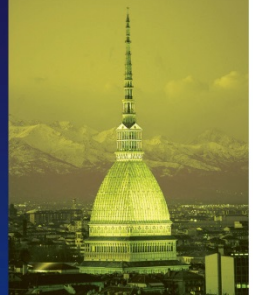
TURIN, October 25th-27th 2018 Starhotels Majestic

GIORNATE CARDIOLOGICHE TORINESI 30



UNIVERSITÁ DEGLI STUDI DI TORINO

AZIENDA OSPEDALIERO - UNIVERSITARIA Città della Salute e della Scienza di Torino

TEMPORARY CIRCULATORY SUPPORT FOR HIGH RISK INTERVENTIONAL PROCEDURES

Giacomo Boccuzzi, MD, FESC

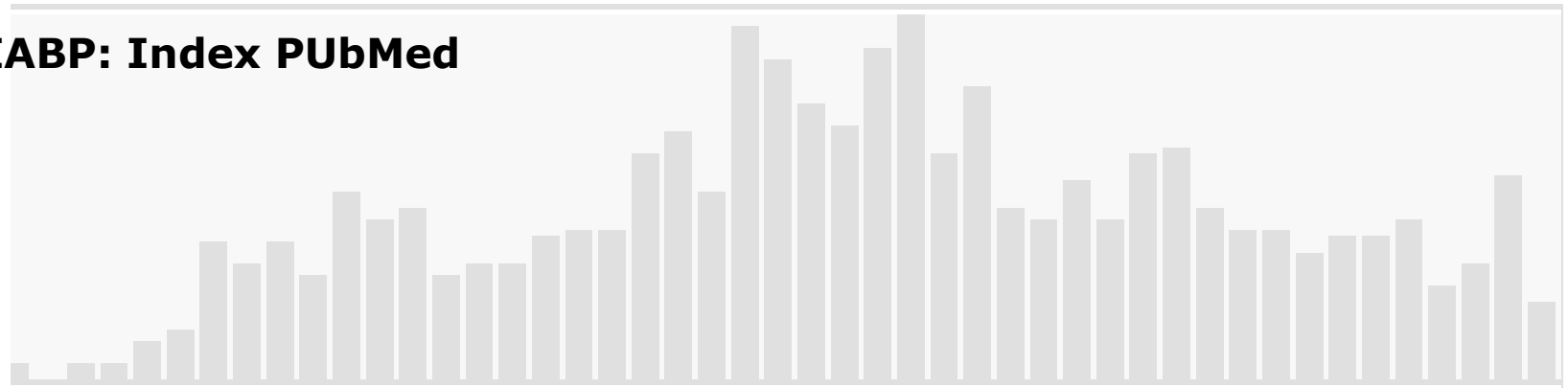
S.C Cardiologia

Ospedale San Giovanni Bosco, Torino, Italy

FOCUS ON TEMPORARY CIRCULATORY ASSISTANCE: FROM CARDIOGENIC SHOCK TREATMENT TO SUPPORTIVE THERAPY FOR INTERVENTIONAL CARDIOLOGY

Percutaneous mechanical circulatory support (MCS) has evolved dramatically since the first IABP was used in humans in the 1960s.

IABP: Index PUbMed



1962 **2018**

Trans Am Soc Artif Intern Organs. 1962;8:85-9.

Extracorporeal assistance to the circulation and intraaortic balloon pumping.

MOULOPOULOS SD, TOPAZ SR, KOLFF WJ.

Parissis *et al. Journal of Cardiothoracic Surgery* (2016) 11:122
DOI 10.1186/s13019-016-0513-0

Journal of Cardiothoracic Surgery

REVIEW Open Access

IABP: history-evolution-pathophysiology-indications: what we need to know

IABP has been the the mainstay of MCS (for high risk PCI)

Recent studies have demostrated lack of efficacy

Assistenza ventricolare. DATI GISE 2017

(156.000 PCI anno)

il giornale italiano di
CARDIOLOGIA INVASIVA
Anno 2018
Volume 15
ISSN 1824 - 7008

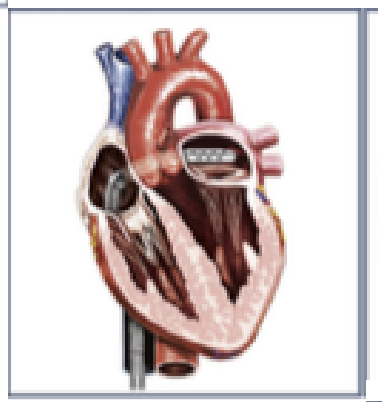
Regione	N. procedure IABP	N. procedure in elezione IABP	N. procedure in urgenza IABP	N. procedure IMPELLA	N. procedure in elezione IMPELLA	N. procedure in urgenza IMPELLA	N. procedure ECMO	N. procedure in elezione ECMO	N. procedure in urgenza ECMO
ABRUZZO	42	0	42	5	4	1	3	0	3
ALTO ADIGE	4	0	4	0	0	0	0	0	0
BASILICATA	13	4	15	0	0	0	0	0	0
CALABRIA	116	13	104	2	2	0	3	0	5
CAMPANIA	197	30	167	26	22	4	8	0	8
EMILIA ROMAGNA	300	14	209	2	0	0	9	0	7
FRIULI VENEZIA GIULIA	152	10	82	2	1	1	5	0	5
LAZIO	201	31	194	31	18	13	15	4	11
LIGURIA	77	17	60	1	1	0	2	2	0
LOMBARDIA	853	139	597	51	18	5	102	9	69
MARCHE	40	7	34	12	2	10	2	0	2
MOLISE	10	0	10	0	0	0	0	2	0
PIEMONTE	333	74	259	4	4	0	10	5	5
PUGLIA	202	20	180	17	7	9	3	0	3
SARDEGNA	67	10	57	8	8	0	3	0	3
SICILIA	195	82	110	13	11	1	27	0	27
TOSCANA	212	28	184	3	2	1	26	1	25
TRENTINO	45	0	45	1	1	0	0	0	0
UMBRIA	90	32	58	6	3	3	3	0	3
VALLE D'AOSTA	11	3	8	0	0	0	0	0	0
VENETO	329	53	256	16	12	4	29	1	28
ITALIA	**3.489**	**567**	**2.675**	**200**	**116**	**52**	**250**	**24**	**204**

3500 **200** **250**

The introduction of newer devices coupled with data from clinical trials is challenging the role of IABP

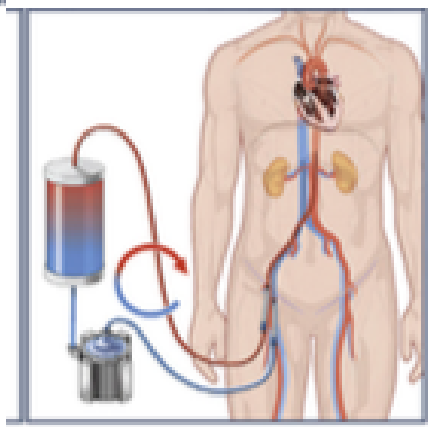
Impella

Axial Flow pumps



TandemHeart
Centrifugal
Pump

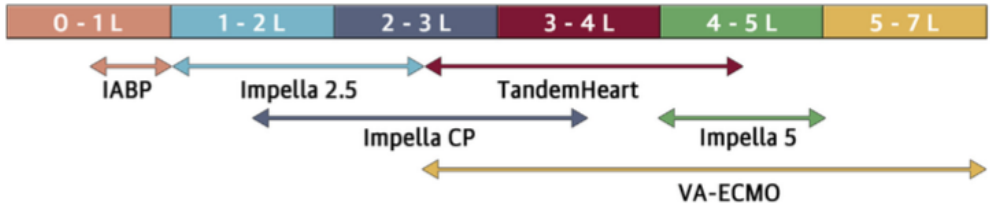
Left atrial to Aorta bypass pumps

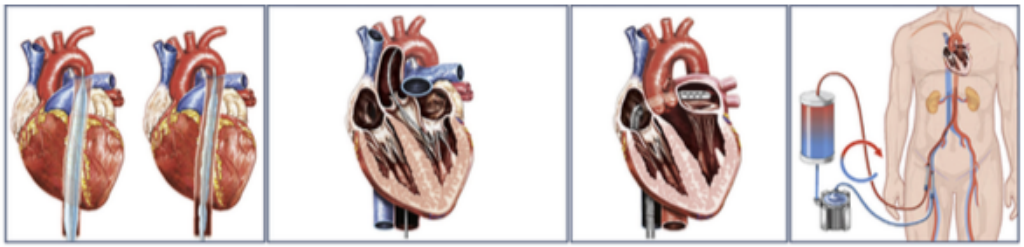


Extracorporeal membrane oxigenation (ECMO)

The introduction of newer devices coupled with data from clinical trials is challenging the role of IABP

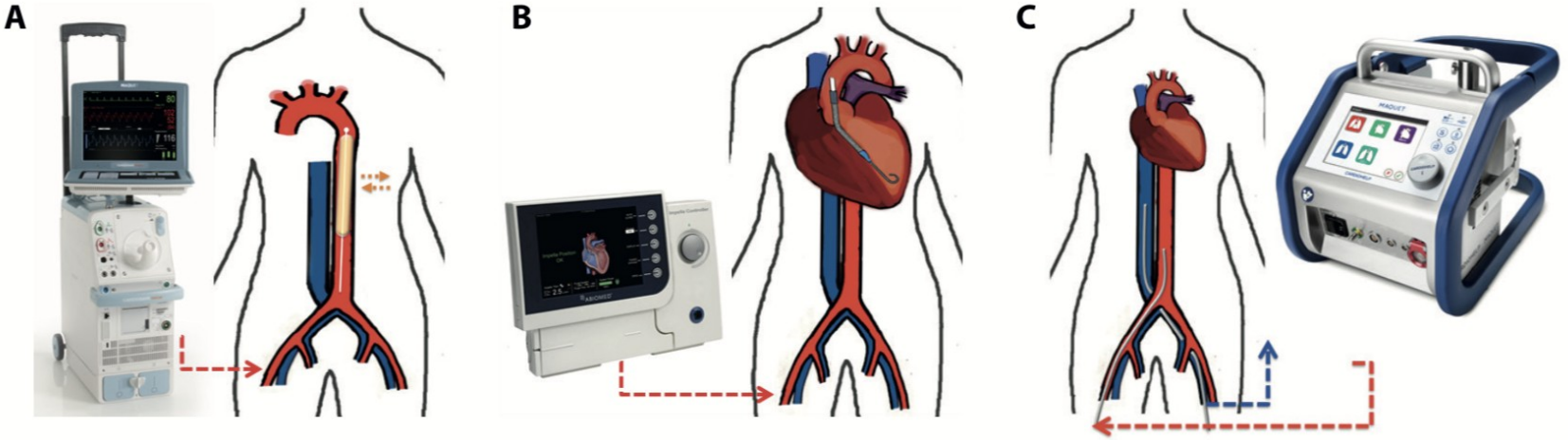
Comparison of MCS Devices and Their Impact on Cardiac Flow





