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Effect of gender on efficacy of preoperative intra-aortic balloon pump in high risk patients undergoing surgical coronary revascularisation

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Abstract

Background: There is no strong evidence supporting the use of preoperative intra-aortic balloon pump (IABP) in high-risk patients undergoing coronary artery bypass grafting (CABG). This issue has only been investigated in small studies which analysed the general population of patients, without focusing on specific subgroups, including gender.

Aim: We sought to determine if there is any benefit from preoperative IABP in high-risk patients undergoing CABG with the analysis of its determinants including gender.

Methods: We randomly assigned 502 high-risk patients (351 men, 151 women) to the group receiving preoperative IABP support or to the control group with no preoperative IABP. Primary end-point was a major adverse cardiac or cerebrovascular event (MACCE), defined as death from any cause, myocardial infarction, cerebrovascular accident or repeat revascularisation within 30 days post-surgery.

Results: A significant reduction of MACCE rate in patients with the preoperative IABP counterpulsation in comparison to controls was noticed in the total population of high risk patients ($p = 0.001$) and in the female subgroup ($p = 0.005$). After adjustment for baseline characteristics, the hazard ratio for MACCE was 0.7 ($p = 0.005$) in the total population; 0.6 ($p = 0.01$) for females and 0.8 ($p = 0.1$) for males.

Conclusions: There is a beneficial effect of preoperative IABP use in high-risk patients undergoing CABG, particularly in women and patients with co-morbidities (diabetes, obesity, and peripheral vascular disease).

Key words: intra-aortic balloon pump counterpulsation, cardiac surgery, coronary artery bypass grafting, mechanical support, preoperative risk

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INTRODUCTION

The intra-aortic balloon pump (IABP) is the most commonly used mechanical assist device for supporting haemodynamic function of the heart. The well accepted indications for IABP use include low cardiac output in a setting of cardiogenic shock after myocardial infarction (MI), bridge to heart transplant or weaning of the cardiopulmonary bypass [1, 2]. The optimal timing and further improvement of the outcomes led to an expansion of the indications for IABP support towards ongoing and progressing ischaemia contributing to the increase of preoperative IABP use [3, 4]. There are multiple preoperative risk factors which help to identify high risk patients who are prone to develop haemodynamic collapse and irreversible heart damage and who can particularly benefit from preoperative IABP insertion [5, 6]. However, this benefit is still accompanied by a risk of potential complications associated with IABP support despite many refinements in catheter technology (smaller, sheathless catheters) [7, 8]. Indications for the IABP use and the outcome of the IABP-supported patients were demonstrated in numerous non-randomised clinical trials, retrospective studies and observational series [4, 5] but there is still a paucity of convincing data from

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randomised controlled trials. Analysing subgroups of patients in relation to their gender appears to be interesting from clinical point of view. Women have smaller body surface area and smaller coronary vessels which are recognised as risk factors predisposing to perioperative morbidity, which may also be related to the increased number of vascular complications associated with IABP [5, 9, 10].

The authors of the recently published metaanalysis of trials on preoperative IABP in patients undergoing coronary artery bypass grafting (CABG) indicated that a well designed randomised study with a sample size of at least 330 patients is needed to assess the effectiveness of this treatment strategy [11]. We performed a single-center prospective randomised controlled study to determine if there is any benefit from preoperative IABP counterpulsation in high-risk patients undergoing surgical coronary revascularisation with the subsequent assessment of its determinants including gender.

METHODS

This randomised clinical controlled trial was conducted in a single cardiac surgery centre and included high-risk CABG patients admitted between 2004 and 2008. The study was approved by the local Ethics Committee and was conducted in accordance with the ethical principles of the Helsinki Declaration regarding investigation in humans. All patients gave their written informed consent.

Study population

Over a 60-month enrollment period, 621 high-risk patients qualified to CABG were screened. High risk was defined using two separate risk scoring systems and was recognised in patients who met at least two of the following criteria: left ventricular ejection fraction (LVEF) < 35% (calculated from the preoperative echographic study), unstable angina (CCS class IV), left main (LM) stem stenosis of at least 80% or redo CABG, and simultaneously had a EuroSCORE of plus 6. The flow chart of the participating patients, including exclusion criteria in shown as Figure 1.

