Hemodynamic effects of larger volume intra-aortic balloon pump during high-risk percutaneous coronary interventions

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ABSTRACT

Background: Percutaneous coronary intervention in high-risk patients (HRPCI) is associated with increased risk of complications. Mechanical circulatory support devices, including intra-aortic balloon pump (IABP) may bridge patient safely throughout the procedure.

Aim: We aimed to describe hemodynamic effects of larger (MEGA) compared to standard (STRD) volume IABP or no balloon control group (CTRL) during HRPCI.

Methods: In this single-center, open-label randomized controlled trial HRPCI were randomly assigned to three groups according to planned hemodynamic support: MEGA, STDR and CTRL in a 1:1:1 scheme. Screening failure patients formed registry (REG). We analyzed data from pulmonary artery catheter especially cardiac output and cardiac power output (CPO) with Fick method and pulmonary artery wedge pressure (PCWP), as well as left ventricle systolic pressure (LVSP) with PIGTAIL catheter. We also calculated endocardial viability ratio (EVR) and analyzed pressure tracings from the IABP console. We compared baseline and on-support values. Final hemodynamic analysis was done on per-treatment basis, including REG patients.

Results: A total of 47 patients were analyzed (16 MEGA, 10 STRD and 21 CTRL). Compared to CTRL we found significant increase from baseline to on-support value for cardiac output and CPO in the MEGA, but not in the STRD group. The change in EVR (increase) and in LVSP (decrease) was significant equally in MEGA and STRD vs. CTRL group, but PCWP did not change significantly for both balloons vs. CTRL. Diastolic augmented pressure with IABP was higher in MEGA than STRD and was positively correlated with systolic unloading.

Conclusions: We observed more favorable hemodynamic effects of larger compared to standard volume balloon.

Key words: complex high-risk and indicated patients, high-risk percutaneous coronary intervention, intra-aortic balloon pump, pulmonary artery catheter, right heart catheterization

INTRODUCTION

Percutaneous coronary intervention (PCI) in patients with many well-known clinical, anatomical, and procedural risk factors, so called complex high-risk and indicated patients (CHIP) is associated with higher risk of complications [1, 2]. Percutaneous mechanical circulatory support devices (MCS) are often used to decease this risk — the strategy named "protected PCI" [3]. However, randomized data do not show clear benefit of this practice, so guidelines give only a weak indication for it use [4, 5]. Of the 3 widely available systems, the intraaortic balloon pump (IABP) is the least potent, but at the same time less invasive and cheaper than hemodynamically more effective but larger devices, like percutaneous axial flow pump (AFP) Impella (2.5/CP) or even

WHAT'S NEW?

Percutaneous coronary intervention in high-risk patients is frequently protected with mechanical circulatory support. Despite increasing use of more powerful devices, like Impella, the proof for their superiority in reduction of hard clinical endpoints is lacking. Our detailed assessment of data from right and left heart catheterization and arterial pressure tracings, including index of oxygen delivery and consumption (endocardial viability ratio) during high-risk coronary intervention demonstrate that intraaortic balloon of higher volume may have more favorable hemodynamic profile than standard balloon and hence might be a cheaper alternative to more potent but expensive devices for this indication.

more aggressive extracorporeal membrane oxygenator [6]. Currently the Impella pump is being increasingly used for high-risk PCI (HRPCI) [7], but due to high cost, poor availability, and complications rate, IABP is not completely abandoned by many operators worldwide. The larger volume type balloon was not well studied so far and theoretically may have more favorable hemodynamic profile than standard one.

In our previous work we were able to show that it might be more effective in reducing hemodynamic instability during HRPCI without effect on major adverse cardiovascular events (MACE) and safety endpoints compared to standard balloon or no-balloon control group [8]. Now, we aimed to describe in detail the effects of larger volume balloon by analyzing the additional hemodynamic data obtained during that study by right (RHC) and left heart catheterization (LHC).

METHODS

The hemodynamic data for the present analysis come from an already published study from a large academic tertiary center [8]. Study methodology was presented in detail previously, so they need only to be briefly mentioned. We included patients if they were rejected from coronary artery bypass grafting by Heart Team because of advanced age or many comorbidities and had left ventricular ejection fraction (EF) equal of less than 35% with significant unprotected left main stenosis, multivessel or last remaining vessel disease. The main exclusions were: 1) acute coronary syndrome of less than 48 hours before PCI; 2) cardiogenic shock; 3) acute stoke or 4) contraindications to IABP placement e.g., due to severe peripheral arterial disease (PAD) or 5) contraindications to dual antiplatelet therapy.