	IABP	IMPELLA	TANDEMHEART	VA-ECMO
Cardiac Flow	0.3-0.5 L/ min	1-5L/ min (Impella 2.5, Impella CP, Impella 5)	2.5-5 L/ min	3-7 L-min
Mechanism	Aorta	LV → AO	LA → AO	RA → AO
Maximum implant days	Weeks	7 days	14 days	Weeks
Sheath size	7-8 Fr	13-14 Fr Impella 5.0 - 21 Fr	15-17 Fr Arterial 21 Fr Venous	14-16 Fr Arterial 18-21 Fr Venous
Femoral Artery Size	>4 mm	Impella 2.5 & CP - 5-5.5 mm Impella 5 - 8 mm	8 mm	8 mm
Cardiac synchrony or stable rhythm	Yes	No	No	No
Afterload	↓	↓	↑	↑↑↑
MAP	↑	↑↑	↑↑	↑↑
Cardiac Flow	↑	↑↑	↑↑	↑↑
Cardiac Power	↑	↑↑	↑↑	↑↑
LVEDP	↓	↓↓	↓↓	↔
PCWP	↓	↓↓	↓↓	↔
LV Preload	---	↓↓	↓↓	↓
Coronary Perfusion	↑	↑	---	---
Myocardial oxygen demand	↓	↓↓	↔↓	↔

IABP	Axial Flow pumps IMPELLA	Extracorporeal membrane oxigenation (ECMO)

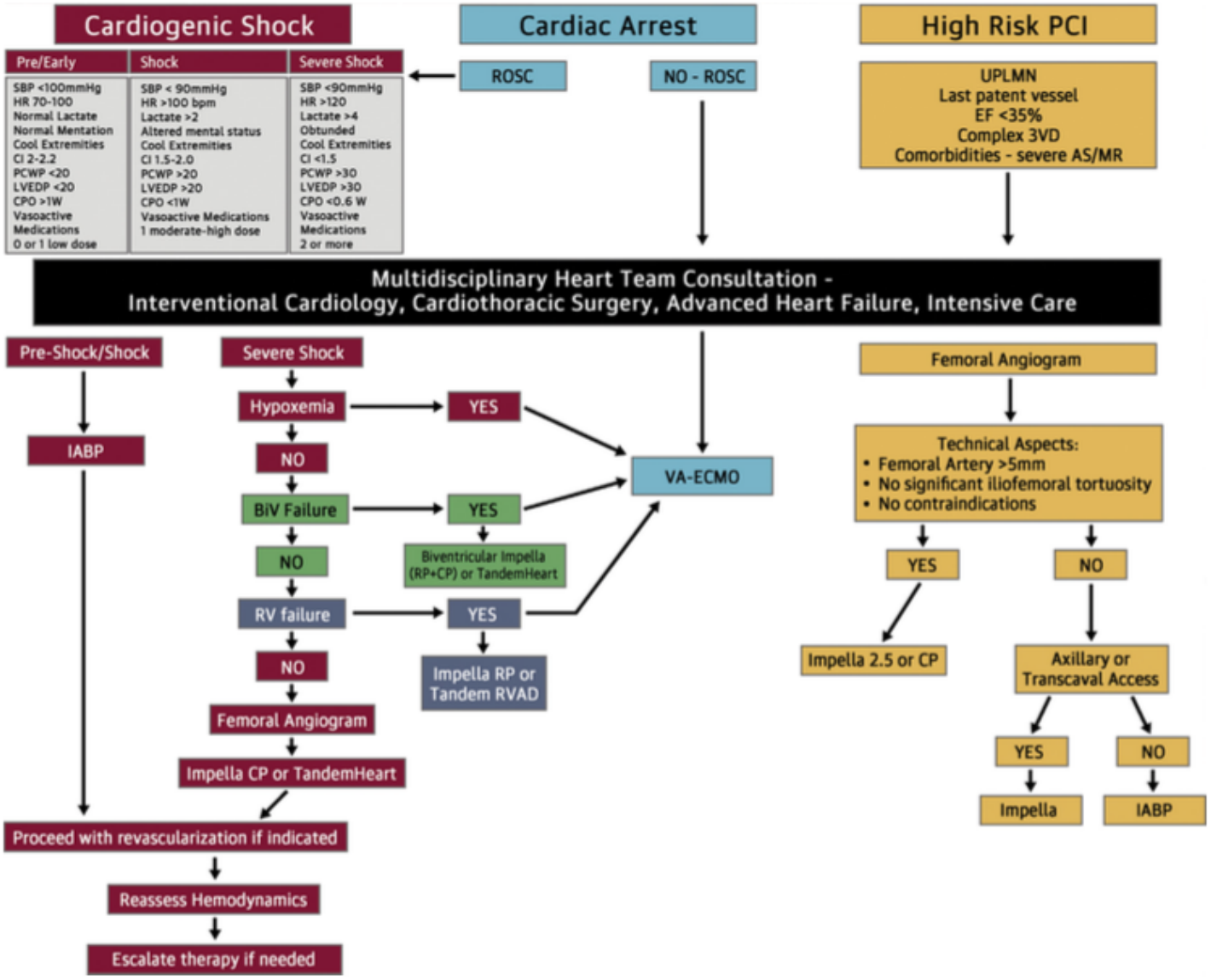


Accesso arterioso	8-9 F
Lavoro cardiaco	–
PA media	↑
Gittata cardiaca	↑
Flusso coronarico	↑
Unloading VSx	↑

Accesso arterioso	13 F (2.5) – 14 F (CP)
Lavoro cardiaco	↓
PA media	↓
Gittata cardiaca	↑↑
Flusso coronarico	↑↑
Unloading VSx	↑↑

Accesso arterioso	15-17 F
Accesso venoso	21-23 F
Lavoro cardiaco	↑
PA media	↑
Gittata cardiaca	↑↑↑
Flusso coronarico	↑↑↑
Unloading VSx	–/↓

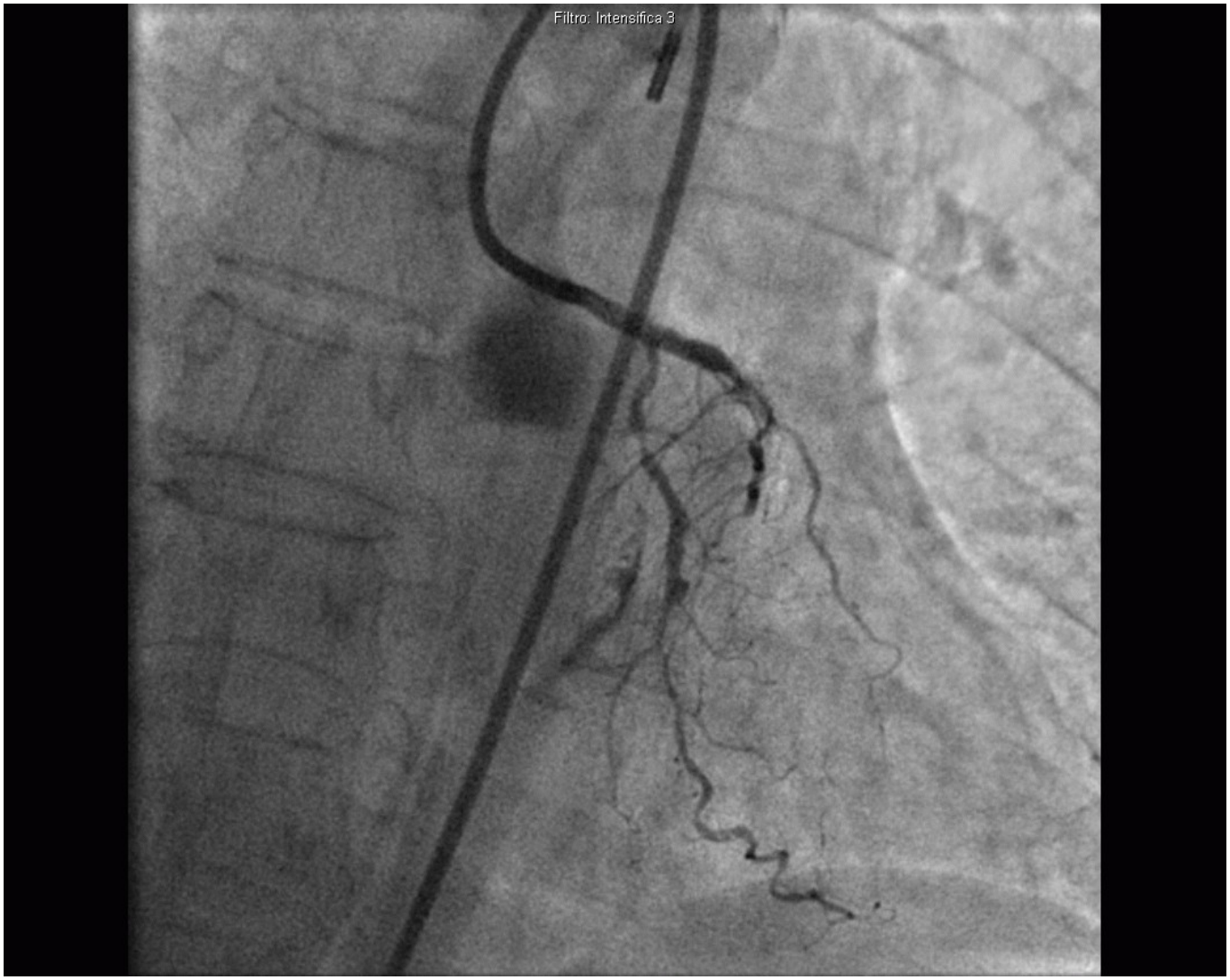
CENTRAL ILLUSTRATION **Algorithm for Percutaneous MCS Device Selection in Patients with Cardiogenic Shock, Cardiac Arrest, and HR-PCI**

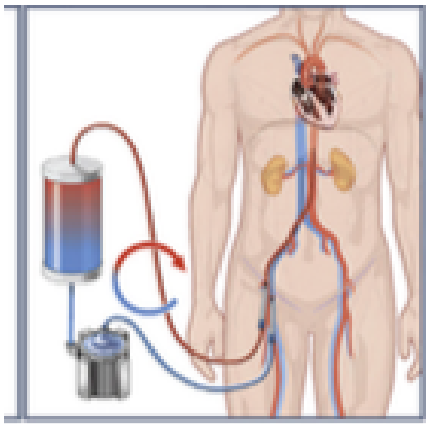


Atkinson, T.M. et al. J Am Coll Cardiol Intv. 2016;9(9):871-83.

