

Best oral communications

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LA VIA OMERALE PERCUTANEA PER L'INSERZIONE DI IMPELLA 2,5L PER IL SUPPORTO CIRCOLATORIO DURANTE PCI AD ALTO RISCHIO

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Il supporto circolatorio percutaneo consente l'esecuzione di interventi coronarici percutanei in situazioni anatomiche e cliniche sempre più complesse come ad esempio la malattia del tronco comune della coronaria sinistra o la coronaropatia plurivasale con o senza disfunzione ventricolare sinistra. Queste situazioni sono frequentemente accompagnate da arteriopatia ostruttiva di altri distretti, in particolare quelli degli arti inferiori. Ciò costituisce una significativa limitazione per l'inserzione di sistemi di supporto circolatorio costituiti da cateteri di alto calibro. Un'alternativa è costituita dall'accesso ascellare, percutaneo o chirurgico, tuttavia con particolari requisiti tecnici soprattutto per quel che riguarda l'emostasi vascolare al termine della procedura.

Viene descritto, in questo report, il caso di un approccio percutaneo omerale per il posizionamento di Impella 2,5L per supporto circolatorio durante una PCI di tronco comune.

Un maschio di 64 anni, obeso (138 kg x 180 cm, BMI 43) viene ricoverato per angina instabile ed insufficienza cardiaca acuta congestizia in un quadro di nota cardiopatia ischemica cronica postinfartuale. Concomitano diabete mellito tipo 2 in terapia insulinica, malattia renale cronica stadio IV e sindrome delle apnee notturne. Nonostante pregresse procedure di rivascularizzazione percutanea degli arti inferiori, erano presenti occlusione totale dell'arteria iliaca comune sinistra all'origine e successione di stenosi severe dell'asse iliaco-femorale destro da patologia severamente calcifica non risolta da precedenti stenting. La coronarografia mostra malattia trivascolare con stenosi significativa, calcifica del tronco comune associata a occlusione totale di coronaria destra e del ramo circonflesso, diffusa ateromasi del ramus e malattia di discendente anteriore ostiale; la ventricolografia evidenzia ipocinesia globale con FE 42%. La terapia chirurgica veniva esclusa per elevato rischio operatorio (EuroSCORE II: 14.52%). Una procedura percutanea di stenting con eventuale atrectomia rotazionale del tronco comune veniva quindi programmata con supporto circolatorio, dato il quadro di last remaining vessel e disfunzione del VS. Una valutazione angiografica dell'asse arterioso dell'arto superiore sinistro aveva precedentemente dimostrato un'arteria omerale di 5,5 mm di calibro. Impella 2,5L è stato introdotto con tecnica percutanea attraverso questa arteria con regolare navigazione del sistema all'ingresso toracico e semplice posizionamento transvalvolare aortico. La procedura interventistica ha comportato atrectomia rotazionale di tronco comune e DA prossimale con stenting e duplice stenting del ramo intermedio. La durata del supporto circolatorio è stata di 105 minuti. L'emostasi omerale è stata ottenuta inizialmente in modo manuale; nei giorni seguenti, lo sviluppo di uno pseudoaneurisma omerale ha richiesto l'impianto, per via percutanea dalla radiale omolaterale, di stent graft con risoluzione della complicità vascolare. Al follow-up del terzo mese il paziente è asintomatico, in classe funzionale NYHA II, con FEVS 48% e senza segni di ischemia dell'arto superiore sinistro.

Quando il diametro del lume vascolare è adeguato e nessun altro accesso vascolare è disponibile, l'arteria omerale può essere una porta di entrata utile per i cateteri ad alto calibro dei sistemi di supporto circolatorio quali Impella 2,5L. Il decorso relativamente rettilineo dell'asse arterioso dell'arto superiore appare particolarmente favorevole alla navigazione del sistema. Il pre-posizionamento di un sistema di chiusura vascolare e un accesso addizionale radiale omolaterale possono costituire un ragionevole complemento della procedura per ottenere un'efficiente emostasi e un completo successo procedurale.