Our study was prospective and randomized. Eligible patients were randomized in 1:1:1 ratio using multiple permuted blocks utilizing online tool to one of the three study groups: 1) PCI without any MCS (CTRL); 2) PCI with a standard volume IABP (STRD): 40 cc >162 cm and 34 cc <162 cm; 3) PCI with a larger volume IABP (MEGA): 50 cc >162 cm and 40 cc <162 cm. Screening failure patients were assigned to registry (REG). Before PCI, RHC with pulmonary artery catheter (PAC) and LHC with PIGTAIL catheter were done. During PCI invasive, uninterrupted blood pressure tracing was taken from independent (usually radial) arterial catheter. From PAC standard hemodynamic values were obtained including cardiac output (CO) and index (CI) by the Fick principle, cardiac power output (CPO), which was calculated as mean arterial pressure (mm Hg) times CO (l/min) divided by 451 to express value in (W), as well as pulmonary artery wedge pressure (PCWP), stroke volume (SV) and mixed venous oxygen saturation (SvO_2). LHC was done to access left ventricular systolic (LVSP) and end-diastolic pressures (LVEDP), contractility (product od pressure and time – dP/dt) and endocardial viability ratio (EVR), which is an indirect measure of the balance between oxygen supply and demand of the left ventricle [9]. To calculate EVR the area between diastolic aortic and LVEDP (diastolic pressure time index) is divided by the area under LVSP (tension time index TTI), which is illustrated in Figure 1.

We also analyzed data from IABP console set in 1:2 mode (Figure 2). On the aortic pressure curve, it can be seen, among others, augmented diastolic pressure (D) when balloon inflates and systolic unloading (B–F) i.e., the drop of systolic pressure after balloon deflation.

All interventions were done by two experienced operators aiming at achieving complete revascularization based on viability testing and optimal angiographic result implanting 2nd generation drug eluting stents (DES) and using rotational atherectomy and intravascular ultrasound as needed. Procedural success was defined as combined: residual stenosis of less than 30%, TIMI 3 flow, and no major complications. Patient received periprocedural pharmacotherapy and general care according to existing guidelines. The protocol was approved by the Jagiellonian University Ethics Committee (decision number 122.6110.63.2016) and was done in accordance with Declaration of Helsinki. Signed, written, informed consent was obtained from every patient.

Statistical analysis

We used all available data obtained from the whole cohort of patients included in the study and categorized according to final hemodynamic support implemented (per-treatment analysis). Categorical variables were presented as counts and percentages, and continuous variables were presented as mean with standard deviation or median with the first and the third quartile as appropriate. Normality was assessed using the Shapiro–Wilk test. Equality of variances was tested using the Levene test. Comparisons of continuous variables were preformed using analysis of variance

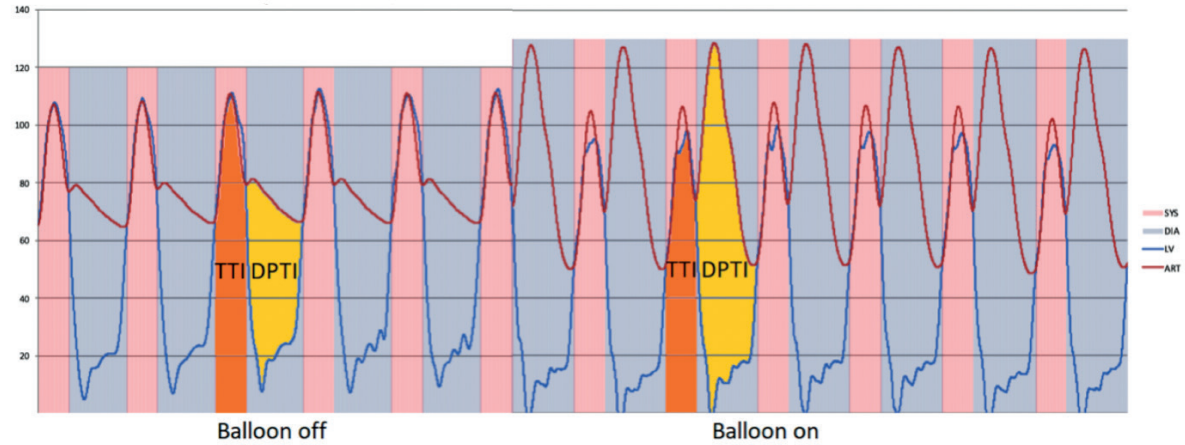

Figure 1. Calculation of EVR — in this example EVR was 0.76 off- vs. 1.71 on-support