Randomization and study treatment

There were 502 patients fulfilling the eligibility criteria (351 men and 151 women). Randomisation was based on the block method using randomly varying block sizes and was stratified by gender (in a 1:1 ratio). It was performed by an investigator who was blinded for the clinical status of the patients. The stratification procedure was conducted to assess the impact of gender on postoperative major adverse cardiac or cerebrovascular event (MACCE) rate. Male subpopulation was randomly assigned to group M1 who received preoperative IABP support (study group), and group M2 (controls) who did not receive preoperative IABP. A similar procedure was carried out on the female population; resulting in creation of groups F1 (study group) and F2 (control group) respectively. The between-group crossover consisted of 116 patients, 78 males and 38 females, who received IABP postoperatively (Fig. 1).

All in-hospital procedures performed in studied patients were standardised. All CABG procedures were performed on-pump.

IABP management

In most cases (78%) percutaneous access for intra-aortic balloon catheter (8.0 F, 40 mL Datascope Corp, Fairfield, NJ) was used, connected to a Datascope portable console. Pa-

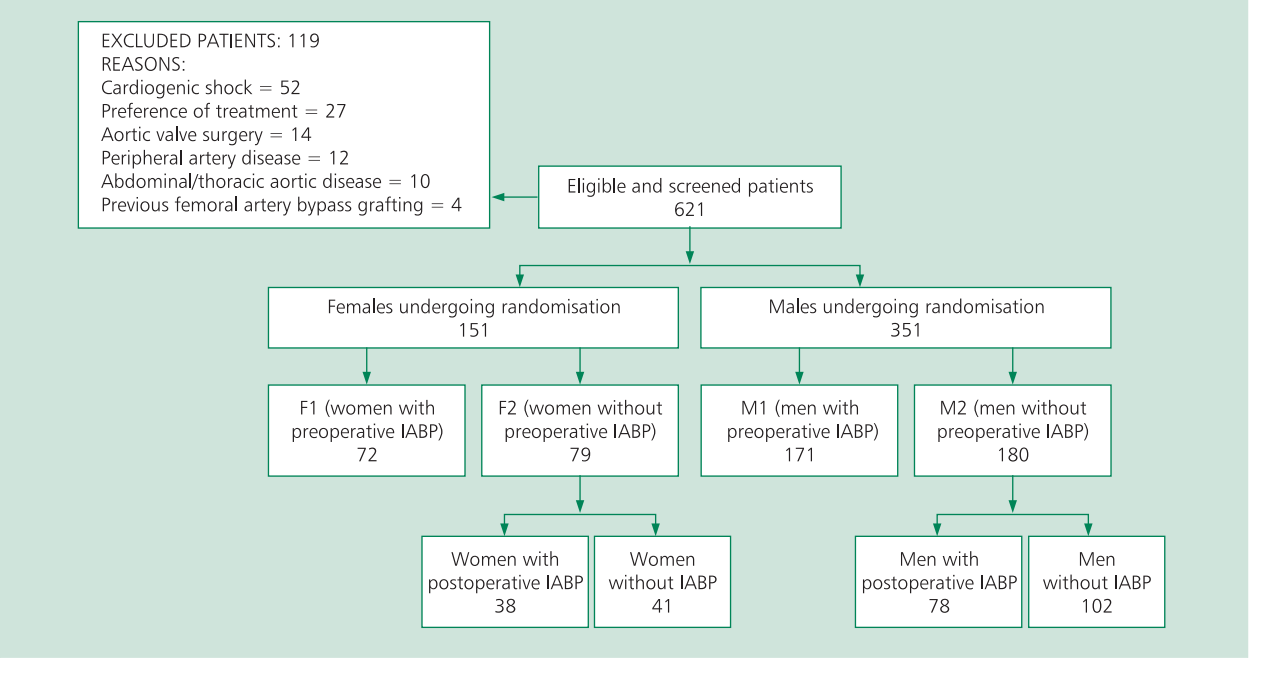

Figure 1. Patients' flow chart; IABP — intra-aortic balloon pump

tients with adjusted body mass index ≤ 22 kg/m^2 had catheters of smaller diameter (7.5 F). The surgical visualisation of femoral artery (22%) was required when placing of guide wire was troublesome (documented peripheral vascular disease (PVD), during cardiopulmonary bypass and in obese patients). The IABP was inserted intra- and post-operatively when haemodynamic stability could not be maintained — cardiac index lower than 1.8 L/m^2 despite inotropic support (dopamine 10 μg/kg/min, adrenaline 0.1 μg/kg/min, amrinone or combination). Adequate anticoagulation was achieved with 2 × 0.6 mL subcutaneous injections of nadroparine before (in preoperative IABP) and 24 hours after operation (in all cases). The weaning from IABP support took place once cardiac index was higher than 1.8 L/m^2 with mild inotropic support (dopamine 5 μg/kg/min, amrinone or combination). Preoperative insertion of IABP was performed in all patients from groups M1 and F1 in the operative room, one hour prior to surgery.

Definitions

The criteria for diagnosing peri-operative MI were based on the recent guidelines [12] as either a new Q-wave in two or more leads or a new left bundle branch block in postoperative standard ECG together with the serum concentration of troponin I > 10 ng/mL or the serum concentration of troponin I > 13 ng/mL without a new Q-wave in ECG, but with decreased contractility in echocardiography. Taking into account preoperative high prevalence of ischaemia we arbitrarily set the troponin threshold on the basis of its true distribution as values exceeding 95 percentile level.

Study endpoints

Primary end-point of the study was the postoperative incidence of MACCE defined as death from any cause, MI, cerebrovascular accident including transient ischaemic attack or repeat revascularisation within 30 days post-surgery.