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EFFECTIVENESS OF UPFRONT COMBINED STRATEGY FOR ENDOVASCULAR HAEMOSTASIS IN TRANSFEMORAL TRANSCATHETER AORTIC VALVE REPLACEMENT

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Introduction. Vascular complications following transfemoral transcatheter aortic valve replacement (TF-TAVR) have been reducing over years thanks to the growing expertise of operators and the refinements of transcatheter system. Currently, suture-based devices (SBDs) are the most used endovascular systems to obtain femoral access haemostasis after large-bore arteriotomy. Nevertheless, rates of major vascular complications and bleeding still represents an important issue, that

impacts on patients' early recovery and mobilization, as well as on mid-term prognosis. In this setting, the aim of our study was to assess the effectiveness of upfront use of an adjunctive Angio-Seal (AS) plug-based system (Terumo Inc, Tokyo, Japan) on top of SBDs for endovascular haemostasis after TF-TAVR in terms of reduction of access-related complications due to endovascular closure system failure, and therefore of resources utilization and costs reduction.

Methods. Study population: This is a single-center, retrospective analysis obtained from a prospective local TAVR registry. Consecutive patients undergoing fully percutaneous TF-TAVR with pre-procedural computed tomography angiography (CTA) assessment in our institution from January 2019 to April 2020 were included. Femoral arteriotomy was performed percutaneously with angiographic guidance in all patients. Arteriotomy site had previously been identified by pre-procedural CTA scans in order to select the most favourable ileo-femoral axis, in terms of vessels tortuosity ($<90^\circ$), diameters and calcifications. In particular, patients with calcium in the femoral artery anterior wall or circumferential calcification greater than 180° , as well as sheath-to-femoral artery ratio (SFAR) higher than 1.0 as were excluded. All study management activities including data management and statistical analyses were performed at the Policlinico-Vittorio Emanuele Hospital, Catania. All subjects provided written informed consent for the procedure. The study was conducted according to the principles of the Declaration of Helsinki and Good Clinical Practice. The study did not undergo ethical committee approval, considering the retrospective nature of the analysis. The authors wrote all drafts of the paper and vouch for the integrity of and completeness of the data and analyses. **Closure technique:** Either single Prostar XL or dual PerClose Proglide SBDs (both Abbott Vascular, Santa Clara, CA) were used for obtaining common femoral artery (CFA) haemostasis. Endovascular closing SBDs were pre-implanted before insertion of transcatheter aortic valve (TAV)'s sheath as per standard practice. At the end of TAVR procedure, transcatheter systems were pulled out, leaving the stiff guidewire inside, and one of the two pre-implanted knots was gently push towards CFA, without tightening, in order to reduce actual bleeding. At this point, AS was advanced through the in-situ guidewire into the artery. The addition of the AS plug-based device on top of SBDs was implemented regardless the residual bleeding. Then, SBDs knots were tightened over the AS device and therefore collagen-based plug was released. Finally, SBDs knots were re-tightened after AS system removal. Step-by-step implantation technique was illustrated in Online Video 1. In order to proper assess vascular complications after TF-TAVR, a final digital subtraction angiography of femoral artery was performed in LAO and RAO projections, as per standard practice in our Institution. **Study endpoints:** The primary outcomes were VARC-2 defined major vascular complications due to endovascular closure system failure and major or life-threatening (LT) bleeding at 30 days. Specific costs analysis was performed taking into account only additional costs related to vascular complications. First, we compared 30-day outcomes of patients undergoing TF-TAVR and receiving only SBD or AS + SBD for endovascular closing considering the entire population. Then, we accounted for any confounding variables between the two groups through a propensity matching adjustment, and re-assessed outcomes of SBD and SBD+AS matched groups. All outcomes were reported according Valve Academic Research Consortium-2 definitions. **Statistical analysis:** Continuous variables were reported as mean \pm standard deviation (SD) whereas dichotomous parameters as frequencies and percentage. Comparisons were made using a Pearson's Chi-Square test and t-test for categorical and continuous variables, as appropriate. Odds ratios (ORs) were reported as absolute values and 95% confidence interval (CI). To adjust for potential bias in treatment assignment, two groups of patients with similar pre-procedural characteristics were selected using propensity score (PS) matching with the nearest neighbour method using a non-parsimonious approach. The matching algorithm used in this analysis is implemented in the PS Matching package (IBM SPSS Statistics, USA, vers. 3.0.4) whose details have been reported elsewhere. To account for the matched design, the baseline characteristics and the clinical outcomes after matching were analysed using the Spearman's rank correlation and Mann-Whitney U tests among the two groups, as appropriate. A sensitivity analysis was performed excluding patients treated with dual PerClose Proglide SBDs. All statistical tests were performed two-tailed, and a significance level of $p < 0.05$ was considered to indicate statistical significance. The statistical software IBM SPSS Statistics 25.0 was used for all statistical analyses.