Parameters of IABP support (1:2 mode)

Unassisted diastolic pressure (A)	mmHg
Unassisted systolic pressure (B)	mmHg
Dicrotic notch pressure (C)	mmHg
Augmented diastolic pressure (D)	mmHg
Assisted end-diastolic pressure (E)	mmHg
Assisted systolic pressure (F)	mmHg
Systolic unloading (B-F)	mmHg
Diastolic augmentation (D-A)	mmHg
Diastolic unloading (A-E)	mmHg
Deflation pressure (D-E)	mmHg

Print from the console with marked measurement points

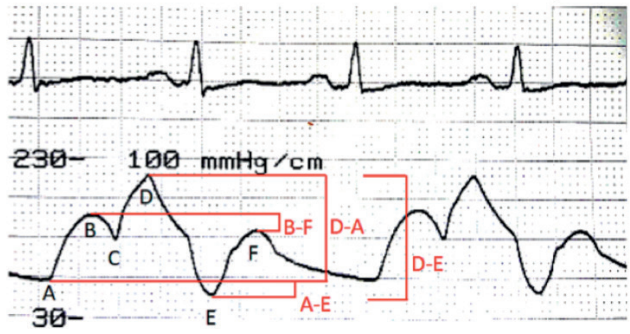

Figure 2. Hemodynamic parameters taken from the IABP console (1:2 setting)

or Kruskal–Wallis test as appropriate. *Post hoc* analysis, if necessary, was performed using Tukey's HSD or the Steel-Dwass test, as appropriate. Pearson's or Spearman's correlation coefficients were calculated, as appropriate, based on the normality of the data. Fisher's exact test or the χ^2 test were used to compare distributions of nominal variables.

Paired analysis was performed using the mixed effect models. For each analyzed variable, a mixed effect model was created with time point of measurement as well as group as fixed effects and patient ID as a random effect — which allows for the correlation between two measurements for the same patient to be taken into account. Then comparisons of patient-wise differences between time-points across groups were performed.

All tests were two-sided, and P <0.05 was assumed to indicate statistical significance. All data management and analysis activities were performed using JMP 14.2 (2019, SAS Institute Inc., Cary, NC, US) and R 3.5.3 (R Core Team [2019]).

RESULTS

In the study period we were able to screen 47 patients, 36 of which were randomized: 13 in MEGA, 14 in STDR and 9 in CTRL group. 4 patients in STDR group and 1 patient in MEGA group did not receive IABP because of severely angulated and/or calcified femoral/iliac arteries precluded device placement. 11 patients were screening failures but were treated according to the study protocol (4 of them received IABP of larger volume) and formed a REG. Ultimately, for the present study, we included all patients, randomized and from the registry and performed per-treatment analysis. Final cohort was composed of 47 subjects: 21 in CTR, 10 in STD and 16 in MEGA group, as is illustrated in a study flow chart — Supplementary material, *Figure S1*.

There were no significant baseline differences between the groups except for more frequent incidence of PAD in CTRL. The risk profile of the patients was very high with a mean EF of 32%, median Syntax Score of 38 points, median Euroscore II mortality risk of 6%, and median

Table 1. Clinical, demographic, echocardiographic, angiographic and procedural data

