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PROGNOSTIC VALUE OF TROPONIN I AFTER CORONARY ARTERY BYPASS GRAFTING (AMIRI-CABG STUDY)

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In 2017, the European Society of Cardiology outlined the importance of the problem of diagnosing myocardial ischemia-reperfusion injury following coronary artery bypass grafting. Myocardial injury can be accompanied by a critical decline in the cardiac index and an increase in cardiac troponin I plasma levels. The prognostic value troponin I elevation after coronary artery bypass grafting is poorly understood. **Objective:** to determine the prognostic value of troponin I plasma levels in relation to a fall in the cardiac index after coronary artery bypass grafting (CABG). **Task:** To determine the probability the cardiac index falling below 2.2 for troponin I levels in the first hours, and on days 1, 2, 3, 4 after CABG. **Materials and methods.** The single-center, non-randomized prospective study, running from 2016 to 2019, included 336 patients admitted for elective surgical treatment of coronary artery disease. The CABG patients were divided into three observation groups: off-pump (n = 175), on-pump (n = 128), and pump-assisted (n = 33). Troponin I levels were measured in the first hours, and on days 1, 2, 3, 4 after surgery using the Pathfast Compact immunoassay analyzer. Cardiac index was measured by invasive method. **Results.** In patients with a cardiac index higher than 2.2, troponin I level did not exceed 0.5 ng/mL in the off-pump group, 6 ng/mL in the on-pump group, and 3.5 ng/mL in the pump-assisted group. Patients with cardiac index lower than 2.2 have comparable troponin I levels in all groups – 21 ng/mL. Troponin I thresholds on day 1 after surgery, which, when exceeded, was associated with the likelihood of the cardiac index falling below 2.2, was 3.78 ng/mL in the off-pump group, 9.67 ng/mL in the on-pump group and 17.06 ng/mL in the pump-assisted group. **Conclusion.** After off-pump CABG, clinically significant myocardial injury should be expected at lower troponin I levels (3.78 ng/mL) than after on-pump CABG (9.67 ng/mL) and pump-assisted CABG (14.7 ng/mL).

Keywords: beating coronary artery bypass grafting, off-pump, on-pump, pump-assisted, ischemia-reperfusion, myocardial injury, troponin I, troponin I prognostic value.

INTRODUCTION

CABG surgery is a recognized and effective treatment for coronary heart disease in multivessel coronary artery disease. Despite the effectiveness and widespread use of CABG, myocardial ischemia-reperfusion injury associated with coronary artery surgery remains an unresolved problem [1, 2]. For instance, it is reported that 30-day mortality after a CABG surgery ranges from 1 to 3% despite advances in medical technology [3]. Existing methods of cardioprotection, such as cardioplegia, do not always provide sufficient myocardial protection [2]. A solution to this problem is being sought in different directions, e.g., development of more advanced cardioplegic solutions [4–8]. Another possible approach may be off-pump CABG [9]. However, the risk of incomplete revascularization has been reported in off-pump CABG operations [10]. The possibility of stimulating myocardial regeneration with the help of cell therapy, which can level out the regular ischemia-reperfusion injury caused by surgery, is being considered [11–14]. The possibility of myocardial ischemic preconditioning, which should reduce myocardial injury area has been studied [15]. Another approach may consist of timely diagnosis of the severity of perioperative myocardial ischemia-reperfusion injury during a CABG surgery [16]. Timely and accurate diagnosis of ischemia-reperfusion injury after a CABG surgery and an accurate assessment of its severity and clinical significance remain unresolved challenges [16]. Myocardial ischemia-reperfusion injury after a CABG surgery can be accompanied by a significantly decreased cardiac index (CI) and death, and therefore is of great clinical importance [16]. Rapid diagnosis of the severity of perioperative myocardial ischemia-reperfusion injury is a relevant approach. A working group of the European Society of Cardiology distinguishes perioperative myocardial injury and type 5 myocardial infarction [16]. Criteria for the diagnosis of type 5 myocardial infarction have been proposed, which include an elevation of cardiac troponin values of more than 10 times the 99th percentile upper reference limit