Results. Baseline and procedural characteristics: From January 2019 to April 2020, a total of 298 consecutive patients with favorable ileo-femoral axes at pre-procedural CTA assessment underwent TF-TAVR in our Institution. Patients had a mean age and STS Mortality score of 80.5 ± 6.8 years and $3.7 \pm 2.2\%$, respectively, and received Prostar XL SBD for endovascular closing in most of cases (92.3%). One hundred fifty-four

patients (51.7%) were treated with isolated SBD, whereas 145 patients (48.3%) were treated with a SBD+AS combined strategy. At baseline, pre-existing atrial fibrillation (AF) (24.8% vs. 13.1%, $p<0.01$) was more frequent in patients treated with isolated SBD. After PS matching, 123 pairs of patients receiving SBD or SBD+AS for endovascular haemostasis were included in the main analysis. No differences in baseline and procedural characteristics were encountered between the two matched groups. Baseline and procedural characteristics, before and after adjustment, are reported in Tables 1 and 2, respectively. **Thirty-day outcomes:** Thirty-day outcomes, before and after adjustment, are reported in Supplementary Table 1 and Table 3, respectively. After adjustment, patients receiving SBD+AS had a significant lower risk of major/life-threatening bleeding (8.9% vs. 1.6%; OR 0.17, 95% CI 0.04-0.78; $p=0.01$), major vascular complications (8.9% vs. 1.6%; OR 0.17, 95% CI 0.04-0.78; $p=0.01$) at 30 days. Furthermore, SBD+AS group showed a higher rate of percutaneous transluminal angioplasty (PTA) of CFA with covered stent implantation (4.1% vs. 17.9%, $p<0.01$). No differences in terms of all-cause (3.3% vs. 1.6%, for SBD and SBD+AS matched groups, respectively; OR 0.49, 95% CI 0.09-2.74; $p=0.41$) and cardiovascular mortality (3.3% vs. 0.8%, for SBD and SBD+AS matched groups, respectively; OR 0.24, 95% CI 0.03-2.21; $p=0.18$), any stroke (0.8% vs. 0.8%, for SBD and SBD+AS matched groups, respectively; OR 1.00, 95% CI 0.06-16.17; $p=1.00$), and permanent pacemaker implantation (PPI) (8.1% vs. 8.1; OR 1.00, 95% CI: 0.40-2.50; $p=1.00$) were reported between matched groups at 30 days. **Post-procedural length of stay and cost analysis:** After TAVR, patients were transferred directly in general ward in most of cases (97.7%). Median length of stay (LoS) after TAVR was 2 days [interquartile range (IQR) 2-4 days] and median additional cost due to vascular event was 114,00 € per patient (IQR 0-114,00 €). After adjustment, patients receiving SBD+AS had a higher probability to be discharged the day after the procedure (30.9% vs. 16.3%, OR 2.30, 95% CI 1.25, 4.25; $p<0.01$) (Table 3), and showed a significant costs reduction related to vascular events [mean difference -315,30 € per patient, 95% CI (-566,40)-(-64,10)€, $p=0.01$].