Variable	MEGA	STRD	CTRL	Total	*P*-value
N (%)	16 (34)	10 (21)	21 (45)	47 (100)	0.81
Demographic data:					
Age, years, mean (SD)	71.4 (8.4)	71.3 (11.5)	71.7 (10.1)	71.5 (9.7)	0.99
Male sex, n (%)	13 (81.3)	8 (80.0)	18 (85.7)	39 (82.9)	0.90
ACS, n (%)	11 (68.8)	3 (30.0)	8 (38.1)	22 (46.8)	0.08
Clinical symptoms:					
CCS class 3/4, n (%)	10 (62.5)	7 (70.0)	10 (47.6)	27 (57.5)	0.56
NYHA class 3/4, n (%)	11 (68.8)	8 (80.0)	14 (66.7)	33 (70.2)	0.16
Medical history:					
Hypertension, n (%)	16 (100.0)	10 (100.0)	20 (95.2)	46 (97.9)	0.44
Diabetes, n (%)	7 (43.8)	6 (60.0)	10 (47.6)	23 (48.9)	0.71
Smoking, n (%)	8 (53.3)	8 (80.0)	16 (76.2)	32 (69.6)	0.25
Previous MI, n (%)	8 (50.0)	6 (60.0)	13 (61.9)	27 (57.5)	0.76
Previous PCI, n (%)	5 (31.3)	4 (40.0)	7 (33.3)	16 (34.0)	0.90
Previous CABG, n (%)	2 (12.5)	1 (10.0)	2 (9.5)	5 (10.6)	0.96
Previous stroke, n (%)	2 (12.5)	0 (0.0)	6 (28.6)	8 (17.0)	0.11
Heart failure, n (%)	10 (62.5)	6 (60.0)	16 (76.2)	32 (68.1)	0.57
Atrial fibrillation, n (%)	5 (31.3)	5 (50.0)	6 (28.6)	16 (34.0)	0.48
Dyslipidemia, n (%)	13 (81.3)	6 (60.0)	15 (71.4)	34 (72.3)	0.54
CKD, n (%)	7 (43.8)	1 (10.0)	5 (23.8)	13 (27.7)	0.15
PAD, n (%)	6 (37.5)	0 (0.0)	11 (52.4)	17 (36.1)	0.004*
Echo examination:					
EF, %, mean (SD)	33 (9)	29 (11)	33 (13)	32 (11)	0.67
Significant MR, n (%)	8 (50.0)	4 (40.0)	8 (38.1)	20 (42.6)	0.78
Risk scales:					
Syntax score, median (Q1–Q3)	36.5 (29.1–49.6)	38.5 (29.6–43.0)	36.3 (27.8–45.5)	38.0 (29.0–44.5)	0.45
EuroScore II, median (Q1–Q3)	8 (4–14)	6 (2–8)	5 (4–15)	6 (3–12)	0.72
BCIS-1 JS, median (Q1–Q3)	12.0 (9.0–12.0)	12.0 (10.0–12.0)	12.0 (8.0–12.0)	12.0 (8.0–12.0)	0.24
Angiographic data:					
Left main stenosis, n (%)	11 (68.8)	6 (60.00)	15 (71.43)	32 (68.09)	0.82
CTO, n (%)	12 (75.0)	9 (90.00)	17 (80.95)	38 (80.85)	0.64
PCI ≥2 vessels, n (%)	13 (81.3)	7 (70.00)	17 (80.95)	37 (78.72)	0.76
Radiation, mGy, median (Q1–Q3)	1819 (1295–3200)	1628 (1360–3603)	2067 (1566–3072)	1947 (1331–3173)	0.93
Contrast volume, ml, mean (SD)	317 (89)	310 (94)	295 (71)	305 (81)	0.88
No. of stents, median (Q1–Q3)	2.0 (1.0–3.0)	2.0 (1.0–2.3)	2.0 (1.5–2.5)	2.0 (1.0–3.0)	0.82
Rotablation, n (%)	2 (12.5)	3 (30.0)	5 (23.8)	10 (21.3)	0.53
IVUS usage, n (%)	3 (18.8)	5 (50.0)	5 (23.8)	13 (27.7)	0.21
PCI success, n (%)	11 (68.8)	8 (80.0)	16 (76.2)	35 (74.5)	0.07

Data are presented as numbers (n) and percentages (%), mean and standard deviation (SD) or median and interquartile range (IQR: Q1–Q3)
**Post-hoc* analysis: MEGA vs. CTR $P = 0.87$; MEGA vs. STD $P = 0.012$; STD vs. CTR $P = 0.11$

Abbreviations: ACS, acute coronary syndrome; BCIS JS, British Cardiovascular Intervention Society Jeopardy Score; CABG, coronary artery bypass grafting; CCS, Canadian Cardiovascular Society; CKD, chronic kidney disease; CTO, chronic total occlusion; IVUS, intravascular ultrasound; MI, myocardial infarction; MR, mitral regurgitation; NYHA, New York Heart Association, PAD, peripheral arterial disease; PCI, percutaneous coronary intervention

BCIS-1 Jeopardy Score of 12.0. The overall success rate of PCI was 74.5%. The clinical data are presented in Table 1.