Statistical analysis

To determine the efficacy of IABP in the randomised patients, we calculated that with 90% power, using a two-sided test and a significance level of 5% a number of 428 patients are needed to detect an absolute difference in MACCE incidence of 5% (i.e. between 20 and 25%). The statistical analysis was conducted with the use of Statistica 7.1 (Tulsa, OK, USA) software procedures. All end points were analysed according to the intention-to-treat principle; subjects who crossed over were analysed in their original treatment assignment. Quantitative data are expressed as means and standard deviations, and qualitative variables are presented as crude numbers and percentages. Between-group differences were assessed using student t-test or U Mann-Whitney test for quantitative data, and χ^2 or Fisher's exact test for qualitative data. The log-rank statistic, stratified according to gender, was used to compare MACCE rates between groups. The incidence of primary endpoint was evaluated with a Cox proportional-hazards model, adjusting for baseline characteristics. A two-sided probability of < 0.05 was considered statistically significant.

RESULTS

Baseline characteristics

The group of patients assigned to preoperative IABP insertion (study group, n = 243) consisted of 171 males (M1) and 72 females (F1). The group of those without preoperative IABP support (control group, n = 259) comprised 180 men (M2) and 79 women (F2). Despite a complete revascularisation, 78 (43.6%) men and 38 (48.7%) women who were primarily randomised to control group required IABP insertion postoperatively (Fig. 1). The male (M1 + M2) and female (F1 + F2) populations statistically significantly differed according to age, obesity and LM stenosis occurrence, CCS class 4 distribution and EuroSCORE (Table 1). No differences were found in terms of demographic and clinical features between the study and control groups, even after gender stratification (F1 *vs* F2 and M1 *vs* M2; Table 2). There were significant differences in the control group between men and women with regard to age, CCS class, incidence of obesity and diabetes, EuroSCORE and nitroglycerin infusion. In the study group significant differences were found with regard to age, LM stenosis, obesity, EuroSCORE and nitroglycerin infusion (Table 2).

Primary outcome

A marked benefit of preoperative use of IABP was found both in males and females. The MACCE incidence rate in the study group was 30.9%; in men (M1) — 33.9% and in women (F1) — 23.6%. In the control group, the MACCE incidence was 44.8%; 44.4% in the male group (M2) and 45.6% in the female group (F2). A significant reduction of MACCE rate in patients with IABP inserted preoperatively in comparison to controls was noticed in the general population (absolute difference of 13.8%, p = 0.001), and in the female subgroup (absolute difference of 22%, p = 0.005). In the male subgroup that difference remained statistically non-significant, however a trend towards lower incidence of MACCE was also observed (absolute difference of 10.5%, p = 0.05). The comparison of MACCE rates between groups is presented in Figures 2A, B and 3.