Conclusions. The optimization of pre-procedural planning by CTA assessment and the improvements of new generation TAV delivery systems, as well as the consolidate experience of operators with endovascular SBDs have been contributing to lower the rate of vascular complications and bleeding after TAVR over latest years. Nevertheless, a not negligible percentage of patients still experience vascular complications due to SBDs failure after transfemoral TAVR, which could impact on mid-term prognosis. The aim of the present analysis was to evaluate the effectiveness of the upfront use of additional AS plug-based device on top of SBDs in patients undergoing TF-TAVR, comparing this novel strategy to the standard use of isolated SBD for endovascular haemostasis. The main findings of our study are: 1) vascular complications and bleeding due to SBDs failure still represent an important issue, even avoiding unfavorable vascular access sites by proper pre-procedural CTA assessment; 2) a strategy of upfront addition of AS plug-based device on top of SBDs showed to significantly lower vascular complications and bleeding after transfemoral TAVR; 3) this strategy demonstrated to reduce hospital resources utilization by reducing the LoS and lowering procedure-related costs. Although, the extensive use of pre-procedural CTA assessment has allowed to identify several anatomical and procedural predictors of vascular complications after TF-TAVR over past decade, SBDs for endovascular closing showed a not negligible percentage of failure, which results in various grades of vascular complications. In this setting, a dual Proglide strategy seems to have better results in terms of major vascular complications compared to single Prostar XL use, even if the real benefit of a datum SBD over the other is still debated. In our analysis, we considered only patients undergoing transfemoral TAVR, who did not have unfavorable ileo-femoral characteristics at pre-procedural CTA assessment, and treated with either isolated SBDs or by combining a SBD with the upfront addition of AS plug-based device for obtaining endovascular closure. Considering the entire population, 30-day rates of all-cause mortality, major vascular complications related to closing systems failure and major or life-threatening bleeding after TAVR were 2.7%, 5.4% and 5.4% respectively, which are in line with those reported in large, prosthesis-specific, TF-TAVR registries. The use of an additional AS on top of dual Proglide has been previously investigated in a retrospective study. It reported that this strategy is safe and feasible for obtaining complete haemostasis after TAVR, even if there was no clear benefit in terms of vascular complications and bleeding compared to the use of isolated dual Proglide strategy. Nevertheless, this study suffered from important limitations: AS was added in case of residual bleeding at discretion of the operators and patients were not selected according CTA characteristics of ileo-femoral vessels, as well as patients groups were not adjusted to take into account any confounding variables. In our study, after propensity-matching adjustment, we reported significant differences between the use of isolated SBD and the upfront addition of AS plug-based device on top of SBDs in terms of vascular complications and bleedings after TAVR. In particular, SBD+AS combined strategy showed significant lower risk of major vascular complications (8.9% vs. 1.6%; OR 0.17, 95% CI 0.04-0.78; $p=0.01$) and major/LT bleeding (8.9% vs. 1.6%; OR 0.17, 95% CI 0.04-0.78; $p=0.01$) at 30 days. As a corollary finding, patients receiving SBD+AS for endovascular closing underwent femoral PTA with covered

stent implantation in a lower percentage of cases (4.1% vs. 17.9%, $p<0.01$). However, the difference in rates of vascular events did not affect overall mortality (3.3% vs. 1.6% for SBD and SBD+AS groups, respectively; $p=0.41$). Vascular complications and bleeding after TAVR significantly affect the post-procedural in-hospital care. Although, the majority of vascular events can be immediately recognized and solved during the index procedure by endovascular treatments, the presence of a significant haemoglobin drop at post-procedural blood exams may rise concerns about any further unnoticed vascular damage during TAVR. As a consequence, post-procedural LoS and resources utilization increase after TAVR. In this setting, our findings showed that the benefit of the combined use of SBD+AS for endovascular closing, in terms of reduction of vascular complications and bleeding, is in turn reflected in a significant vascular complication-related costs saving of approximately 315 € per patients. In addition, patients treated with SBD+AS had a more than two-fold probability to undergo a faster recovery and to be discharged the day after TAVR (30.9% vs. 16.3%). **Limitations.** The main limitation of our study lies in its single center, retrospective design with a relatively small sample size. Furthermore, the influence of unknown confounders cannot be excluded, despite propensity matching adjustment. Finally, we did not assess the distance between common femoral artery and patients skin, that could differ between the two groups and we used mainly Prostar XL device in our TAVR practice, even if the rational of integrating different mechanisms to improve artery haemostasis do not differ between Prostar XL and dual Proglide. An upfront combined strategy with an additional AS plug-based device on top of SBDs showed to reduce major vascular complications and major/LT bleeding after TF-TAVR. This approach was associated with a cost saving and with a higher probability to be discharged the day after the procedure compared to the use of isolated SBD. These results need to be confirmed in larger, comparative studies.