Percutaneous mechanical circulatory support is used in 3 populations:

CARDIAC ARREST





Extracorporeal membrane oxigenation (ECMO)

ECMO IN CARDIAC ARREST

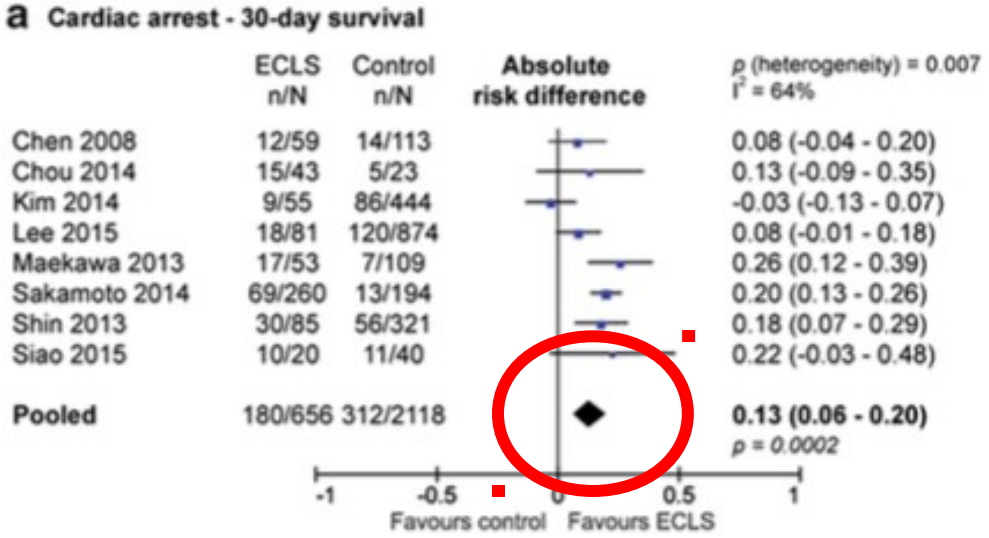
Intensive Care Med (2016) 42:1922–1934
DOI 10.1007/s00134-016-4536-8

SYSTEMATIC REVIEW

Extracorporeal life support during cardiac arrest and cardiogenic shock: a systematic review and meta-analysis

Dagmar M. Ouweneel[1], Jasper V. Schotborgh[1], Jacqueline Limpens[2], Krischan D. Wim K. Lagrand[3], Thomas G. V. Cherpanath[3], Antoine H. G. Driessen[1], Bas A. J. M. and José P. S. Henriques[1*]

NNT : 7

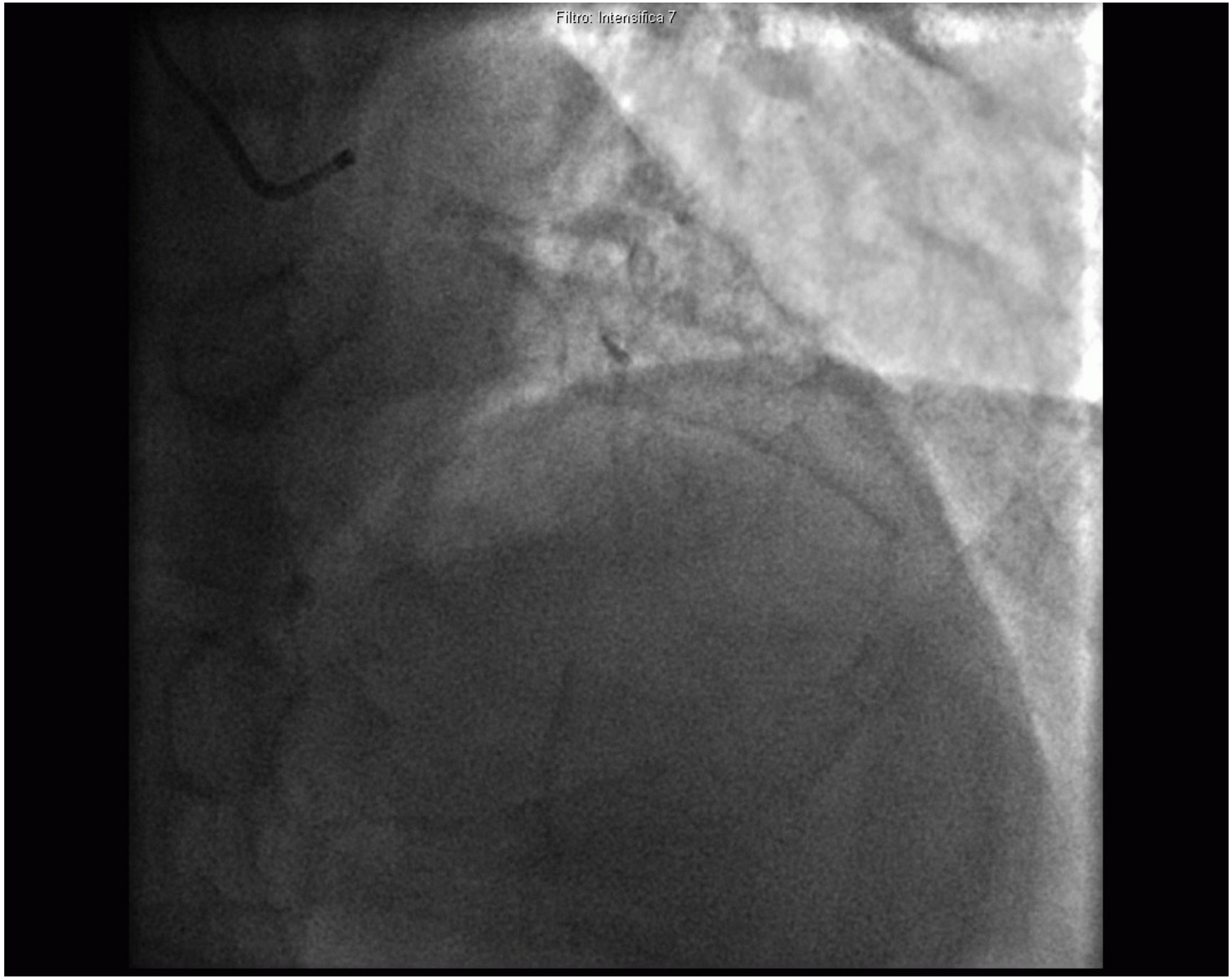


Conclusions: In cardiac arrest, the use of ECLS was associated with an increased survival rate as well as an increase in favourable neurological outcome. In the setting of cardiogenic shock there was an increased survival with ECLS compared with IABP.

Keywords: Extracorporeal membrane oxygenation, Extracorporeal life support, Acute myocardial infarction, Cardiac arrest, Cardiogenic shock, Cardiopulmonary resuscitation, Systematic review

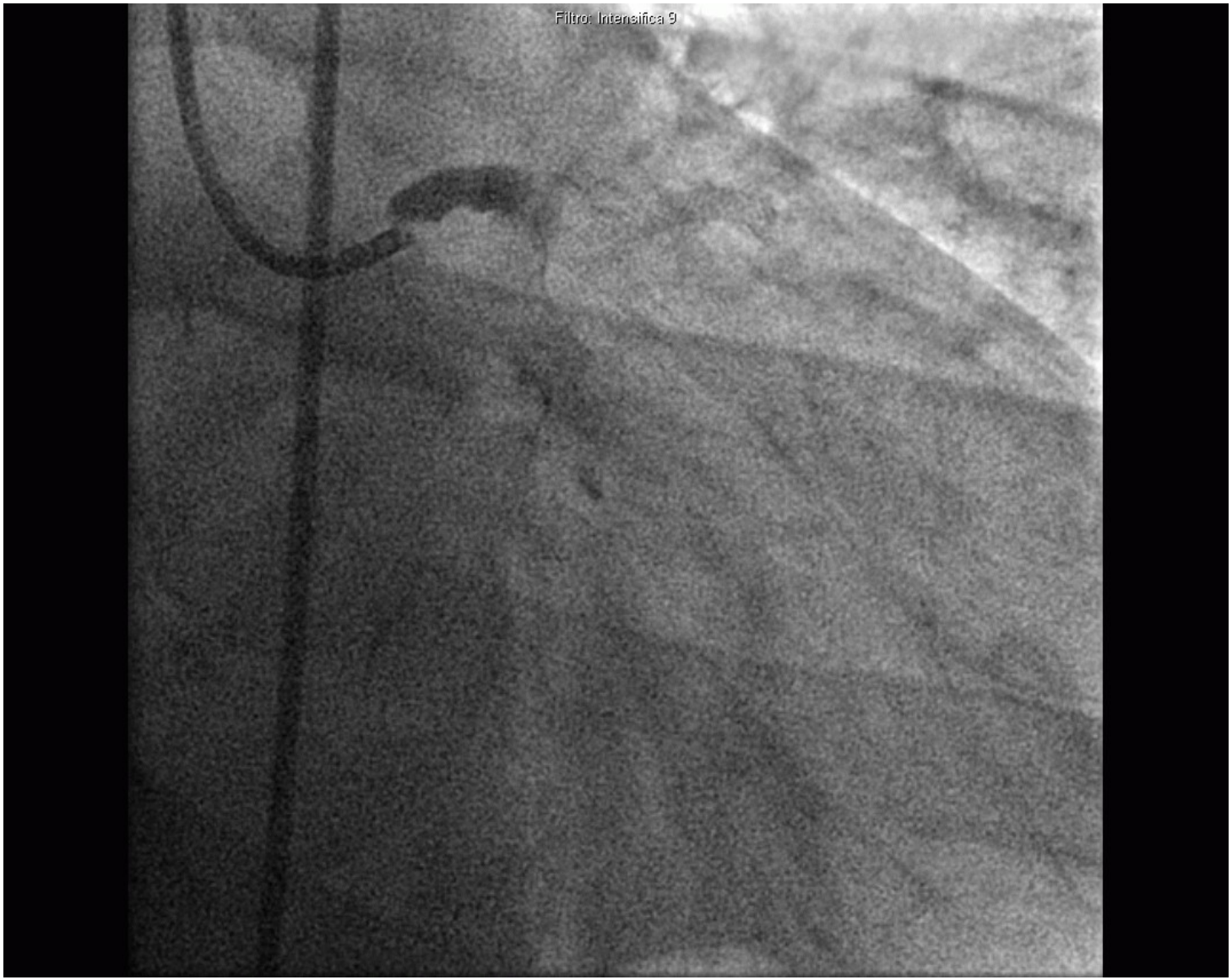
Percutaneous mechanical circulatory support is used in 3 populations:

HIGH RISK PCI



Percutaneous mechanical circulatory support is used in 3 populations:

CARDIOGENIC SHOCK



Come orientarsi tra contropulsatore, Impella e ossigenazione a membrana extracorporea