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value during the first 48 hours following CABG surgery in patients with normal preoperative cardiac troponin levels together with either a new Q wave and/or newly detected left bundle branch block by electrocardiogram (ECG) and/or angiographic documented new occlusion of the coronary artery and/or shunt and/or newly detected new areas of myocardial death by imaging and/or new areas of myocardial kinetics disturbance [16]. It is reported that the upper reference limit value for the increase in cardiac troponin differs depending on the manufacturer of the diagnostic kit and each clinic should determine its own threshold cardiac troponin level; available data are contradictory [16]. Thus, clarification of the predictive value of an increase in cardiac troponin levels associated with increased risk of a clinically significant decrease in CI may improve CABG outcomes.

Objective: to determine the prognostic value of troponin I plasma levels in relation to a fall in CI following a CABG surgery.

Task: to determine the probability of the CI falling below 2.2 for troponin I levels in the first hours, at days 1, 2, 3, 4 after coronary bypass surgery.

MATERIALS AND METHODS

The study included patients with coronary heart disease admitted at the Pavlov First St. Petersburg State Medical University in St. Petersburg for planned surgical treatment in the period from 2016 to 2019. Inclusion criteria for the study included presence of ischemic heart disease (exertional angina pectoris functional class 3–4) with proven multivessel coronary artery disease, patient's consent. Exclusion criteria: patient refusal, presence of heart valve pathology, acute coronary syndrome.

Of the patients with coronary heart disease admitted at the Research Institute of Surgery and Emergency Medicine, Pavlov First St. Petersburg State Medical University from 2016 to 2019, 336 people who met the inclusion criteria were included in the study.

Study type: the prospective non-randomized, single-center study approved by the local ethics committee and confirmed by the Academic Council of Pavlov First St. Petersburg State Medical University is registered in the international register of clinical trials U.S. National Library of Medicine, ClinicalTrials.gov Identifier: NCT03050489 "Assessment of myocardial ischemic-reperfusion injury during off- and on-pump CABG (AMIRI-CABG)".

The patients were divided into the following observation groups: off-pump CABG (n = 175), on-pump CABG (with aortic clamping, n = 128), pump-assisted CABG (without aortic clamping, n = 33). On-pump CABG surgeries were performed routinely, according to the standard technique, through a median sternotomy. A HL-20 heart-lung machine from Maquet and a single-use circuit of a heart-lung machine with the Affinity Fusion oxygenator from Medtronic were used. Extracorporeal cardiopulmonary bypass circuit was connected according to the aorta-right atrium-inferior vena cava scheme (one two-stage cannula). Filling the apparatus: mannitol 15% – 200 ml, gelofusin – 500 ml, sterofundin – 500 ml, $NaHCO_3$ 5% – 50 ml, tranexam – 20 ml, antibiotic 2 g, heparin 2 mL, insulin 10 U, dexamethasone 24 mg. Cardiopulmonary bypass was performed either in hypothermia at 32.0 °C temperature with aortic clamping (on-pump CABG), or under normothermal conditions (36.6 °C) without aortic clamping (pump-assisted CABG). In pump-assisted CABG, tissue stabilizer Medtronic Octopus was used during shunt placement.

If aortic clamping was necessary, antegrade and retrograde administration of blood cardioplegia (2–6 °C) with the addition of glucose (5% – 250 mL), potassium chloride (10% – 30 mL), magnesium sulfate (25% – 20 mL), and lidocaine (10% – 2 mL) was used to stop cardiac activity and protect the myocardium. Off-pump surgeries were performed routinely, according to the standard technique, through a median sternotomy. During shunt placement, tissue stabilizer Medtronic Octopus was used.

Regardless of coronary bypass type, 100% of patients included in the study underwent mammary-coronary anastomosis to the anterior interventricular artery. Ischemia-reperfusion injury was assessed by determining the troponin I levels before CABG, after CABG, and also on days 1, 2, 3, 4 after CABG. Troponin I levels were determined using immunoanalyzer Pathfast Compact. A CI $\leq$2.2, measured by an invasive technique was the criterion for postoperative heart failure [17, 18].