The results of hemodynamic measurements before and post-IABP placement (or after 15 min from baseline in CTRL) obtained from PAC and LHC are shown in Table 2. There was significant difference in LVSP (MEGA 112 vs. STRD 113 vs. CTRL 145 mm Hg; $P < 0.01$) and EVR values (1.97 vs. 1.68 vs. 0.82, respectively; $P < 0.01$) on-support between the groups. dP/dt value was also close to reach statistical significance. All other parameters did not differ, although CO, CI and CPO were numerically higher in MEGA than STRD or CTRL group.

Then, using paired analysis-mixed effect models, we assessed device specific change (i.e., the difference between first and second measurement) for all analyzed hemodynamic parameters. We observed significant increase of on-support CO, CI, SV, CPO, and SvO_2, as well as a decrease of dP/dt in respect to CTRL in the MEGA, but not in the STRD group. The change in EVR (increase) and in LVSP (decrease) was significant both in MEGA and STRD vs. CTRL group, but at the same time, PCWP did not changed significantly vs. CTRL either in MEGA or in STRD. Results are shown in Figure 3.

Finally, we compared balloon function parameters from the IABP console (as shown in Figure 2). We found that diastolic augmented pressure (D) was significantly greater in MEGA vs. STRD group (170.1 vs. 139.5 mm Hg; $P = 0.02$). Moreover, there was a trend towards higher di-

Table 2. The results of hemodynamic measurements before and post-IABP placement

VARIABLE	time	MEGA	STRD	CTRL	*P*-value
LVSP, mm Hg	1st	135 (29)	126 (30)	135 (28)	0.75
	2nd	113 (22)	112 (23)	145 (26)	0.003
dP/dt, mm Hg × s^{-1}	1st	1292 (426)	1079 (389)	1302 (485)	0.48
	2nd	1166 (429)	991 (418)	1389 (464)	0.09
EVR	1st	0.81 (0.16)	0.88 (0.16)	0.86 (0.16)	0.75
	2nd	1.97 (0.39)	1.68 (0.28)	0.82 (0.14)	<0.001
MAP, mm Hg	1st	88 (16)	82 (8)	85 (15)	0.53
	2nd	93 (17)	89 (10)	88 (16)	0.88
PCWP, mm Hg	1st	15.7 (9.5)	15.8 (7.6)	14.0 (4.7)	0.88
	2nd	11.9 (7.7)	11.9 (6.2)	11.7 (4.7)	0.97
MPAP, mm Hg	1st	27.6 (16.4)	24.1 (7.4)	25.6 (8.8)	0.93
	2nd	22.5 (12.5)	22.2 (7.2)	22.9 (10.1)	0.97
HR, min^{-1}	1st	74 (8)	69 (15)	72 (13)	0.31
	2nd	71 (8)	70 (19)	67 (10)	0.55
SV, ml	1st	57 (15)	63 (19)	59 (24)	0.75
	2nd	64 (12)	65 (21)	61 (18)	0.72
CO, l/min	1st	4.17 (1.04)	4.07 (0.59)	4.04 (1.4)	0.77
	2nd	4.52 (0.84)	4.24 (0.59)	3.98 (1.02)	0.17
CI, l/min/m^2	1st	2.25 (0.58)	2.11 (0.23)	2.18 (0.67)	0.73
	2nd	2.44 (0.48)	2.22 (0.36)	2.13 (0.46)	0.20
CPO, W	1st	0.82 (0.26)	0.74 (0.12)	0.80 (0.36)	0.91
	2nd	0.94 (0.27)	0.83 (0.16)	0.79 (0.29)	0.32
SvO_2, %	1st	61 (11)	63 (7)	62 (12)	0.99
	2nd	64 (8.0)	64 (8)	63 (11)	0.91

Data are presented as a mean and standard deviation (SD)
Time: 1st — baseline, 2nd — after IABP placement (MEGA or STRD) or after 15 min in CTRL

Abbreviations: CI, cardiac index; CO, cardiac output; CPO, cardiac power output; dP/dt, pressure time product; EVR, endocardial viability ratio; HR, heart rate; LHC, left heart catheterization; LVSP, left ventricle systolic pressure; MAP, mean arterial pressure; MPAP, mean pulmonary artery pressure; PAC, pulmonary artery catheter; PCWP, pulmonary artery wedge pressure; SV, stroke volume; SvO_2, mixed venous oxygen saturation