The adjusted hazard ratio for MACCE incidence was 0.7 (p = 0.005) in the total population. The predictors of outcome are summarised in Table 3 and Figure 4. In gender strata, the hazard ratio in the female group was 0.6 (p = 0.01) and for males it was 0.8 (p = 0.1). The only statistically significant predictor of outcome was age, both for men (p = 0.04) and women (p = 0.03).

Secondary outcomes

According to operative details, there were no gender- or group-based differences concerning the number of distal anastomoses and cardiopulmonary bypass time (Table 4). Postoperative outcomes are summarised in Table 5. Patients with

Table 1. Preoperative profile of the enrolled patients

Variable	Women (F1 + F2) (n = 151)	Men (M1 + M2) (n = 351)	P (men *vs* women)
Age [years]	68.4 ± 11.0	65.3 ± 7.1	0.006
LVEF [%]	37.2 ± 11.8	38.0 ± 12.9	0.4
LM	116 (76.8)	301 (85.8)	0.01
CCS 4	78 (51.6)	259 (73.8)	< 0.001
Reoperation	6 (4.0)	9 (2.6)	0.4
Hypertension	73 (48.3)	170 (48.4)	0.99
Obesity	31 (20.5)	24 (6.8)	0.001
DM	29 (19.2)	45 (12.8)	0.06
PVD	44 (29.1)	87 (24.8)	0.3
preCVA	30 (19.9)	59 (16.8)	0.4
preMI	67 (44.4)	164 (46.7)	0.8
prePCI	13 (8.6)	36 (10.2)	0.6
EuroSCORE (points)	7.36 ± 4.1	6.29 ± 3.4	0.025
NTG i.v.	133 (88.1)	307 (87.5)	0.9

Quantitative data is presented as mean ± SD and qualitative data as crude numbers and percentages (in brackets); CCS 4 — Canadian Cardiovascular Society class equal 4; DM — diabetes mellitus; LVEF — left ventricular ejection fraction; LM — left main stem stenosis; NTG i.v. — intravenous infusion of nitroglycerine; Obesity — body mass index ≥ 30 kg/m^2; preCVA — history of cerebrovascular accident; preMI — history of myocardial infarction; prePCI — history of percutaneous coronary intervention; PVD — peripheral vascular disease

Table 2. Preoperative differences in men and women in relation to the treatment group

	Women with pre-operative IABP (F1) (n = 72)	Women without pre-operative IABP (F2) (n = 79)	P F1 *vs* F2	Men with pre-operative IABP (M1) (n = 171)	Men without pre-operative IABP (M2) (n = 180)	P M1 *vs* M2	P F1 *vs* M1 F2 *vs* M2
Age	66.81 ± 9.17	67.5 ± 10.36	0.5	64.56 ± 7.37	64.28 ± 8.22	0.85	0.05 0.008
LVEF	37.12 ± 12.15	36.88 ± 11.81	0.88	37.03 ± 13.53	36.34 ± 9.07	0.55	0.9 0.9
LM	55 (76.4)	61 (77.2)	0.92	144 (84.2)	157 (87.2)	0.79	0.2 0.04
CCS 4	40 (55.5)	38 (48.1)	0.64	70 (40.9)	89 (49.4)	0.31	0.03 0.8
Reoperation	4 (5.55)	2 (2.5)	0.63	5 (2.9)	4 (2.2)	0.95	0.3 0.9
Hypertension	38 (52.8)	35 (44.3)	0.57	72 (42.1)	98 (54.4)	0.16	0.1 0.1
Obesity	14 (19.4)	17 (21.5)	0.77	10 (5.8)	14 (7.8)	0.49	0.001 0.001
DM	9 (12.5)	20 (25.3)	0.09	45 (26.3)	40 (22.2)	0.77	0.02 0.6
PVD	20 (27.8)	24 (30.4)	0.77	36 (21.0)	51 (28.3)	0.21	0.2 0.7
preCVA	11 (15.3)	19 (24.0)	0.25	26 (15.2)	33 (18.3)	0.49	0.9 0.3
preMI	27 (37.5)	40 (50.6)	0.29	80 (46.8)	84 (46.7)	0.98	0.2 0.5
prePCI	7 (9.7)	6 (7.6)	0.69	15 (8.8)	21 (11.7)	0.41	0.8 0.3
EuroSCORE	7.4 ± 1.83	7.28 ± 1.17	0.66	6.15 ± 1.68	6.36 ± 1.37	0.59	0.001 0.001
NTG i.v.	60 (83.3)	73 (92.4)	0.63	161 (94.2)	146 (81.1)	0.34	0.007 0.02