STATISTICAL DATA PROCESSING

All parameters studied were tested for normal distribution (Shapiro–Wilk test, Kolmogorov–Smirnov test). Incidence of complications was compared using Fisher's exact test. Construction of logistic regression, ROC-curve, calculation of the probability of postoperative heart failure was performed using the SAS Enterprise Guide 9.4 software. Troponin I thresholds were determined using the Youden index. Graphs were plotted in SAS Enterprise Guide 9.4.

RESULTS

The severity of coronary lesions and comorbidities were comparable in all observation groups (Table).

Baseline troponin I levels were normal in all the groups, <0.05 ng/ml. In the AMIRI-CABG study, troponin I thresholds, conditionally distinguishing between regular ischemia-reperfusion injury and type 5 myocardial infarction, was determined at 12.4 ng/ml within 24 to 48 hours after CABG surgery. According to different researchers, cardiac troponin threshold ranges from 9 ng/ml to 25 ng/ml [19].

Incidence of myocardial infarction (new ST elevation of more than 2 mm in two or more leads, new Q wave, new left bundle branch block) was 1.1% (n = 2),

0.78% (n = 1), and 0% in the off-pump, on-pump, and pump-assisted groups, respectively. The differences were statistically insignificant, Fisher's exact test p = 1.0. The presented data were obtained on a sample of n = 336 patients, of whom myocardial infarction signs were observed in three people by ECG. The incidence of a fall in CI below 2.2 was 8.57% (n = 15) in the off-pump CABG group, 11.72% (n = 15) in the on-pump group, and 3.03 % (n = 1) pump-assisted group. Differences in the observation groups were statistically insignificant (Fisher's exact test). The mean troponin I level on day 1 after CABG in the off-pump and on-pump groups in patients whose CI fell below 2.2 was comparable – 21 ng/mL. Troponin I levels in hemodynamically stable patients with a CI >2.2 varied significantly across the groups (Fig. 1).

Table

Basic patient characteristics

	Group 1: off-pump CABG, n = 175 (181)*	Group 2: on-pump CABG with aortic clamping, n = 128	Group 3: off-pump CABG without aortic clamping, n = 33 (27)**	p
Age, years, av. ± SD	63.5 ± 7.3	63.5 ± 7.13	64.3 ± 8.9	p > 0.05
Gender				
male	78.3 %	74.2%	74.1%	0.7
female	21.7 %	25.8 %	25.9%	
Syntax Score II	41.35 [32.7–50.8]	42.25 [31.1–49.9]	43.5 [34.5–53.6]	0.6
Euroscore II	1.03 [0.7–1.5]	0.97 [0.6–1.6]	0.79 [0.6–1.4]	0.3
Charlson/Deyo Index	5 [4–7]	5 [4–6]	5 [4–6]	0.1
EF (Simpson method) before surgery (%)	62.0 [55.0–67.0]	62 [59–66]	63 [55–65]	0.9
Preoperative troponin I levels, ng/mL				
Median Lower and upper quartile	0.008 [0.003–0.018]	0.014 [0.007–0.025]	0.014 [0.005–0.06]	0.09
Main characteristics of surgical intervention				
Surgery duration, min	290 [250–330]	330 [300–363]	335 [290–355]	
Average number of shunts	3	3	3	

Note. Charlson/Deyo Index – comorbidity index, allows taking into account comorbidities, EDVI – end-diastolic volume index, ESVI – end-systolic volume index, av. – average, SD – standard deviation, EF – ejection fraction, LCA trunk – left coronary arterial trunk, AIB – anterior interventricular branch, DB – diagonal branch, CB – circumflex branch, OMB – obtuse marginal branch, RCA – right coronary artery, PIB – posterior interventricular branch. Median [upper quartile – lower quartile] values are indicated. * The number of surgeries that began without CPB is indicated in brackets; conversion was performed in 6 cases. ** The number of operations planned with concurrent CPB is indicated in brackets.