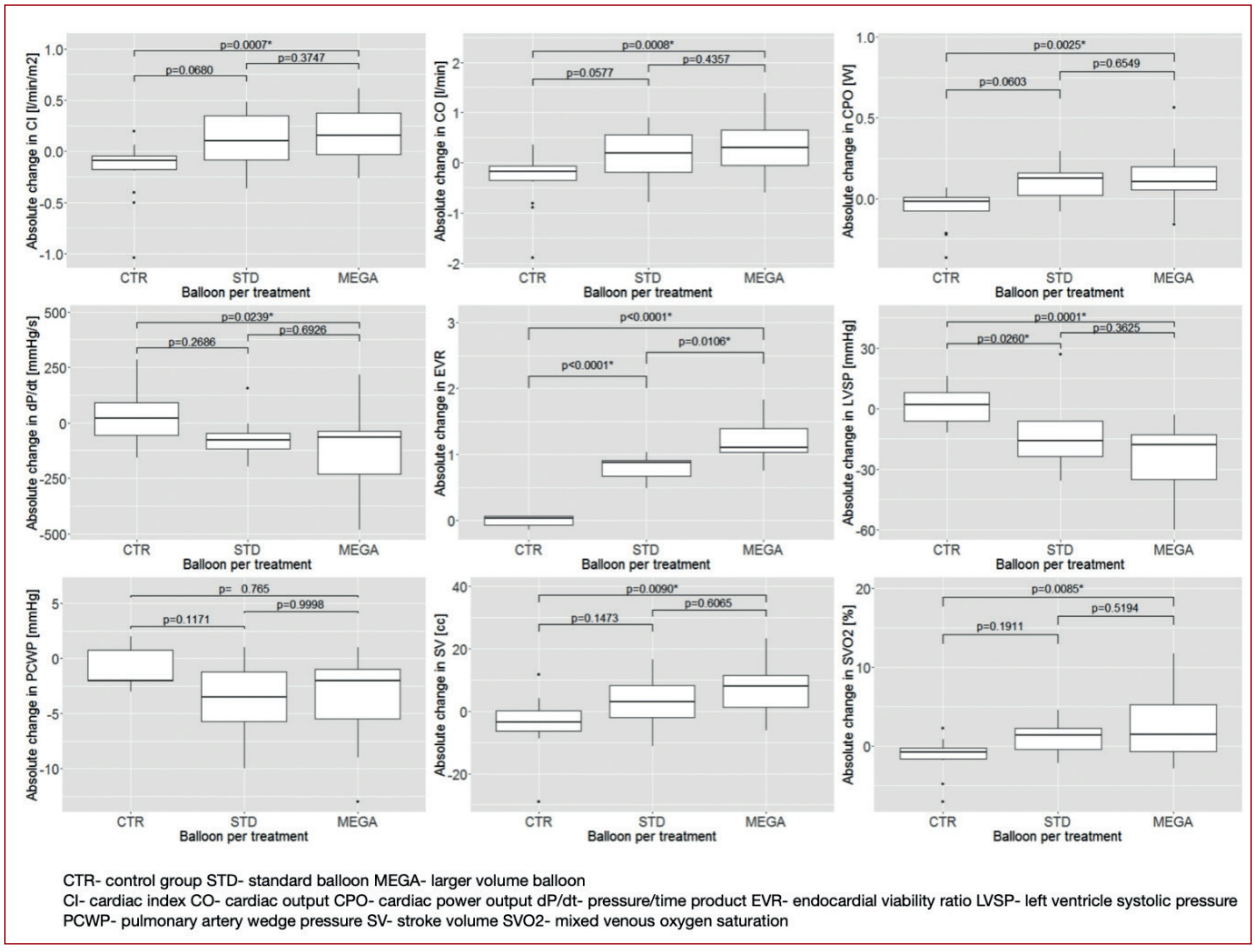

Figure 3. Device-specific change (on-support vs. off-support) of hemodynamic parameters