Quantitative data is presented as mean ± SD and qualitative data as crude numbers and percentages (in brackets); IABP — intra-aortic baloon pump; rest abbreviations as in Table 1

Table 3. Multivariate analysis for MACCE incidence in the total high risk population

Variable	HR	95% CI	P
Age (for a 10-year increase)	1.04	1.01–1.08	0.03
Gender (0 = female/1 = male)	0.89	0.59–0.91	0.01
preMI (0 = NO/1 = YES)	1.01	0.89–1.13	0.27
prePCI (0 = NO/1 = YES)	0.95	0.62–1.22	0.36
LVEF (< 35% *vs* ≥ 35%)	1.03	0.86–1.38	0.65
Hypertension (0 = NO/1 = YES)	1.16	0.57–1.56	0.26
Obesity (0 = NO/1 = YES)	1.25	0.97–1.49	0.08
DM (0 = NO/1 = YES)	0.94	0.55–1.41	0.44
PVD (0 = NO/1 = YES)	1.41	1.07–1.48	0.03
EuroSCORE (for a 1-point increase)	1.09	0.98–1.1	0.07
Female gender and group interaction	1.11	0.77–1.45	0.68

Hazard ratios (HR) with their statistical significance are shown; in case of multicollinearity the variables of low importance were excluded; CI — confidence interval; rest abbreviations as in Table 1

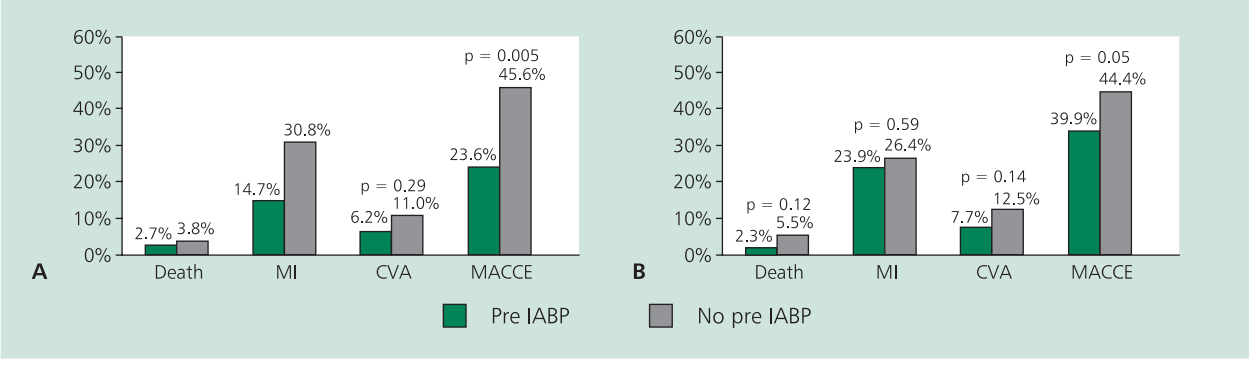

Figure 2. Cardiac or cerebrovascular event (MACCE) rates in the female (**A**) and male (**B**) subgroup; IABP — intra-aortic balloon pump; MI — myocardial infarction; CVA — cerebrovascular accident

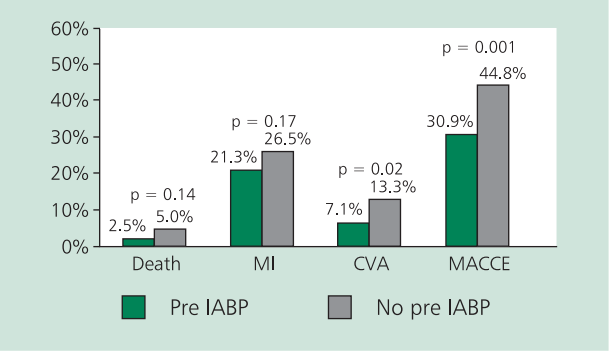

Figure 3. MACCE rates in the whole population of studied patients; abbreviations as in Figure 2