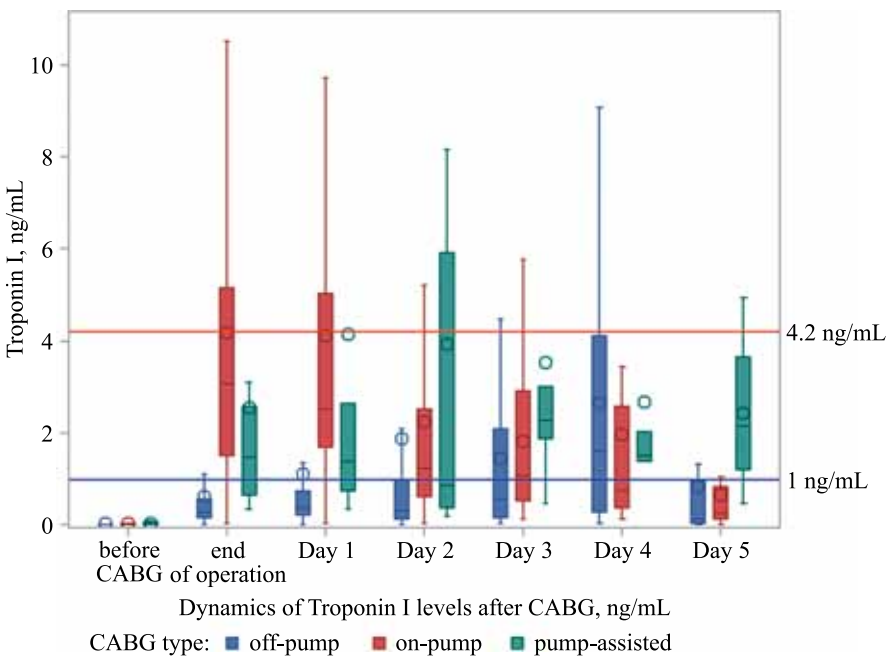

Fig. 1. Troponin I levels after CABG in patients with CI >2.2

The predictive value of increased troponin I level varied among the groups. For example, at 5.1 ng/mL after surgery, the probability of the CI falling below 2.2 was 12% in the off-pump CABG group and 7% in the on-pump CABG group (Fig. 2).

The predictive value of increased troponin I level on day 1 after surgery was also different among the observation groups. At 17.9 ng/mL after surgery, the probability of the CI falling below 2.2 was 71%, 56%, and 10% in the off-pump, on-pump and pump-assisted CABG groups, respectively (Fig. 3).

At 14.7 ng/mL troponin I level on day 2 after surgery, the probability of the CI falling below 2.2 was 38.5%, 67.8%, and 20% in the off-pump, on-pump and pump-assisted CABG groups, respectively (Fig. 4).

At 2.6 ng/mL troponin I level on day 3 after surgery, the probability of the CI falling below 2.2 was 13.2% and 24.3% in the off-pump and on-pump groups, respectively (Fig. 5).

The probability of the CI falling below 2.2 in the pump-assisted CABG group on day 3 after surgery could not be calculated due to unreliable logistic regression.