Table 3. The comparison of balloon function parameters between MEGA and STDR

VARIABLE, mm Hg	MEGA	STRD	*P*-value
Unassisted diastolic pressure (A)	67.14 (11.2)	62.9 (9.89)	0.35
Unassisted systolic pressure (B)	132.50 (26.94)	127.00 (27.94)	0.63
Dicrotic notch pressure (C)	105.60 (24.50)	98.60 (21.44)	0.47
Augmented diastolic pressure (D)	170.07 (36.40)	139.50 (21.16)	0.02
Assisted end-diastolic pressure (E)	56.47 (14.00)	55.90 (14.23)	0.92
Assisted systolic pressure (F)	117.53 (24.61)	113.50 (21.82)	0.68
Systolic unloading (B–F)	17.50 (8.23)	13.50 (10.22)	0.30
Diastolic augmentation (D–A)	97.21 (28.54)	76.60 (21.07)	0.07
Diastolic unloading (A–E)	8.50 (5.49)	7.00 (6.27)	0.54
Deflation pressure (D–E)	113.60 (43.98)	83.60 (24.52)	0.06

Data are presented as a mean and standard deviation (SD); units of pressure are mm Hg

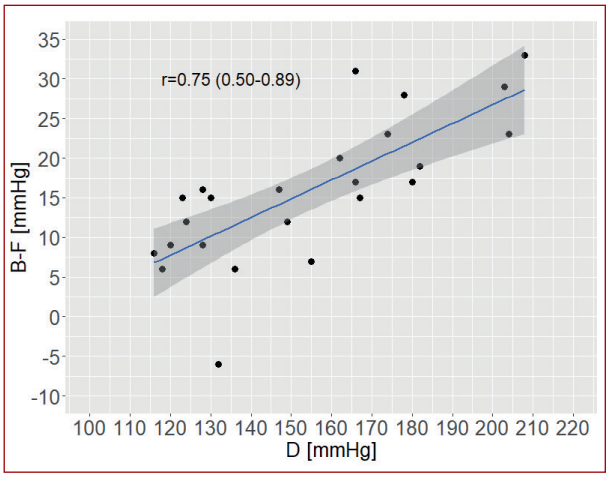

Figure 4. Correlation between diastolic augmented pressure (D) and systolic unloading (B–F)

astolic augmentation (D–A) and deflation pressure (D–E) in MEGA vs. STRD group, which may also indicate clinically significant difference (Table 3).

Additionally, we found significant positive correlation ($r = 0.75$; $P \leq 0.001$) between augmented diastolic pressure (D) with the systolic unloading (B–F), i.e., the higher was augmentation pressure the greater was drop in aortic (and left ventricular — not shown) systolic pressure — Figure 4.

There was no difference in hospital and 1-year follow up in MACE between the groups, as well as in the rate of major and minor bleeding according to Academic Research Consortium (BARC), vascular access site complication or acute renal failure — Supplementary material, *Table S1*. The causes of major bleeds in decreasing order of frequency were: large hematoma at vascular access site (7), bleeding around vascular catheter without hematoma formation (2), significant hemoglobin drop without obvious cause (2), gastrointestinal bleeding (1), coronary artery perforation with tamponade (1), alveolar hemorrhage (1) and vascular surgical intervention (1).

DISCUSSION

In our study we presented in-depth analysis of invasive hemodynamics obtained during HRPCI with or without IABP support. We found that, although majority of on-support values were not different between the groups (except for higher EVR and lower LVSP with both IABP), the change of these parameters from off- to on-support varied significantly, i.e., the measured change in CO, CI, CPO, SV, SvO_2 and dP/dt was statistically significant vs CTRL in MEGA, but not in the STRD group. Both balloons were effective in reducing LVSP and increasing EVR, but none in reducing PCWP. This implies that even very small (10 cc) additional volume of an intra-aortic balloon may have clinically meaningful effect. In fact, we have already demonstrated that IABP of larger volume type implanted electively before HRPCI was able to reduce composite hemodynamic endpoint during the procedure (although in hospital and follow-up MACE were not different) [8]. Moreover, additional analyses of pressure tracings form IABP console, demonstrated that MEGA balloon provide higher diastolic augmentation pressure than STDR one, which in turn, was significantly correlated with greater systolic unloading, meaning less workload for an already severely stressed left ventricle. Likewise, EVR was also numerically higher with the larger vs. standard balloon, which may additionally imply more favorable oxygen supply-demand ratio of the MEGA type.