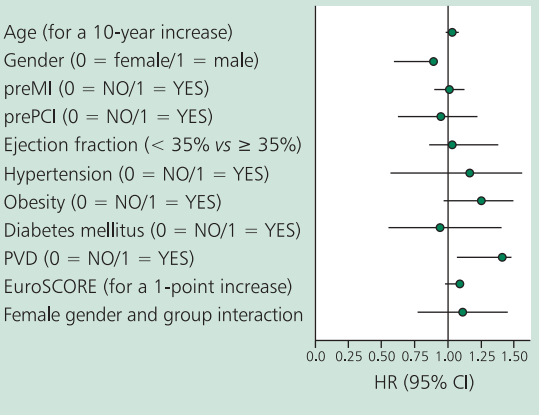

Figure 4. Forest plot for MACCE incidence by categories of risk factors; abbreviations as in Table 1

Table 4. Operative characteristics of the groups

Operative data*	Women		Men	
	Study group (F1)	Control group (F2)	Study group (M1)	Control group (M2)
Mean number of distal anastomoses	3.15 ± 0.34	3.25 ± 0.59	3.66 ± 0.75	3.28 ± 0.58
Mean CPB time [min]	101 ± 27	111 ± 19	96 ± 33	109 ± 29

Variables are presented as means ± SD; *between-group comparisons were not statistically significant; CPB — cardiopulmonary bypass; M1 — men with IABP; M2 — men without preoperative IABP; F1 — women with preoperative IABP; F2 — women without preoperative IABP

Table 5. Postoperative outcomes

Variable	Women			Men		
	Study group (F1)	Control group (F2)	P	Study group (M1)	Control group (M2)	P
Inotropic support [%]*	26.5	34.4	0.29	25.2	33.5	0.09
ICU stay [days]	3.3 ± 0.2	4.5 ± 2.1	< 0.01	3.6 ± 0.6	4.6 ± 2.7	< 0.01
Length of hospital stay [days]	8.4 ± 2.6	10.2 ± 3.4	< 0.01	9.1 ± 2.8	9.5 ± 2.8	0.18
Incidence of arrythmias [%]	23.3	32.3	0.22	26.8	33.1	0.20
Wound infection [%]	2.3	2.9	0.82	2.5	2.8	0.86
Renal failure [%]	2.2	3.4	0.66	2.7	3.2	0.78

Variables are presented as means ± SD or percents; *more than one inotropic agent; ICU — intensive care unit; rest abbreviations as in Table 4

IABP support had shorter intensive care unit stay compared with those from the control group ($p < 0.01$ for males and females).

DISCUSSION

Importance of gender influence

The impact of gender on the postoperative outcomes after surgical revascularisation as well as the influence of preoperative IABP on the results of CABG in the general population of high-risk patients were widely documented in many investigations [5, 10, 11, 13, 14]. The incidence of complications associated with IABP is known to be higher in females, older patients, and those with PVD but the impact of gender on the efficacy of preoperative IABP has not been studied [15]. One could expect that early institution of IABP support in high-risk patients undergoing CABG is safer and more efficacious than after the onset of haemodynamic collapse. Unfortunately, the use of preoperative IABP in the real world still remains highly variable as there is a lack of consensus according to the criteria for institution of early IABP support, and this decision is in most cases discretionary [16, 17]. There are no published studies concerning the influence of gender on the efficacy of preoperative IABP support in high risk patients undergoing CABG and our randomised investigation is the first in this field.

This study confirmed the findings of studies that showed that gender is a typical example of a risk factor, which by itself is not regarded as a predictor of outcome but is associated with particular co-morbid conditions — different patient profiles in male and female population [5, 10, 18]. The prevalence of such variables as: more frequent emergency operation, advanced age, PVD, obesity and less redo surgery in female population is rather stable and can be treated as a combined risk factor inherited to women [5, 10, 18, 19]. There is also emerging evidence that women may be more susceptible than men to microcirculatory endothelial dysfunction, and the use of IABP, with release of endogenous nitric oxide, may preferentially benefit the female population of high risk patients [20].