Table 1. Baseline characteristics before and after adjustment.

	Before Matching			After Matching		
	SBD (n=153)	SBD+AS (n=145)	p-value	SBD (n=123)	SBD+AS (n=123)	p-value
Age (years), mean±SD	80.3±7.3	80.7±6.1	0.55	80.6±6.8	80.6±6.4	0.94
Female, n (%)	87 (56.9)	88 (60.7)	0.50	74 (60.2)	76 (61.8)	0.79
Hypertension, n (%)	128 (83.7)	129 (89)	0.18	108 (87.8)	107 (87)	0.85
NYHA class III-IV, n (%)	103 (67.3)	98 (67.6)	0.96	85 (69.1)	82 (66.7)	0.69
Diabetes, n (%)	55 (35.9)	54 (37.2)	0.99	45 (36.6)	46 (37.4)	0.90
STS Mortality Score, %±SD	3.7±2.0	3.8±2.3	0.57	3.6±1.8	3.9±2.4	0.28
Prior PPI, n (%)	13 (8.5)	8 (5.5)	0.32	9 (7.3)	8 (6.5)	0.80
Prior SAVR, n (%)	4 (2.6)	4 (2.8)	0.94	3 (2.4)	4 (3.3)	0.70
Prior CABG, n (%)	6 (3.9)	7 (4.8)	0.70	6 (4.9)	4 (4.9)	1.00
Prior PCI, n (%)	23 (15)	13 (9)	0.11	17 (13.8)	12 (9.8)	0.32
PAD, n (%)	11 (7.2)	6 (4.1)	0.26	9 (7.3)	6 (4.9)	0.42
COPD, n (%)	29 (19)	22 (15.2)	0.39	23 (18.7)	15 (12.2)	0.16
Renal failure, n (%)	16 (10.5)	11 (7.6)	0.39	11 (8.9)	11 (8.9)	1.00
AF, n (%)	38 (24.8)	19 (13.1)	0.01	20 (16.3)	18 (14.6)	0.72
Echocardiographic assessment						
LVEF, %±SD	53.3±9.4	53.7±10.7	0.78	53.6±9.9	53.8±10.8	0.86
Peak gradient, mmHg±SD	77.6±24.2	77.9±23.6	0.90	80.3±24.1	77.8±24.3	0.43
Mean gradient, mmHg±SD	48.9±16.5	48.8±15.2	0.98	50.7±16.4	48.5±15.1	0.27
AVA, cm²±SD	0.6±0.2	0.67±0.7	0.50	0.6±0.2	0.7±0.8	0.44

AF, atrial fibrillation; AS, Angio-Seal; AVA, aortic valve area, CABG, coronary artery bypass graft; COPD, chronic obstructive pulmonary disease; LVEF, left ventricle ejection fraction; NYHA, New York Heart Association; PAD, peripheral artery disease; PCI, percutaneous coronary intervention; PPI, permanent pacemaker implantation; SAVR, surgical aortic valve replacement; SBD, suture-based device; STS, Society of Thoracic Surgeons.

Table 2. Procedural characteristics before and after adjustment.