Francesco Burzotta, Giulio Russo, Eloisa Basile, Cristina Aurigemma, Antonio Maria Leone, Giampaolo Niccoli, Italo Porto, Piergiorgio Bruno, Massimo Massetti, Filippo Crea, Carlo Trani

Istituto di Cardiologia, Università Cattolica del Sacro Cuore, Policlinico Universitario A. Gemelli, Roma

G ITAL CARDIOL | VOL 19 | SUPPL 1 AL N 6 2018

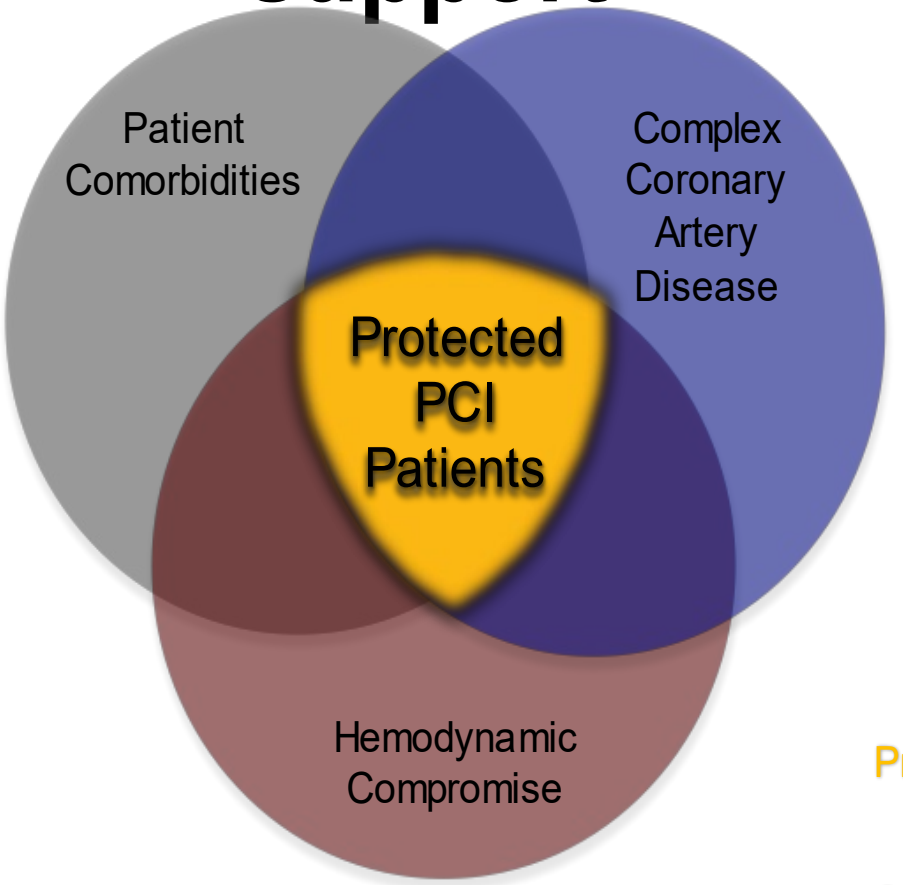
Curr Cardiol Rep (2017) 19:100
DOI 10.1007/s11886-017-0905-3

INTERVENTIONAL CARDIOLOGY (SR BAILEY, SECTION EDITOR)

Hemodynamic Support Devices for Shock and High-Risk PCI: When and Which One

George W. Vetrovec[1]

When to consider hemodynamic support



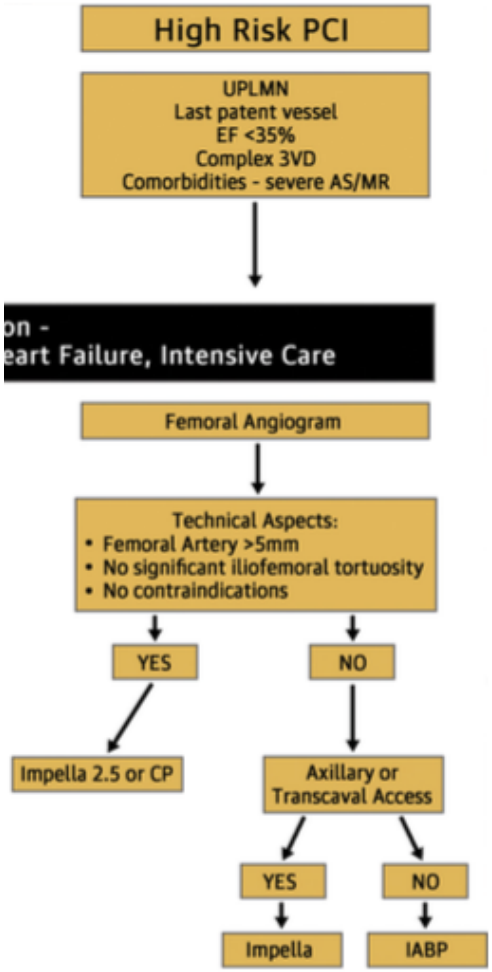
Heart failure, diabetes, advanced age, peripheral vascular disease, complex lesions, unstable angina/NSTEMI, prior surgery, ineligible for cardiac surgery

Multi-vessel disease, Left Main disease, Lesion characteristics (bifurcations, calcification), CTO esp. retrograde approach

Depressed ejection fraction (LVEF≤35%), High LVEDP

Protected PCI with Impella 2.5™
Now found Safe & Effective by FDA for High Risk PCI in hemodynamically stable patients

Percutaneous mechanical circulatory support in HIGH RISK PCI



18% delle PCI sono ad alto rischio.

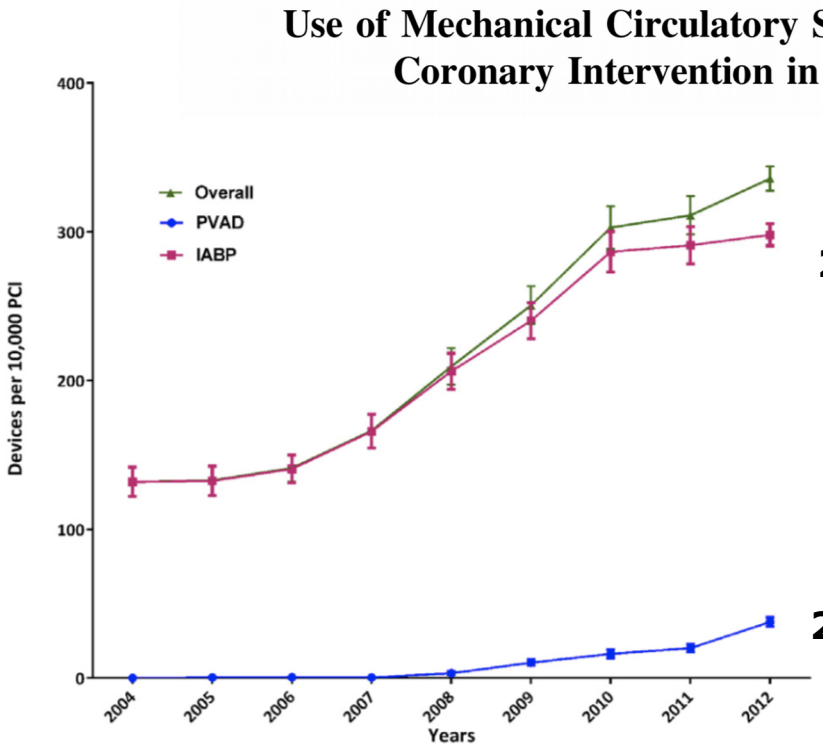


Figure 2. Calendar year trends in the use of MCS devices, overall and for PVAD and IABP.

IABP:

1)US 30/1000

2) ITALIA 23/1000

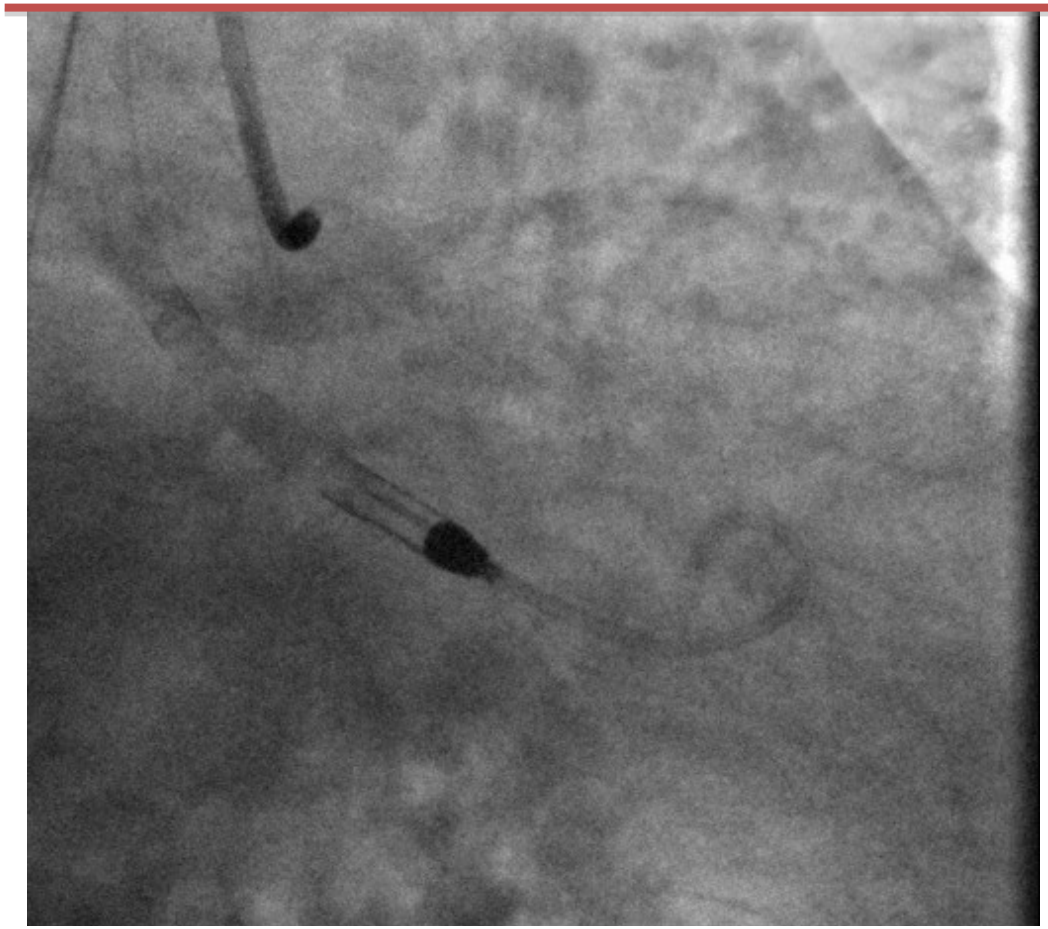
IMPELLA:

1) US 4/1000

2) ITALIA < 1/1000

The American Journal of Cardiology (www.ajconline.org)

Percutaneous mechanical circulatory support in HIGH RISK PCI



The goal of Quality PCI is not only "get out of the Lab"

But

To achieve anatomic outcomes, ideally equivalent to those expected from bypass surgery

Coronaropatia	Aspetti clinici	Aspetti emodinamici
– Malattia multivasale e/o tronco comune non protetto – Occlusioni croniche totali – Rivascolarizzazione estesa – Numero di gonfiaggi di palloni/stent – Impiego di dispositivi aggiuntivi (rotablator)	Comorbilità e condizioni cardiologiche che riducono la tolleranza all'ischemia miocardica quali: – Età avanzata – Diabete – Insufficienza cardiaca – Vasculopatia periferica	– Disfunzione ventricolare sinistra – Instabilità emodinamica transitoria – Scompenso cardiaco congestizio

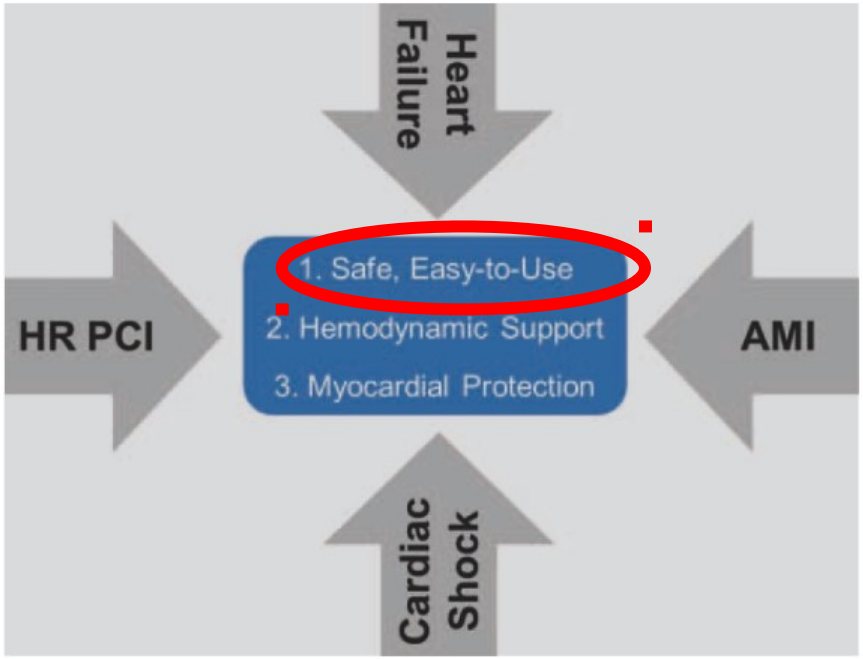
Characteristics of Optimal Mechanical Hemodynamic support

Catheterization and Cardiovascular Interventions 00:000–000 (2012)

Hemodynamic Rounds

The Science Behind Percutaneous Hemodynamic Support: A Review and Comparison of Support Strategies

Daniel Burkhoff,[1*] MD, PhD, and Srih



PHYSIOLOGIC EFFECTS OF INTRA AORTIC BALLOON PUMP

1. Blood pressure
2. Cardiac output
3. Cardiac Power output
4. Coronary Flow

1. LV filling pressure
2. LV Volume

PHYSIOLOGIC EFFECTS OF LEFT SIDED IMPELLA SUPPORT

1. Blood pressure
2. Cardiac output
3. Cardiac Power output
4. Coronary Flow

1. LV filling pressure
2. LV Volume

IMPELLA PORTFOLIO

	Impella 2.5	Impella CP	Impella 5.0	Impella RP
Flusso (L/min)	**2.5**	**3.7 – 4.0**	**5.0**	**4.4**
VAD		Sinistro		Destro
Supporto circolatorio	Parziale	Parziale - Alto	Alto flusso	Parziale - Alto
Dimensione catetere	9 F	9 F	9 F	9 F
Dimensione pompa	12 F	14 F	21 F	22 F
Dimensione introduttore	13 F	14 F	--	23 F
Metodo di impianto	Percutaneo	Percutaneo	Chirurgico	Percutaneo / venoso

CRITICHE

REFERENCES

1. Kumbhani DJ, Bavry AA, Desai MY, Bangalore S, Bhatt DL. Role of aspiration and mechanical thrombectomy in patients with acute myocardial infarction undergoing primary angioplasty: an updated meta-analysis of randomized trials. J Am Coll Cardiol 2013;62:1409–18.

2. Elgendy IY, Huo T, Bhatt DL, Bavry AA. Is aspiration thrombectomy beneficial in patients undergoing primary percutaneous coronary intervention? Meta-analysis of randomized trials. Circ Cardiovasc Interv 2015;8:e002258.

3. Jolly SS, Cairns JA, Yusuf S, et al. Randomized trial of primary PCI with or without routine manual thrombectomy. N Engl J Med 2015;372:1389–98.

4. Jolly SS, Cairns JA, Yusuf S, et al. Stroke in the TOTAL trial: a randomized trial of routine thrombectomy vs. percutaneous coronary intervention alone in ST elevation myocardial infarction. Eur Heart J 2015;36:2364–72.

5. Levine GN, Bates ER, Blankenship JC, et al. 2015 ACC/AHA/SCAI focused update on primary percutaneous coronary intervention for patients with ST-elevation myocardial infarction: an update of the 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention and the 2013 ACCF/AHA guideline for the management of ST-elevation myocardial infarction. J Am Coll Cardiol 2016;67:1235–50.

High-Risk Percutaneous Coronary Interventions

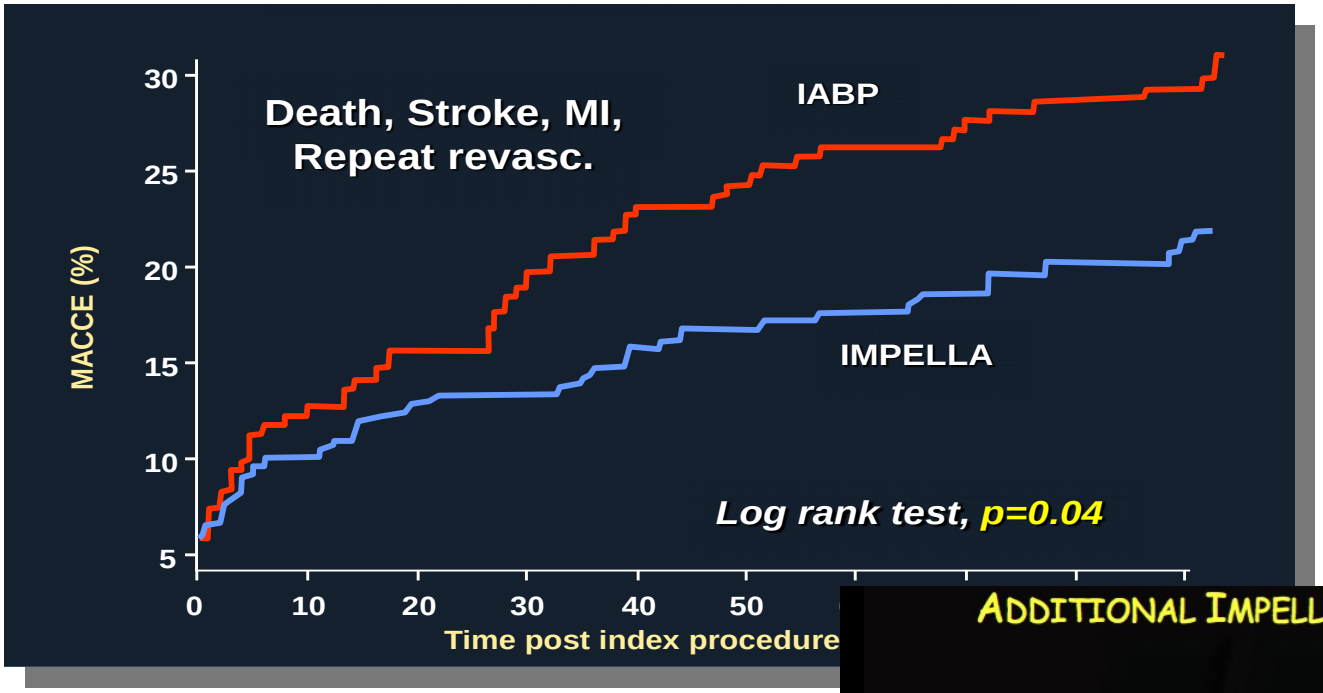
First, Do No Harm

the Impella with an intra-aortic balloon pump, a support device that has historically failed to show any significant benefit in HRPCI.

The hemodynamic benefits of PLVAD are not without risk. In a real-world Impella database, the vascular complication rate was 17%, with need for amputation in 4.4% (3). The composite of major bleeding, hemolysis, and pericardial tamponade occurred in 37.8% of patients in the Impella-EUROSHOCK registry (4). Eleven percent of patients treated in the USpella registry required blood transfusions. Vascular complications requiring surgery occurred in 2.5% of USpella registry patients (5). In PROTECT II, there was a 68.8% composite of adverse events in patients treated with rotational atherectomy with Impella support.

MCS can improve hemodynamic status, but it has not been shown to improve any periprocedural outcomes in this complex higher-risk indicated patient cohort. The use of PLVAD is on the rise, as we work to optimize management of high-risk patients, but this is based largely not on randomized controlled data but on registry experience. We must be mindful that

PROTECT II TRIAL



ADDITIONAL IMPELLA® SAFETY ENDPOINTS[1]

	IABP Control Arm (n=210)	Impella Protected PCI (n=215)	p-value
Aortic Valve Damage	0	0	NA
Vascular Complications[2]	1.9%	1.4%	0.680
Acute Renal Dysfunction (Total Contrast media)[3]	4.8% (241 mL)	4.2% (267 mL)	0.774 (0.036)

1. O'Neill WW et al. Circulation. 2012 Oct 2:126(14):1717-27
2. Vascular complications from Protect II RCT = Cardiac, thoracic, or abdominal operation, or vascular operation for limb ischemia.
3. Acute renal dysfunction was numerically lower even with additional contrast media in the Protected PCI with Impella arm of Protect II RCT

Dangas GD et al. Am J Cardiol 2014 1;113(2):222-8.

