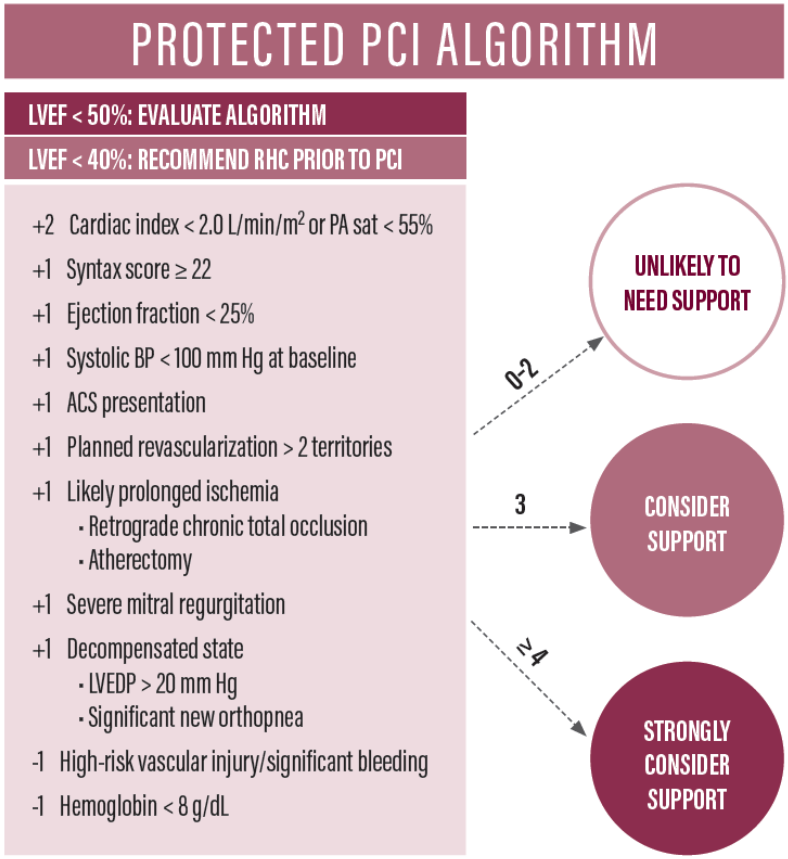

Figure 3. Protected PCI algorithm. This algorithm may help physicians to define the need for MCS pre-procedurally. CARDIAC INTERVENTIONS TODAY JANUARY/FEBRUARY 2019 VOL. 13, NO.

In addition to defining the patient`s risk profile and the adequacy to MCS, the use of multidisciplinary heart teams (MDHTs) is recommended[10]. The MDHT team plays a central role in the treatment of a broad array of complex diseases across multiple cardiovascular medicine subspecialities. The use of MDHTs has origins in clinical trials comparing different modalities of myocardial revascularization, among them the SYNTAX trial. The process requires the interaction between cardiologists, cardiac surgeons, interventional cardiologists and interventional cardiovascular physicians aiming to reach a consensus on the treatment decisions in complex patients for whom different treatment modalities are available, each with its corresponding risks and benefits. Additionally, the discussions should also take into account the patient's preferences (Figure 4).