	Before Matching			After Matching		
	SBD (n=153)	SBD+AS (n=145)	p-value	SBD (n=123)	SBD+AS (n=123)	p-value
CTA measurements						
Annulus perimeter, cm²±SD	7.4±0.6	7.4±0.7	0.99	7.4±0.6	7.4±0.7	0.94
Annulus area, cm²±SD	4.2±0.7	4.2±0.8	0.99	4.2±0.8	4.2±0.8	0.99
TAV implanted						
Sapien 3/ULTRA, n (%)	43 (28.1)	40 (27.6)	0.92	33 (26.8)	38 (30.9)	0.48
20 mm, n (%)	0 (0.0)	1 (0.7)	0.30	0 (0.0)	1 (0.8)	0.32
23 mm, n (%)	17 (11.1)	12 (8.3)	0.41	15 (12.2)	11 (8.9)	0.41
26 mm, n (%)	18 (11.8)	16 (11)	0.84	12 (9.8)	16 (13)	0.42
29 mm, n (%)	8 (5.2)	11 (7.6)	0.41	6 (4.9)	10 (8.1)	0.30
Evolut R/PRO, n (%)	78 (51)	73 (50.3)	0.91	67 (54.5)	62 (50.4)	0.52
23 mm, n (%)	3 (2.0)	3 (2.1)	0.95	3 (2.4)	3 (2.4)	1.00
26 mm, n (%)	38 (24.8)	31 (21.4)	0.48	36 (26.9)	31 (23.1)	0.37
29 mm, n (%)	31 (20.3)	36 (24.8)	0.35	25 (20.3)	30 (24.4)	0.44
34 mm, n (%)	6 (3.9)	3 (2.1)	0.35	6 (4.9)	2 (1.6)	0.15
Portico, n (%)	4 (2.6)	2 (1.4)	0.45	2 (1.6)	2 (1.6)	1.00
23 mm, n (%)	0 (0.0)	0 (0.0)	-	0 (0.0)	0 (0.0)	-
25 mm, n (%)	1 (0.7)	2 (1.4)	0.53	0 (0.0)	2 (1.6)	0.16
27 mm, n (%)	2 (1.3)	0 (0.0)	0.17	2 (1.6)	0 (0.0)	0.16
29 mm, n (%)	1 (0.7)	0 (0.0)	0.33	0 (0.0)	0 (0.0)	-
Accurate NEO, n (%)	28 (18.3)	30 (20.7)	0.60	21 (17.1)	21 (17.1)	1.00
S, n (%)	9 (5.9)	10 (6.9)	0.72	7 (5.7)	8 (6.5)	0.79
M, n (%)	16 (10.5)	11 (7.6)	0.39	12 (9.8)	8 (6.5)	0.35
L, n (%)	3 (2.0)	9 (6.2)	0.06	2 (1.6)	5 (4.1)	0.25
Device success, n (%)	148 (96.7)	142 (97.9)	0.52	120 (97.6)	120 (97.6)	1.00
Optimal implantation depth, n (%)	147 (96.1)	140 (96.6)	0.83	120 (97.6)	119 (96.7)	0.70

AS, Angio-Seal; CTA, computed tomography angiography; SBD, suture-based device; TAV, transcatheter aortic valve.

Table 3. Thirty-day outcomes of patients after adjustment.

	SBD (n=123)	SBD + AS (n=123)	p-value	OR (95% CI)
All-cause death, n (%)	4 (3.3)	2 (1.6)	0.41	0.49 (0.09-2.74)
CV death, n (%)	4 (3.3)	1 (0.8)	0.18	0.24 (0.03-2.21)
Any stroke, n (%)	1 (0.8)	1 (0.8)	1.00	1.00 (0.06-16.17)
PPI, n (%)	10 (8.1)	10 (8.1)	1.00	1.00 (0.40-2.50)
New onset LBBB, n (%)	3 (2.4)	1 (0.8)	0.31	0.32 (0.03-3.20)
AKI 2-3, n (%)	2 (1.6)	2 (1.6)	1.00	1.00 (0.14-7.22)
NDD, n (%)	20 (16.3)	38 (30.9)	<0.01	2.30 (1.25-4.25)
Major/LT bleeding, n (%)	11 (8.9)	2 (1.6)	<0.01	0.17 (0.04-0.78)
Major vascular complications, n (%)	11 (8.9)	2 (1.6)	<0.01	0.17 (0.04-0.78)
Minor vascular complications, n (%)	9 (7.3)	3 (2.4)	0.07	0.32 (0.08-1.20)
Vascular complication treatment				
Covered stent implantation	22 (17.9)	5 (4.0)	<0.01	0.19 (0.07-0.53)
POBA	15 (12.2)	15 (12.2)	1.00	1.00 (0.47-2.15)
Vascular surgery, n (%)	2 (1.6)	1 (0.8)	0.56	0.50 (0.04-5.54)