VASCULAR COMPLICATIONS

Major studies listing vascular complications

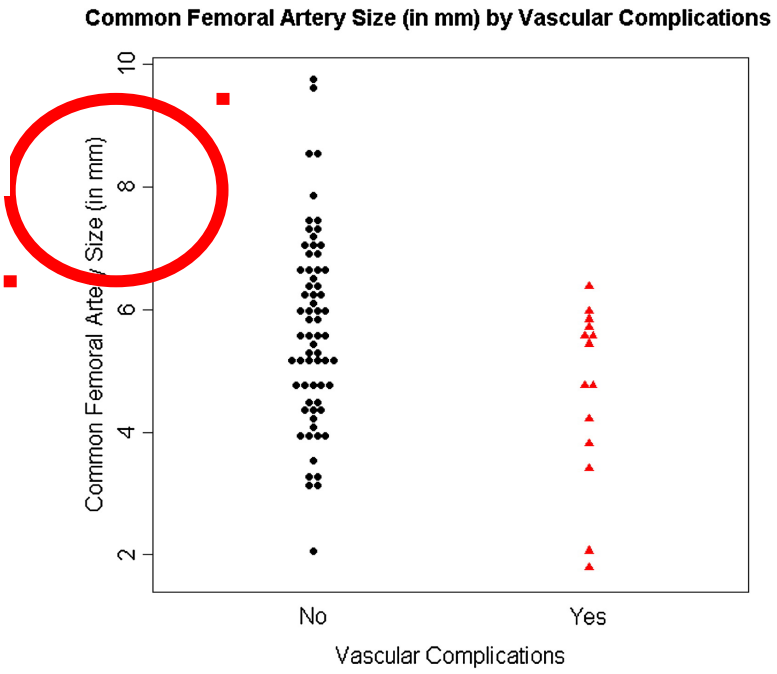
First author	*Vascular complication rate, %*
Pershad[28]	6
Kovacic[26]	8
Sjauw[8]	4
O'Neill[27]	1
Ferreiro[23]	11
O'Neill[24]	10
Lauten[25]	4
Current study	17

ARTERY SIZE

PLANNED VS URGENT/EMERGENT

Variable	*No VC (n = 75), No. (%)*	*VC (n = 15), No. (%)*	*P value*
Elective (planned)	23 (31)	0 (0)	.02
Urgent (preprocedure CS)	32 (43)	7 (21)	
Emergent (intraprocedure CS)	20 (27)	8 (40)	

CS, Cardiogenic shock.



Abaunza M, et al. J Vasc Surg 2015;62:417–23.

JACC: CARDIOVASCULAR INTERVENTIONS
© 2013 BY THE AMERICAN COLLEGE OF CARDIOLOGY FOUNDATION
PUBLISHED BY ELSEVIER INC.

VOL. 6, NO. 7, 2013
ISSN 1936-8798/$36.00
http://dx.doi.org/10.1016/j.jcin.2013.04.003

STATE-OF-THE-ART PAPER

Management of Vascular Access in Transcatheter Aortic Valve Replacement

Part 1: Basic Anatomy, Imaging, Sheaths, Wires, and Access Routes

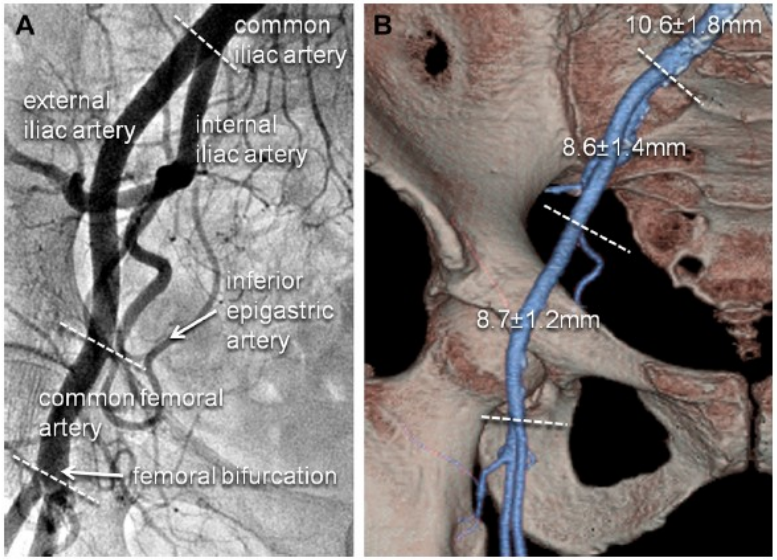


Figure 1. Basic Iliofemoral Anatomy

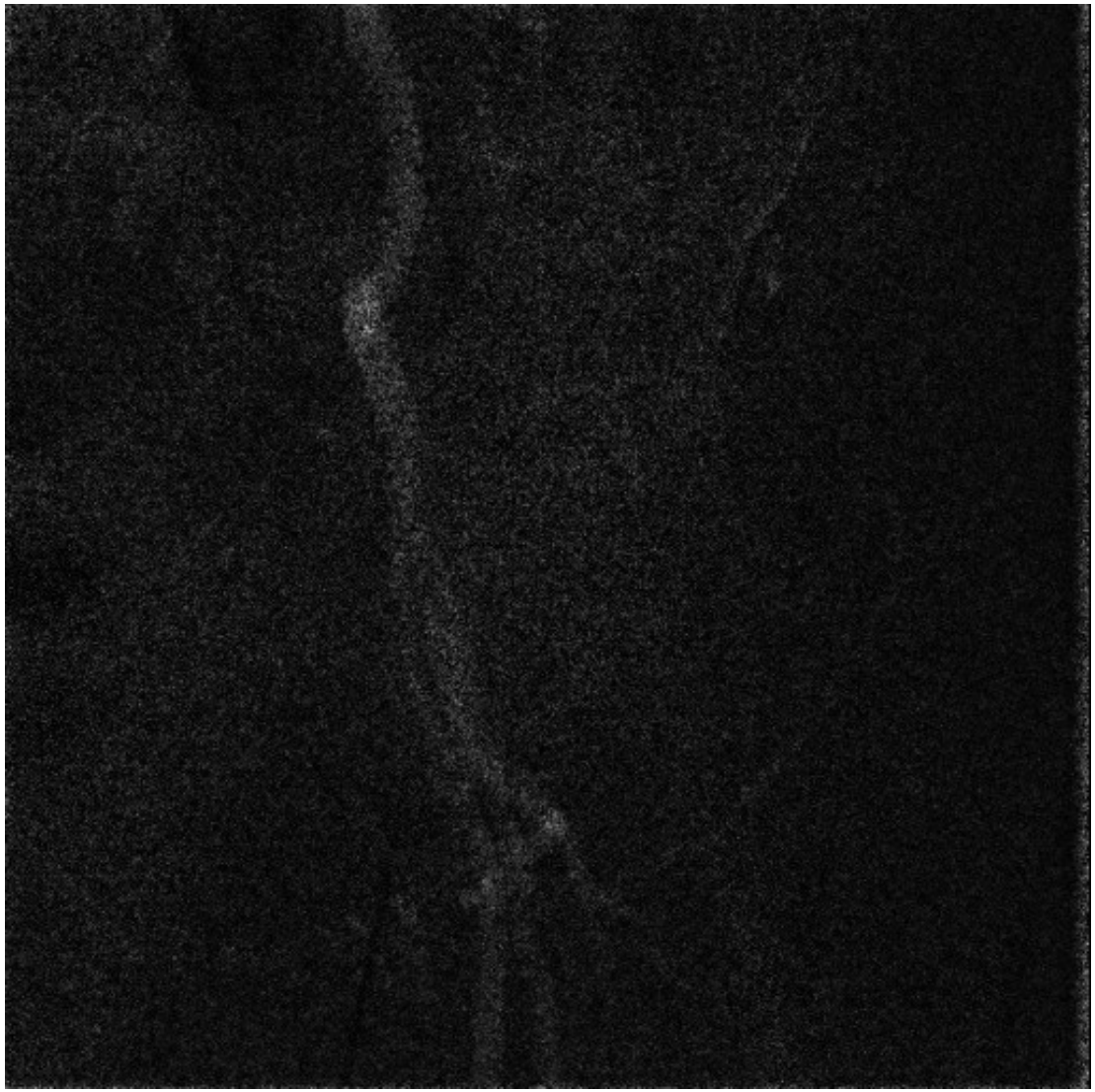
STATE-OF-THE-ART PAPER

Management of Vascular Access in Transcatheter Aortic Valve Replacement

Part 2: Vascular Complications

Controlateral femoral angiogram via a diagnostic catheter

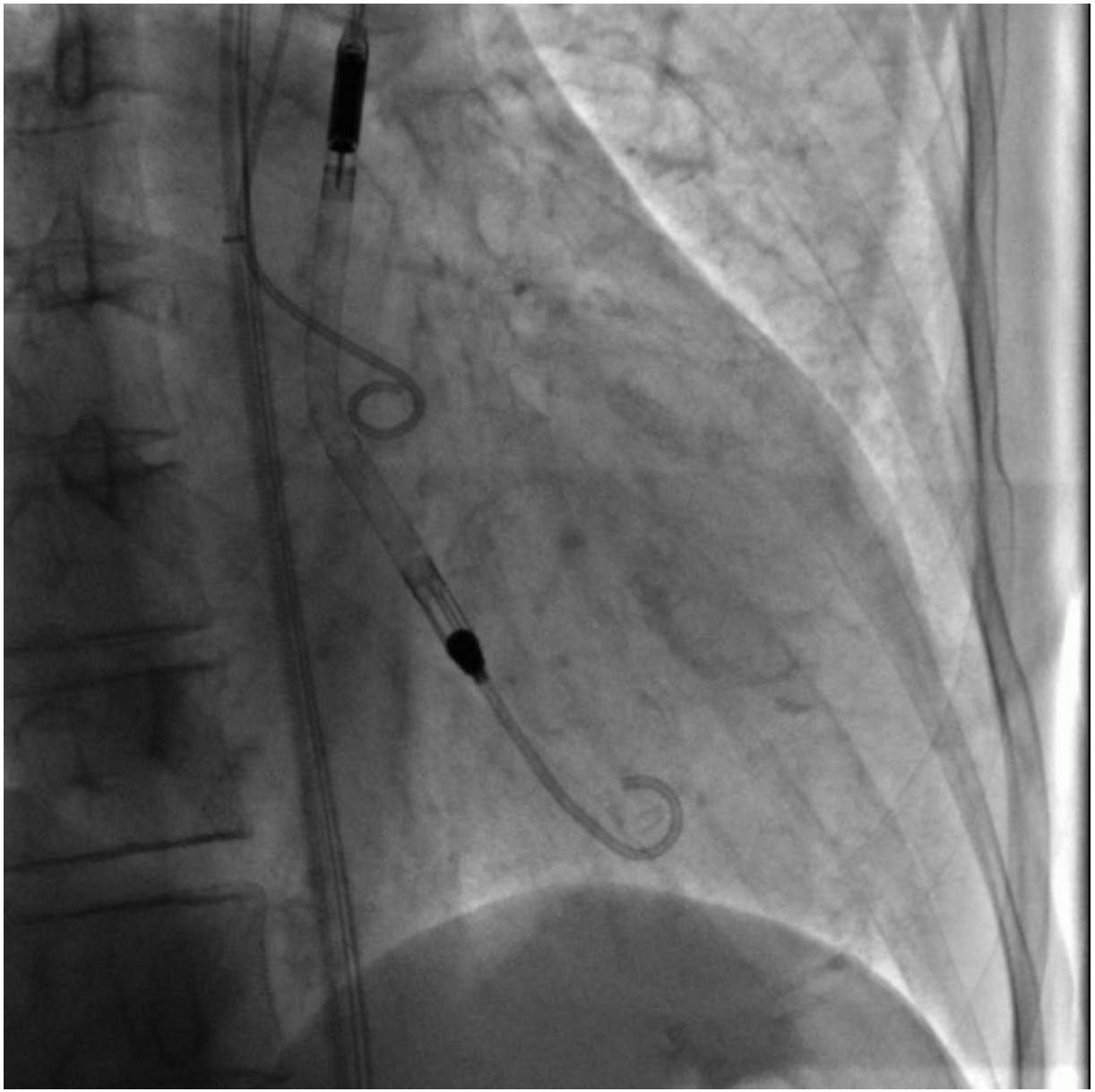
PRECISE PUNCTURE in the center of the lumen