Risk assessment

The necessity of intra- and postoperative IABP insertion occurred in 43.6% and 48.7% of patients from the control groups M2 and F2, respectively. This percentage may seem relatively high but is lower comparing to other investigations. In the study performed by Christenson et al. [14], 77% of the patients from control group finally required IABP insertion in the operating room, and the overall hospital mortality rate in controls was 20%. Indeed, the authors admited that their study group can be regarded as requiring salvage operation (50 out of 60 patients had preoperative LVEF < 0.26) [14]. We believe that the benefit from preoperative IABP in such a population is well established [17, 21, 22]. In our study, we concentrated on the efficacy of preoperative IABP in patients with ongoing, acute ischaemia (consistent with the trends in IABP use), and tried to reduce the impact of confounding

factors, such as deteriorated preoperative LV function. For that reason we set the LVEF inclusion criterion at < 0.35 (76% of patients had LVEF > 30%).

For practical reasons we started the preoperative IABP support one hour prior to surgery, in the operating room, as it was shown that the timing of IABP insertion has no significance [14].

Numerous studies were performed concerning the impact of gender on the outcome of coronary artery bypass surgery [5,10, 18, 22]. It was shown that women, compared to men, have higher morbidity and mortality, especially in the peri-operative period. Female patients undergoing CABG are older, have smaller body surface area, and more frequently require urgent surgical revascularisation in comparison to their male counterparts. There is also a significantly higher incidence of morbid obesity and PVD in the population of female coronary patients [5, 10, 18, 19]. All these issues are crucial in the decision making process concerning the preoperative insertion of IABP.

Limitations of the study

Several potential limitations of the study should be mentioned. First, only small randomised trials have been previously performed on IABP insertion in high-risk patients and the sample size calculation was based on assumptions and indirect literature data. We found that the efficacy of IABP counterpulsation was significantly different in females (absolute difference in MACCE incidence of 22%) and males (difference of 10.5%). So, the sample size determination is supposed to be performed separately for women and men. Second, we assessed in-hospital (or 30-day) MACCE incidence but we made no attempt to investigate the long-term effects. It seems reasonable to extend the study into at least a six-month period to evaluate the efficacy of IABP counterpulastion more precisely. Third, more than 40% of randomised subjects crossed over from the control to study group. It may alter the results of intention-to-treat analysis markedly (in total 249 men and 110 women had IABP inserted perioperatively, in fact). However, we decided not to perform the analysis on the per-protocol population because it would had only strengthened the results.

CONCLUSIONS

Our prospective randomised study showed a clear benefit from preoperative IABP use, which was influenced by gender of participants (more evident in females) and several co-morbidities (eg. diabetes, LM disease, obesity, EuroSCORE and PVD). The recently published guidelines for cardiovascular disease prevention in women reflect the need for revision of existing standards for management of coronary artery disease [23]. Our investigation sheds light on one surgical aspect of this complex problem. Further studies in this field are needed to further define optimal treatment strategies based on gender.

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Wpływ płci na skuteczność przedoperacyjnego zastosowania kontrapulsacji wewnątrzaortalnej u chorych wysokiego ryzyka poddawanych rewaskularyzacji chirurgicznej

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Streszczenie

Wstęp: Nie ma jak dotąd jednoznacznie silnych dowodów przemawiających za korzyścią przedoperacyjnego zastosowania kontrapulsacji wewnątrzaortalnej (IABP) u chorych wysokiego ryzyka poddawanych operacji pomostowania tętnic wieńcowych (CABG). Z kolei chorzy z wysokim ryzykiem przedoperacyjnym stanowią coraz większą grupę pacjentów kierowanych na operację, zwłaszcza w trybie pilnym lub natychmiastowym. Za wzrost ryzyka występowania powikłań, w tym zgonu, odpowiadają przede wszystkim: wiek pacjenta, znaczne upośledzenie funkcji serca oraz obciążenie dodatkowymi chorobami współistniejącymi, zwłaszcza cukrzycą, miażdżycą tętnic obwodowych czy POChP. Zagadnienie to poruszano w badaniach obserwacyjnych i randomizowanych obejmujących stosunkowo nieliczną populację. Ponadto nigdy nie oceniano, czy płeć pacjentów poddawanych CABG wpływa na otrzymane rezultaty.