AKI, acute kidney injury; AS, Angio-Seal; CI, confidence interval; CV, cardiovascular; LBBB, left bundle branch block; LT, life-threatening; NDD, next-day discharge; OR, odds ratio; POBA, plain old balloon angioplasty; PPI, permanent pacemaker implantation; SBD, suture-based device.

C3

CLINICAL IMPACT OF REVASCULARIZATION EXTENT IN PATIENTS UNDERGOING IMPELLA-PROTECTED PCI IN A NATIONWIDE ITALIAN REGISTRY

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Background. The haemodynamic stability provided by Impella may allow perform percutaneous coronary intervention (PCI) with complete revascularization but the clinical impact of pursuing extensive revascularization in specific clinical subsets, such as cardiogenic shock (CS) or high risk PCI (HR-PCI), is debated. We have investigated the impact of coronary revascularization extent on clinical outcome of patients undergoing Impella-protected PCI.

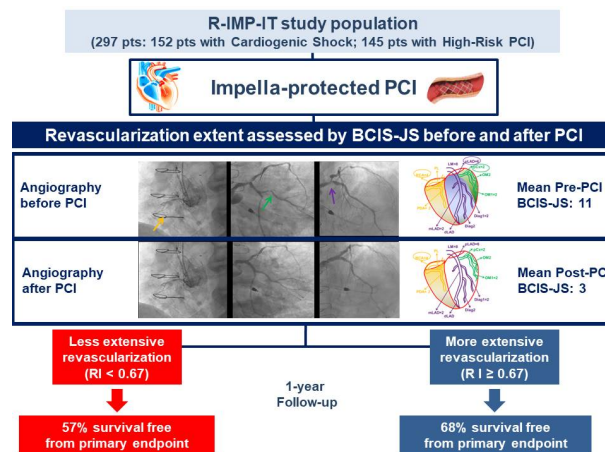


Figure 1. R-IMP-IT study design and main results.

Methods. The patients underwent PCI with Impella-assistance in the nation-level IMPella mechanical circulatory support device in Italy (IMP-IT) registry were identified for the revascularization-extent (R)-IMP-IT study. Revascularization extent was assessed using the British Cardiovascular Intervention Society (BCIS) jeopardy revascularization index (RI). Patients' subgroups were CS and HR PCI. Primary study endpoint was survival free from all death, non-fatal myocardial infarction and non-fatal stroke during 1-year.

Results. Two-hundred ninety-seven patients entered the study (mean age 68 years, 152 CS and 145 HR PCI patients, mean RI 0.70). Over 1 year, patients with more complete revascularization (RI >0.67 to 1.0) had better survival free from adverse events as compared with those with less extensive revascularization (RI <0.66) (p=0.001) (Figure 1). This result was driven by a significant reduction in all death (P=0.024) and non-fatal MI (p=0.046). Similar results were observed in the subgroups of patients with CS (p=0.006) or HR-PCI (p=0.048). At multivariable analysis, the impact of revascularization independently predicted survival free from primary end-point.

Conclusions. The extent of revascularization achieved during Impella-protected PCI impacts on 1-year outcomes. When performing Impella-protected PCI in CS or HR patients, operators may consider achieving more extensive revascularization in order to improve late clinical outcomes.