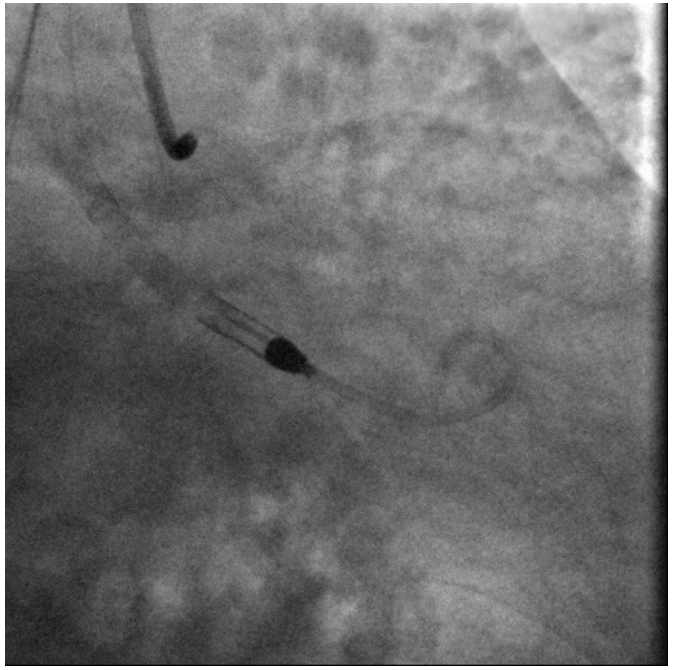
1) DSA (digital subtraction angiography) and road mapping
2) small bolus injections from controlateral side catheter