Cel: Celem niniejszej pracy była ocena korzyści wynikających z przedoperacyjnego zastosowania wspomagania mechanicznego stanu hemodynamicznego, z wykorzystaniem IABP, u chorych z dużym ryzkiem przedoperacyjnym, poddawanych CABG. Dodatkowo oceniano występowanie różnic w zakresie skuteczności przedoperacyjnego zastosowania IABP między kobietami i mężczyznami.

Metody: W modelu randomizowanego badania kliniczno-kontrolnego do próby włączono 502 pacjentów wysokiego ryzyka (351 M, 151 K), których przyporządkowano do grupy badanej (z przedoperacyjnym IABP) i grupy kontrolnej (brak IABP przed operacją) w stosunku 1:1, z uwzględnieniem płci. Okres rekrutacji wynosił 60 miesięcy. Do badania włączano kolejnych chorych, kierowanych na CABG. Kryteria wyłączenia obejmowały: obecność wstrząsu kardiogennego przed operacją (n = 52), brak świadomej zgody na udział w badaniu (n = 0), preferencje chorego lub chirurga odnośnie do leczenia IABP (n = 27), krwawienie wewnętrzne lub skaza krwotoczna (n = 0), współistniejąca istotna hemodynamicznie wada zastawki aortalnej (n = 14), choroby naczyń biodrowo-udowych lub aorty brzusznej (n = 22), obecność jakichkolwiek objawów ostrego niedokrwienia kończyn dolnych (n = 0) oraz przebyta operacja pomostowania naczyń udowych (n = 4). Ostatecznie badane grupy tworzyły: grupa badana — 243 osoby (171 M, 72 K) oraz grupa kontrolna — 259 osób (180 M, 79 K). Wysokie ryzyko definiowano jako obecność co najmniej 2 z następujących kryteriów: EF < 35% i/lub niestabilna dławica piersiowa (CCS IV) i/lub krytyczne (> 80%) zwężenie pnia lewej tętnicy wieńcowej i/lub reoperacja, oraz (dla każdego pacjenta) EuroSCORE ≥ 6 pkt. Pierwszorzędowy punkt końcowy obejmował występowanie MACCE w okresie pobytu w szpitalnego lub 30 dni po operacji; MACCE definiowane było jako obecność: zgonu z jakiejkolwiek przyczyny, zawału serca, zdarzenia naczyniowo-mózgowego lub konieczności powtórnej rewaskularyzacji.

Wyniki: Pierwszorzędowy punkt końcowy (MACCE) stwierdzono u 30,9% osób z grupy badanej (33,9% M, 23,6% K). W grupie kontrolnej MACCE wystąpił u 44,8% chorych (44,4% M, 45,6% K). Zaobserwowano statystycznie znamienną redukcję ryzyka występowania MACCE u chorych z grupy badanej, co było widoczne wśród wszystkich badanych (bezwzględna redukcja ryzyka — BRR 13,8%; p = 0,001), jak i w populacji kobiet (BRR 22%; p = 0,005). U mężczyzn efekt ten, choć widoczny (BRR 10,5%), okazał się nieistotny statystycznie (p = 0,05). Po uwzględnieniu wpływu czynników potencjalnie zakłócających (wiek, przebyty zawał, przebyte PCI, EF, nadciśnienie tętnicze, otyłość, cukrzyca, choroba naczyń obwodowych, EuroSCORE), hazard względny występowania MACCE w wyniku zastosowania CABG wynosił 0,7 w całej populacji (p = 0,005), 0,6 (p = 0,01) wśród kobiet 0,8 (p = 0,1) i wśród mężczyzn.

Wnioski: Zastosowanie IABP u chorych wysokiego ryzyka poddawanych CABG jest korzystne, zwłaszcza w populacji kobiet i u pacjentów z chorobami współistniejącymi (cukrzycą, otyłością, miażdżycą naczyń obwodowych).

Słowa kluczowe: kontrapulsacja wewnątrzaortalna, kardiochirurgia, pomostowanie tętnic wieńcowych, wspomaganie mechaniczne, ryzyko przedoperacyjne

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