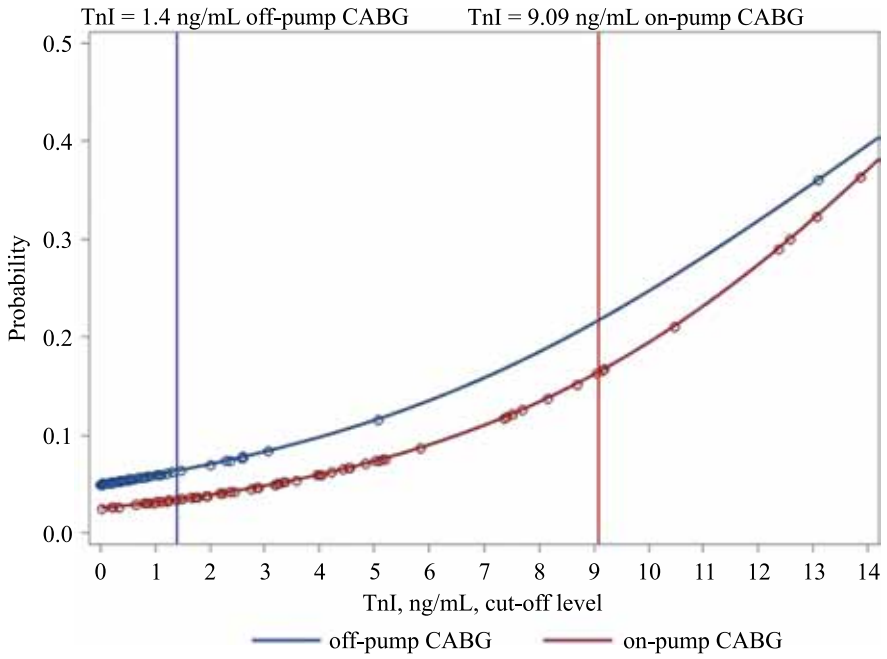

Fig. 2. Probability of CI falling below 2.2 after CABG at different troponin I levels at the end of surgery. The vertical lines indicate troponin I thresholds above which the probability of the CI falling below 2.2 should be considered as clinically significant

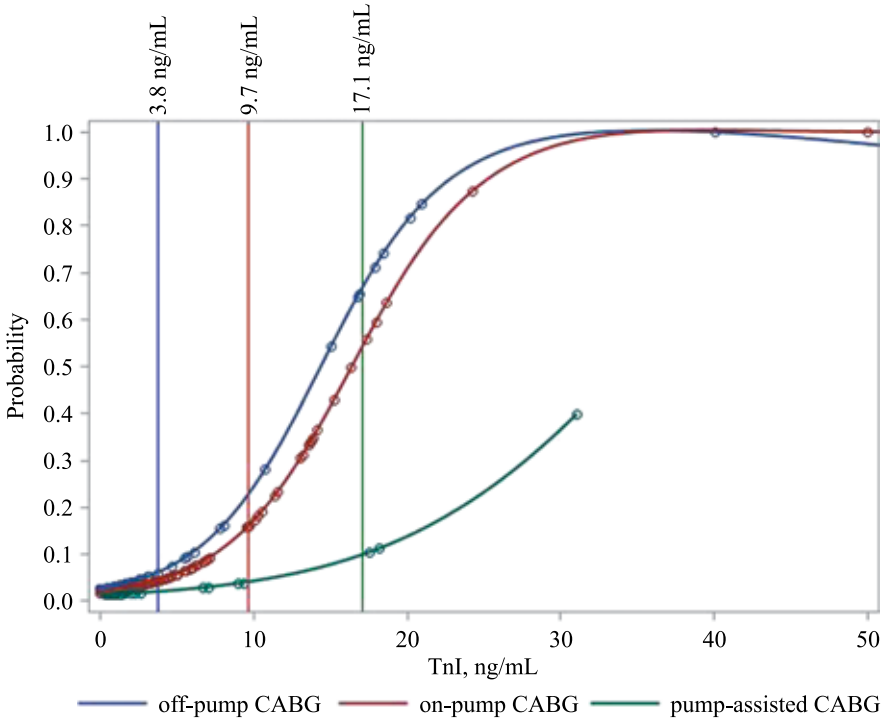

Fig. 3. Probability of CI falling below 2.2 on day 1 after CABG at different troponin I levels. The vertical lines indicate troponin I thresholds above which the probability of the CI falling below 2.2 should be considered as clinically significant

At 2.6 ng/mL troponin I level on day 4 after surgery, the probability of the CI falling below 2.2 was 18.9% and 29.4% in the off-pump and on-pump groups, respectively (Fig. 6).

The probability of the CI falling below 2.2 in the pump-assisted CABG group on day 4 after surgery could not be calculated due to unreliable logistic regression.