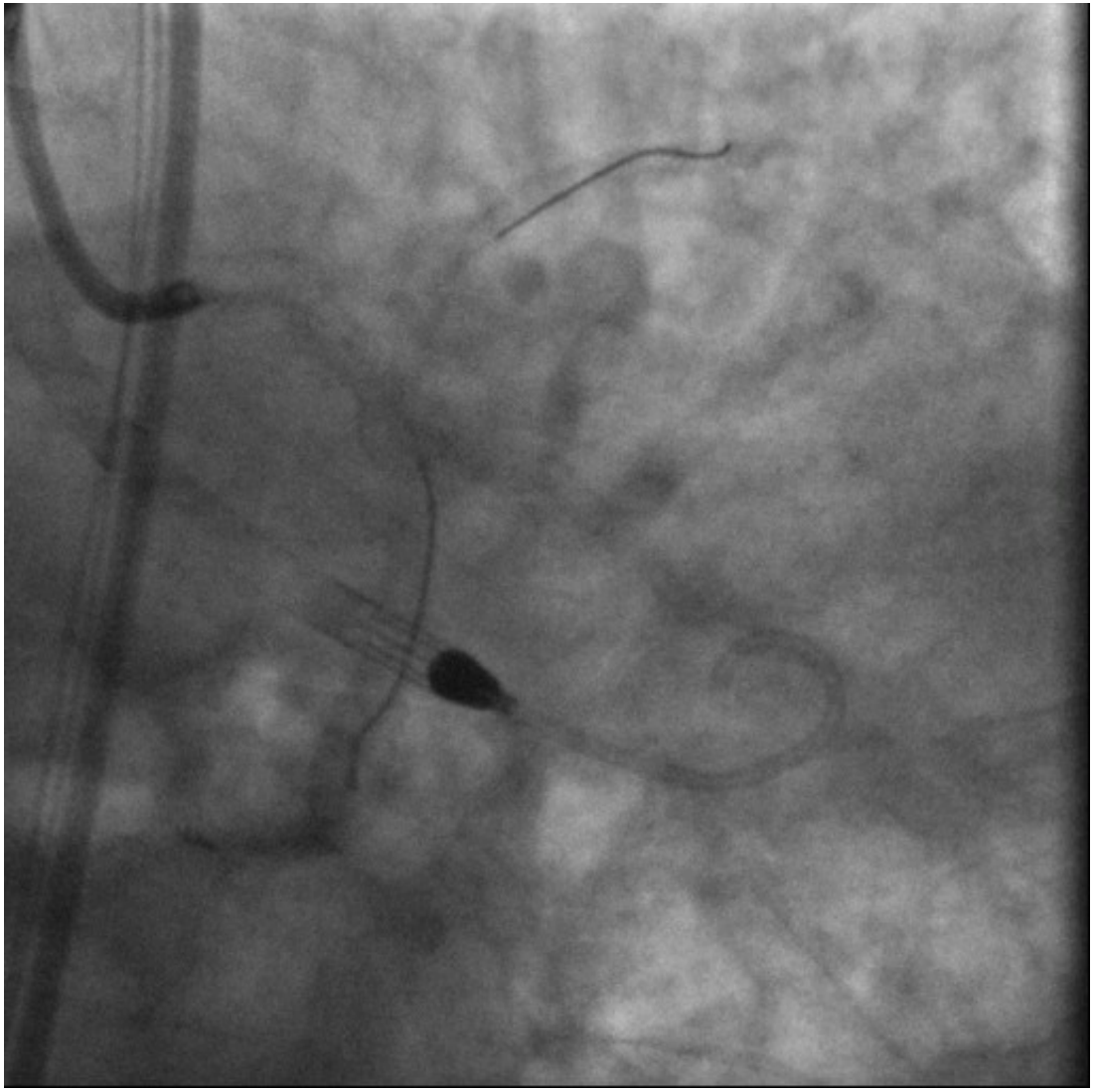
14 Fr


0.018” wire into LV

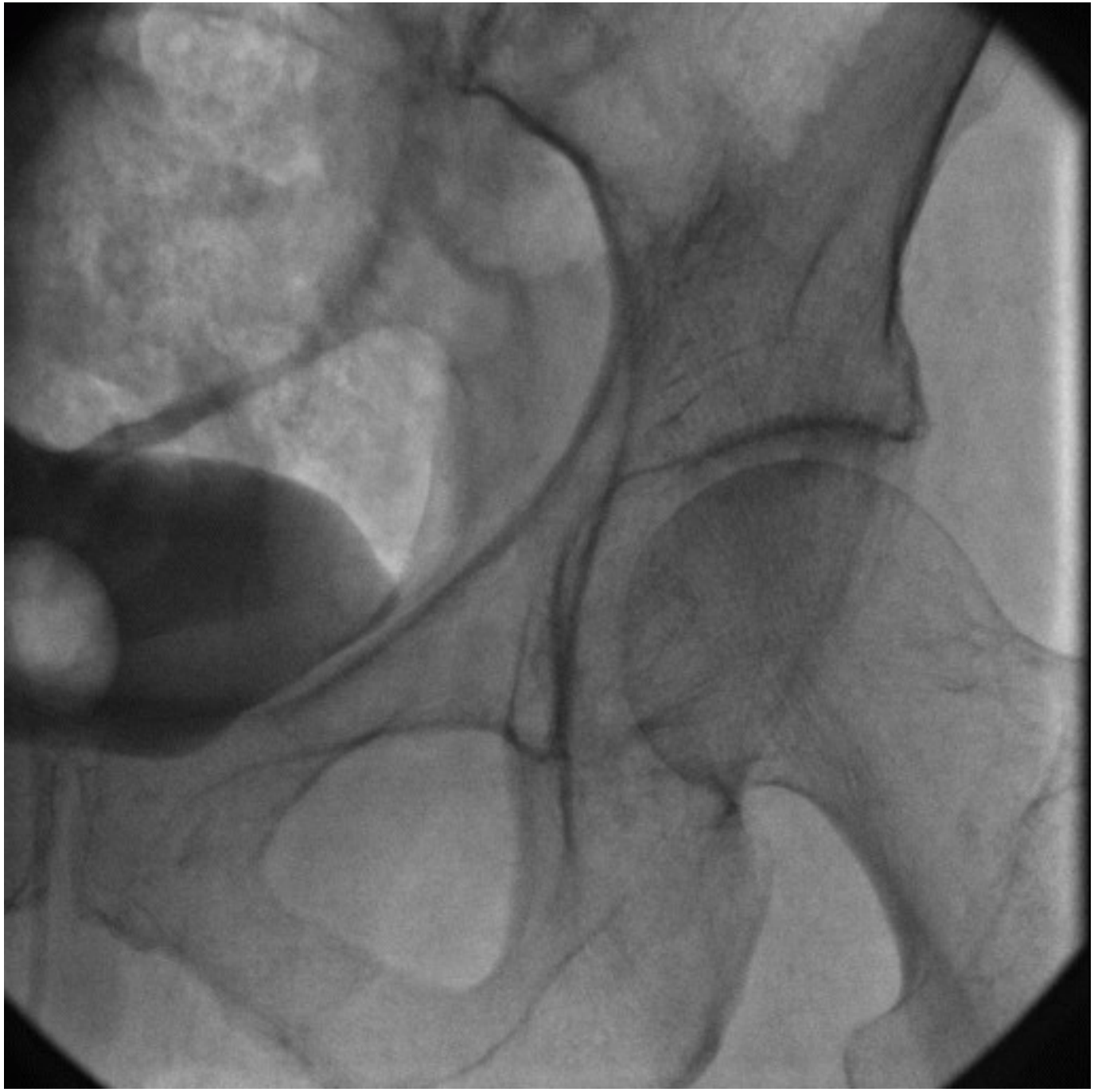


Impella CP positioning across aortic valve with Pigtail injection

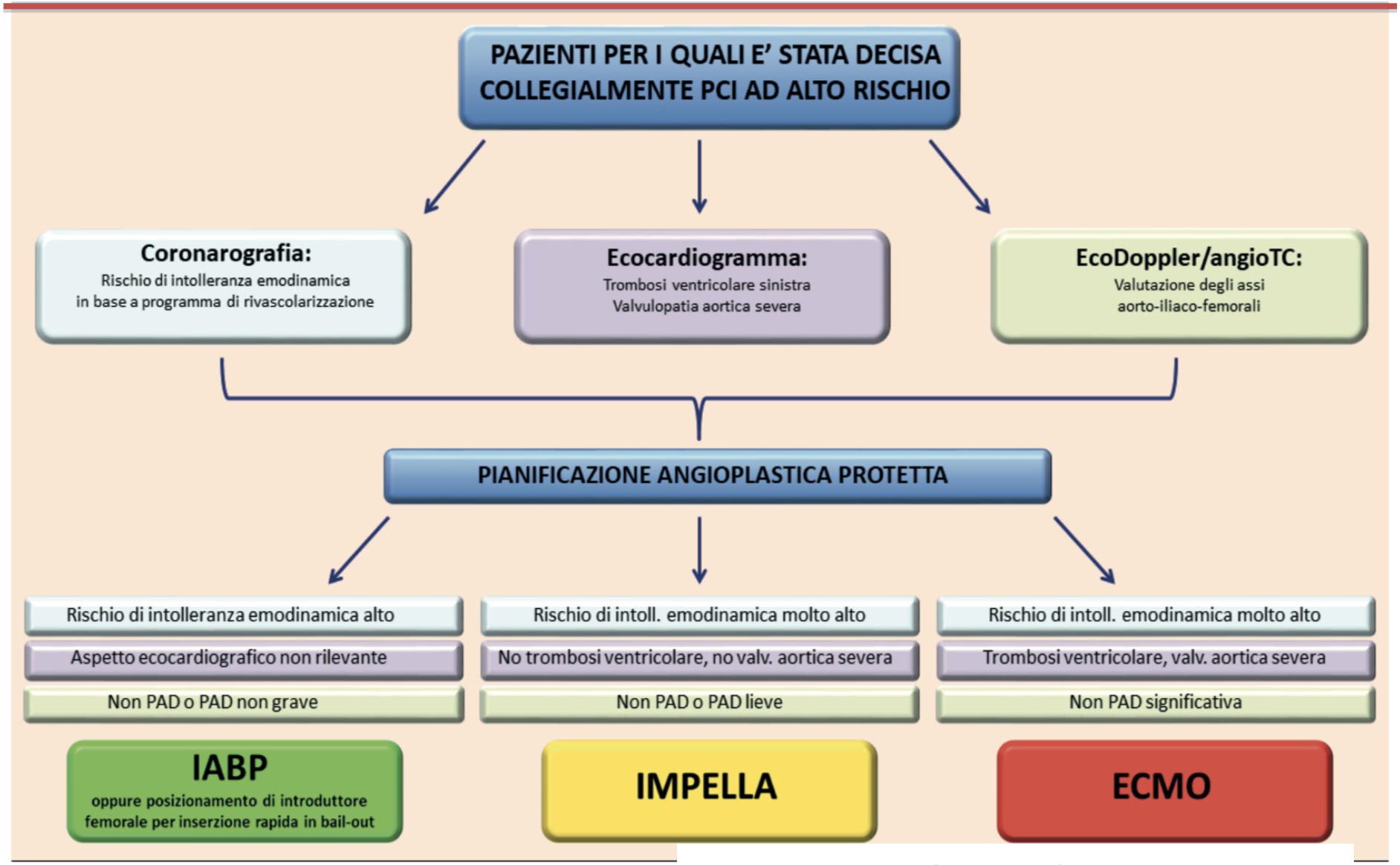


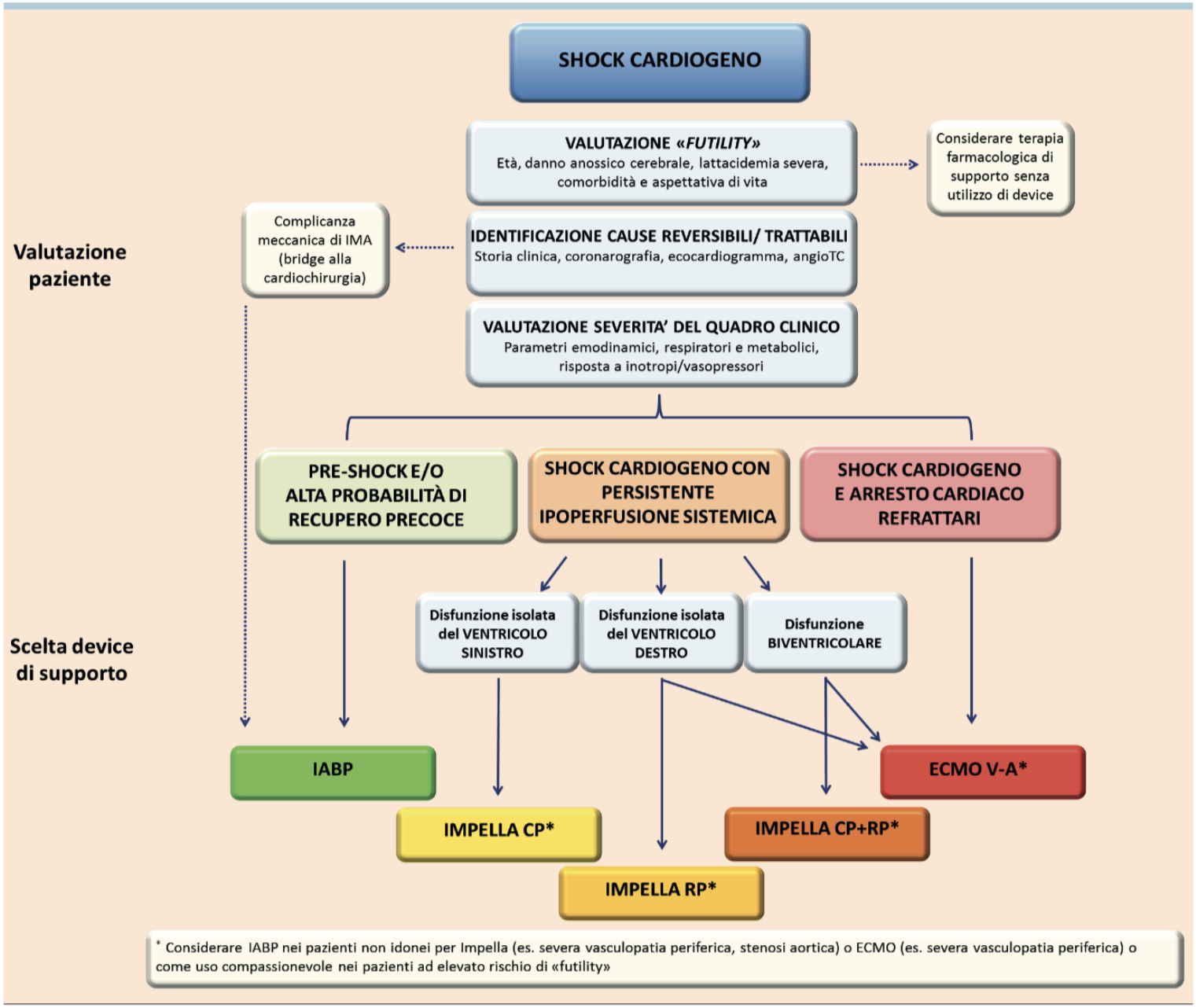


Impella™ removal



Percutaneous mechanical circulatory support in HIGH RISK PCI




SHOCK CARDIOGENO
VALUTAZIONE «FUTILITY»
Età, danno anossico cerebrale, lattacidemia severa, comorbidità e aspettativa di vita
Considerare terapia farmacologica di supporto senza utilizzo di device
Valutazione paziente
Complicanza meccanica di IMA (bridge alla cardiochirurgia)
IDENTIFICAZIONE CAUSE REVERSIBILI/ TRATTABILI
Storia clinica, coronarografia, ecocardiogramma, angioTC
VALUTAZIONE SEVERITA' DEL QUADRO CLINICO
Parametri emodinamici, respiratori e metabolici, risposta a inotropi/vasopressori
PRE-SHOCK E/O ALTA PROBABILITÀ DI RECUPERO PRECOCE
SHOCK CARDIOGENO CON PERSISTENTE IPOPERFUSIONE SISTEMICA
SHOCK CARDIOGENO E ARRESTO CARDIACO REFRATTARI
Scelta device di supporto
Disfunzione isolata del VENTRICOLO SINISTRO
Disfunzione isolata del VENTRICOLO DESTRO
Disfunzione BIVENTRICOLARE
IABP
ECMO V-A*
IMPELLA CP*
IMPELLA CP+RP*
IMPELLA RP*
* Considerare IABP nei pazienti non idonei per Impella (es. severa vasculopatia periferica, stenosi aortica) o ECMO (es. severa vasculopatia periferica) o come uso compassionevole nei pazienti ad elevato rischio di «futility»

LINEE GUIDA

ESC European Society of Cardiology
European Heart Journal (2018) **00**, 1–96
doi:10.1093/eurheartj/ehy394

ESC/EACTS GUIDELINES

2018 ESC/EACTS Guidelines on myocardial revascularization

Recommendations for the management of patients with cardiogenic shock

Recommendations	Class[a]	Level[b]
Emergency coronary angiography is indicated in patients with acute heart failure or cardiogenic shock complicating ACS.[258,269]	I	B
Emergency PCI of the culprit lesion is indicated for patients with cardiogenic shock due to STEMI or NSTE-ACS, independent of time delay of symptom onset, if coronary anatomy is amenable to PCI.[258]	I	B
Emergency CABG is recommended for patients with cardiogenic shock if the coronary anatomy is not amenable to PCI.[258]	I	B
In cases of haemodynamic instability, emergency surgical or catheter-based repair of mechanical complications of ACS is indicated, as decided by the Heart Team.	I	C
In selected patients with ACS and cardiogenic shock, short-term mechanical circulatory support may be considered, depending on patient age, comorbidities, neurological function, and the prospects for long-term survival and predicted quality of life.	IIb	C
Routine use of IABPs in patients with cardiogenic shock due to ACS is not recommended.[260–262]	III	B

CONCLUSIONI

Nelle PCI ad alto rischio, il supporto emodinamico ha la finalità di prevenire il deterioramento emodinamico e l'instaurarsi dello shock cardiogeno durante la procedura, permettendo una rivascolarizzazione ottimale

L'integrazione tra stratificazione del rischio della PCI e del rischio derivante dall'uso del sistema di assistenza dovrebbe guidare la scelta del tipo di assistenza nel singolo paziente

Se si guardano i dati del GISE 2017, il numero di centri in grado di utilizzare soprattutto i sistemi più complessi è limitato. Pertanto è auspicata l'implementazione dell'suo di sistemi di supporto meccanico mediante lo sviluppo di protocolli locali


Grazie