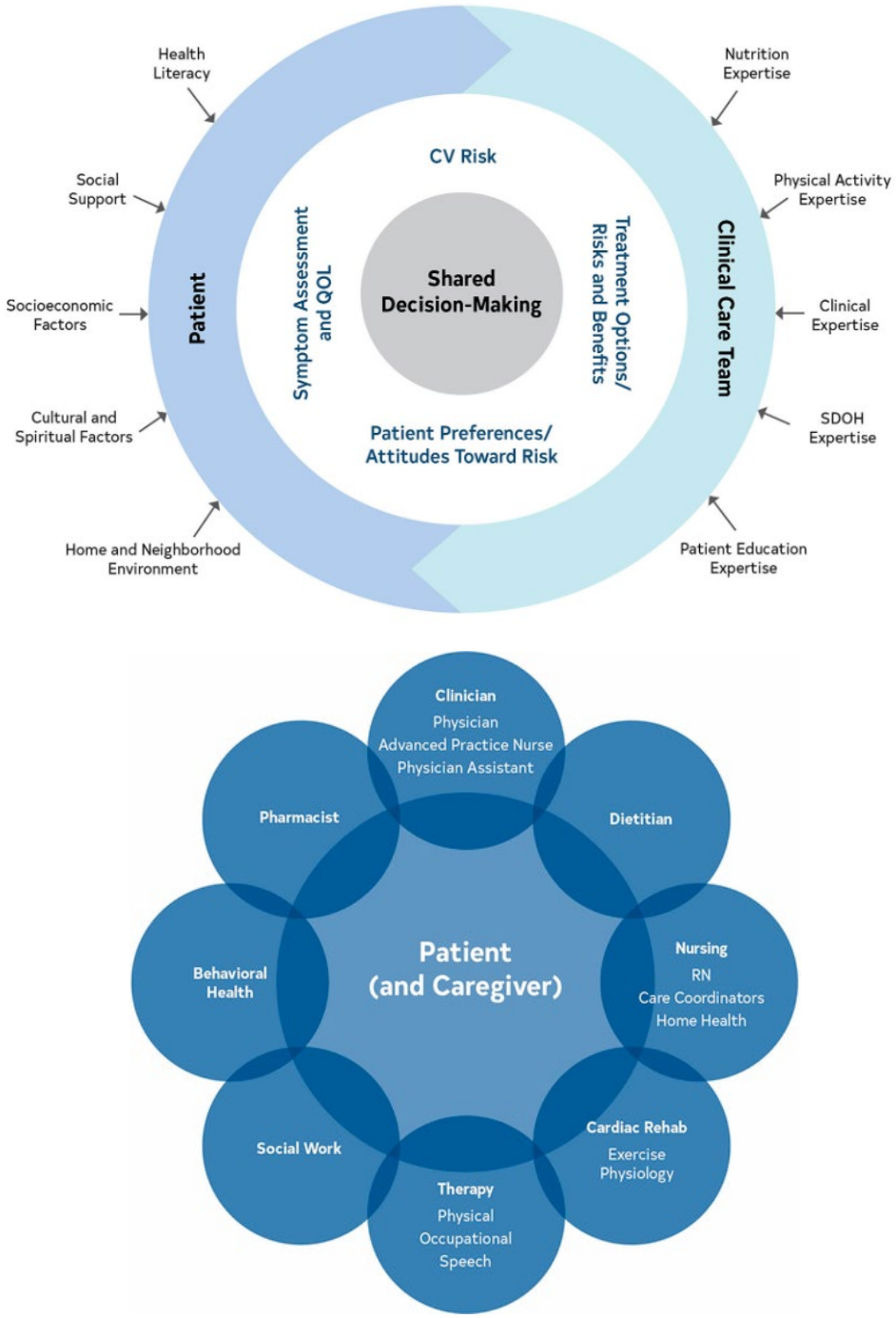

Figure 4. Multidisciplinary Heart Teams are recommended to refine decision making in complex cardiovascular patients.
J Am Coll Cardiol. 2023 Aug, 82 (9) 833–955

Once the indication has been defined, procedural planning should take place. Access management should include previous investigation of the suitability of the ilio-femoral tree to receiving the catheter and the sheath. By default, the inner diameter of the common femoral artery should be no less than 6 mm in order to avoid laceration. Other parameter to be set include adequate monitorization, pre-closure devices, cardiac function

assessments, anti-coagulation and bail-out measures that should be on stand-by. One interesting check-list is proposed by Werner et al[11] (Figure 5).