DISCUSSION

Coronary artery bypass grafting is accompanied by a regular myocardial ischemia-reperfusion injury [2]. It is assumed that off-pump CABG is associated with less myocardial ischemia-reperfusion injury. However, the absence of CPB cannot completely exclude clinically significant myocardial damage. Moreover, the risk of incomplete revascularization in off-pump CABG interventions has been reported [10].

In 2017, the European Society of Cardiology published the conclusion reached by its working group on the assessment of myocardial ischemia-reperfusion injury and diagnosis of type 5 myocardial infarction. In the same year, international register ClinicalTrial.gov (U.S. National Library of Medicine) registered a study by the Department of Faculty Surgery of the Research Institute of Surgery and Emergency Medicine, Pavlov First St. Petersburg State Medical University, dedicated

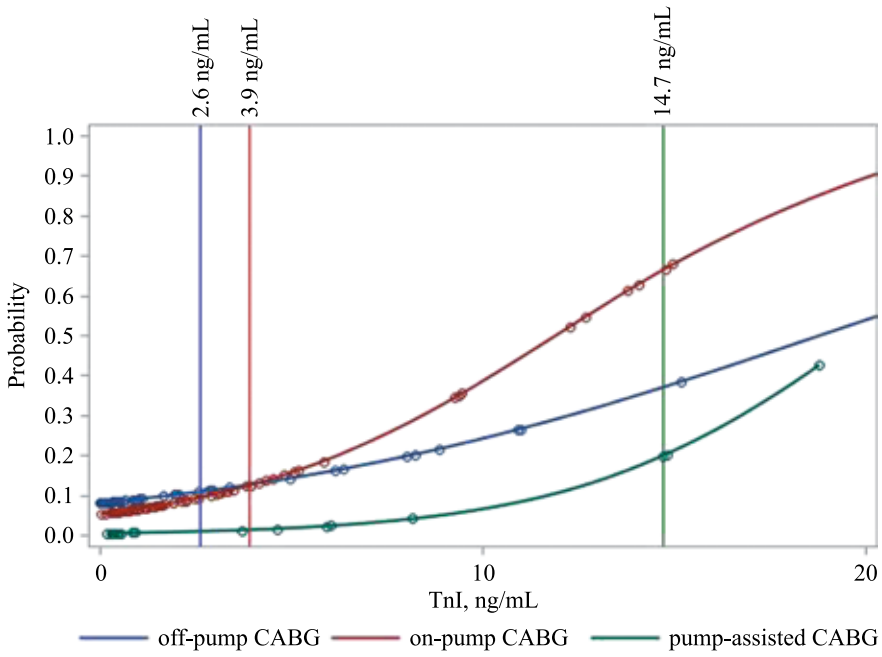

Fig. 4. Probability of CI falling below 2.2 on day 2 after CABG at different troponin I levels. The vertical lines indicate troponin I thresholds above which the probability of the CI falling below 2.2 should be considered as clinically significant