In a small study done by Kapur et al. [10] the authors were also able to demonstrate better hemodynamic profile of higher volume balloon, with greater augmented diastolic blood pressure, greater systolic unloading (which were both linearly correlated), and (contrary to our results) a larger reduction of PCWP of 50 cc balloon in comparison to 40 cc in both HRPCI and shock patients. 50 cc balloon recipients had also greater (and statistically significant) increase in CO and CI [10].

On the other hand, our study showed only modest increase in CO associated with counter-pulsation, e.g., for MEGA it was on average 0.4 l/min, and for STDR just around 0.2 l/min, and no reduction of PCWP. This confirms that IABP is a very weak hemodynamic support device, and it cannot adequately support the patient if serious complications might develop during HRPCI. Accordingly, the only randomized clinical trial (BCIS-1) that tested elective IABP use for HRPCI (but only of standard volume type) did not show any benefit in terms of MACE [11], but interestingly in the

long-term follow-up there was a reduction in mortality [12]. For this reason, nowadays, more potent devices like AFP Impella are being increasingly used for CHIP patients [13–15] and are preferred by various expert consensus statements [16]. In fact, randomized [17] and observational [18] data show greater hemodynamic effect of AFP vs. IABP, but at the same time they failed to show a reduction of hard clinical endpoints. On the contrary, there is some evidence from recent large registries that use of Impella was associated with increased mortality and morbidity, including bleeding, vascular access site and neurologic complications [19, 20].

The recent work from Polish authors compared retrospectively Impella (n = 28) and IABP (n = 22) use during HRPCI. Patients qualified for Impella support had lower EF and were younger despite having similar Euroscore II. Study demonstrated similar MACE and mortality rate during median 224 days of follow-up. On the contrary the major bleeding events and vascular complications were observed more often in the AFP group probably as a consequence of larger bore access side, different modes of vascular closure and higher dose of anticoagulants [21].

Therefore, it should be emphasized that hemodynamic support *per se* is not the primary goal of MCS therapy in the setting of HRPCI. To improve the prognosis, it is necessary to achieve complete and optimal revascularization and the device should provide just enough support for the completion of the complex procedure without hemodynamic compromise that might jeopardize the final result. At the same time, the risk associated with support device should not exceed the possible benefits. Finally, the cost and complexity of given strategy must be considered.

Accordingly, there is some evidence from retrospective studies that contemporary high-risk patients may be effectively treated with PCI without any support device with a very high procedural success and low MACE rate [22]. The authors state that, contrary to current recommendations and practice, HRPCI without any MCS usage is feasible and safe in most of CHIP patients. So, lacking conclusive results from randomized trials, the strategy of unprotected HRPCI must also be considered.

We would also like to stress the importance of hemodynamic monitoring using PAC. RHC is being increasingly advocated during MCS support, esp. in the field of cardiogenic shock [23, 24]. The valuable data that can be derived from RHC could help in choosing the device that best suits the needs of the given patient. Surprisingly often, stable HRPCI patients despite low EF, may have relatively well-preserved SV, CO and CI and a low PCWP, possibly allowing for a standby/bail-out only MCS therapy. On the contrary, in the more acute setting, like acute coronary syndrome or CS, these physiologic parameters may be much more disturbed, necessitating up-front (before PCI) implantation of the support device.

Additionally, it is worth to mention that the art of managing IABP nowadays may be rather lost among interventional cardiologists. To guarantee optimal hemodynamic support it is important to observe diastolic augmentation and systolic unloading on the IABP control panel and arterial pressure tracing after device placement.

Study limitation

Our study has several limitations. It was designed as a randomized study, but due to slow recruitment process (single-center study) we were able to randomize only 36 patients in 18 months. Moreover, we observed some cross-over because of inability to insert IABP when tortuous or calcified femoral and iliac vessels were discovered during the procedure. Additionally, several patients did not meet inclusion criteria, but still were treated according to the study protocol and were included in final per-treatment analysis. Therefore, our results should be considered as exploratory and hypothesis-generating. Nonetheless, the baseline values were well balanced between the groups, except for more frequent occurrence of PAD in CTRL.

CONCLUSION

Our in-depth physiologic analysis adds important new data on hemodynamic effect on higher volume intra-aortic balloon showing that it may have more favorable hemodynamic profile than standard volume IABP and hence might be considered as a possible cheaper alternative for some CHIP patients.

Supplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

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