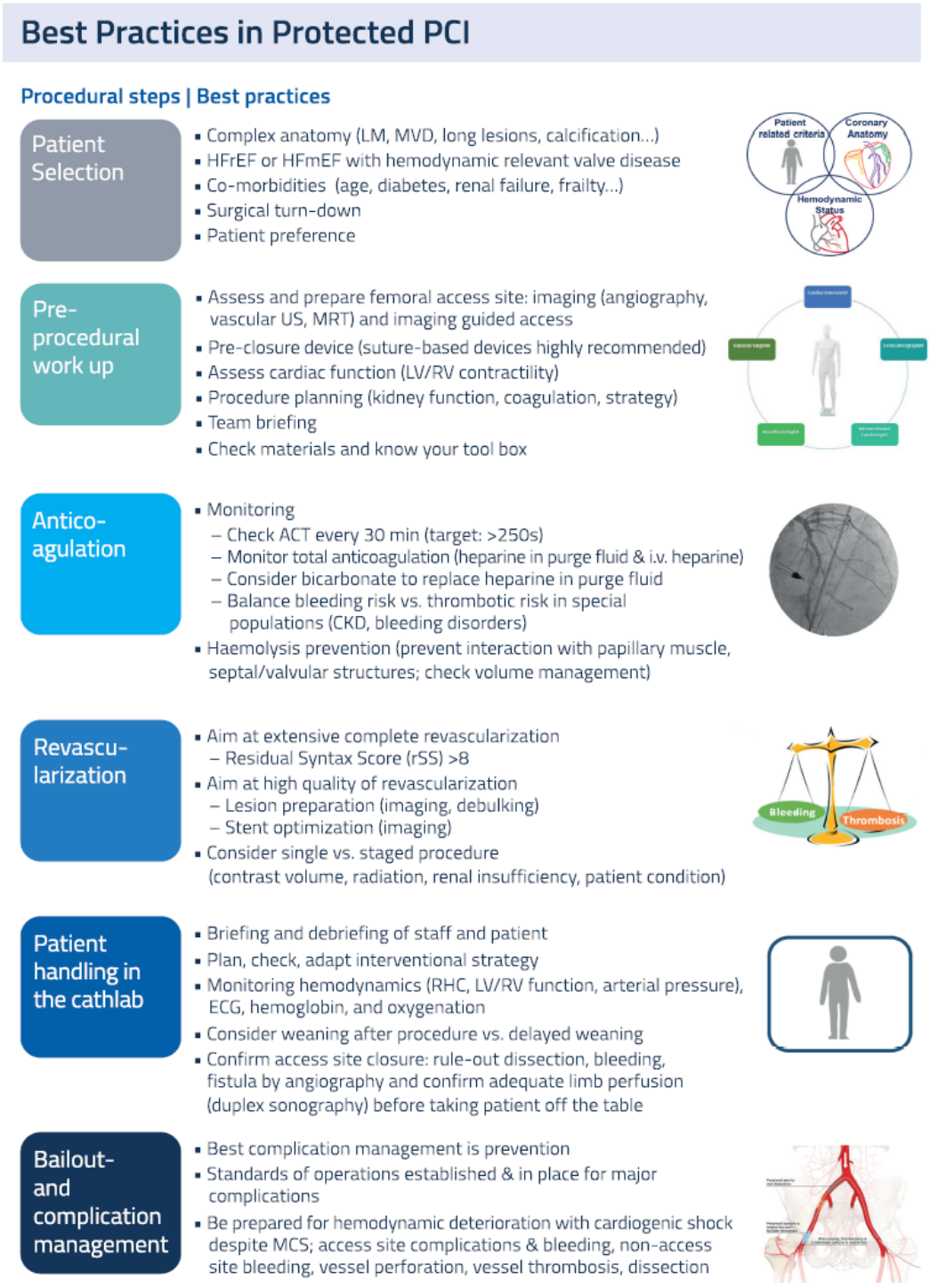

Figure 5. Stepwise approach to high-risk PCI.

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