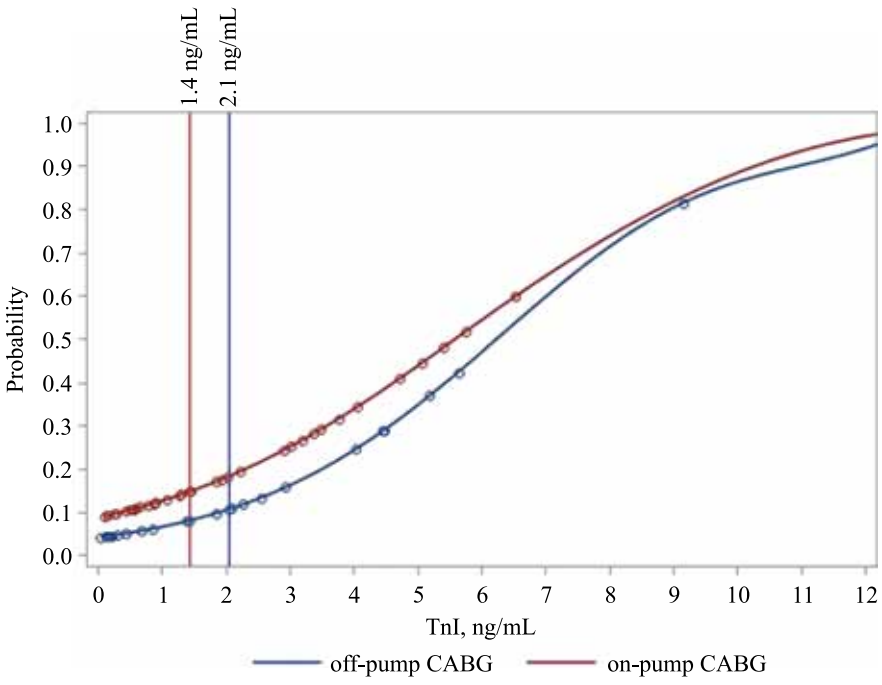

Fig. 5. Probability of CI falling below 2.2 on day 3 after CABG at different troponin I levels. The vertical lines indicate troponin I thresholds above which the probability of the CI falling below 2.2 should be considered as clinically significant

to the assessment of myocardial ischemia-reperfusion injury after different types of CABG – Assessment of Myocardial Ischemic-Reperfusion Injury During Off- and On-Pump CABG (AMIRI-CABG ClinicalTrials.gov Identifier: NCT03050489). Thus, a comparison of myocardial ischemia-reperfusion injury after different types of CABG was, for the first time, performed based on new and more precise criteria proposed by the European Society of Cardiology.

The AMIRI-CABG study established that any increase in troponin I levels after coronary artery bypass surgery above the manufacturer's recommended threshold of 0.05 ng/mL is associated with an increased risk of the CI falling below 2.2.

Troponin I levels exceeded the norm in 100% of patients with a CI exceeding 2.2 in all observation groups. However, the same cardiac troponin levels after a beating heart CABG surgery and under on-pump support is associated with a different probability of the CI falling below 2.2. So, Fig. 3 shows that at 3.8 ng/mL troponin I level, the probability of the CI falling below 2.2 was 6%, 4%, and 2% in the off-pump, on-pump, and pump-assisted CABG groups, respectively. Troponin I thresholds of a clinically significant probability of the CI falling below 2.2 were 3.8 ng/mL, 9.67 ng/mL and 17.1 ng/mL in the off-pump, on-pump, and pump-assisted groups, respectively (Figs. 2–6). This suggests that the prognostic value of an increase in troponin I after an off-pump, on-pump and pump-assisted CABG surgeries is different. We did not find any current studies comparing the prognostic value of troponin I with an accurate calculation of the likelihood of the CI falling below 2.2 after different types of CABG according to the current diagnostic criteria for myocardial ischemia-reperfusion injury following a CABG surgery, proposed by the European Society of Cardiology in 2017. The European Society of Cardiology points out the limited accuracy of isolated elevation in cardiac troponin, used without taking into account imaging and clinical data, in determining the degree of myocardial ischemia-reperfusion injury following a CABG surgery [16]. Thus, the AMIRI-CABG study suggests that the prognostic value of an increase in troponin I after off-pump, on-pump, and pump-assisted CABG surgeries differs significantly. Clinically significant myocardial injury after an off-pump CABG surgery should be expected at lower troponin I levels than after an on-pump CABG. In patients with a CI >2.2, troponin I levels did not exceed 0.5 ng/mL, 6 ng/mL, and 3.5 ng/mL in the off-pump, on-pump, and pump-assisted groups, respectively.

The AMIRI-CABG study has level II evidence. Further studies on the predictive value of cardiac troponin elevation after CABG are needed due to the inherent limitations of single-center and non-randomized studies.

CONCLUSION

After off-pump CABG surgery, clinically significant myocardial injury should be expected at lower troponin I levels (3.78 ng/mL) than after on-pump CABG surgery (9.67 ng/mL) and pump-assisted CABG surgery (14.7 ng/mL). Pump-assisted CABG may be associated with a significantly lower risk of the cardiac index falling. In patients with a cardiac index higher than 2.2, troponin I levels did not exceed 0.5 ng/mL, 6 ng/mL, and

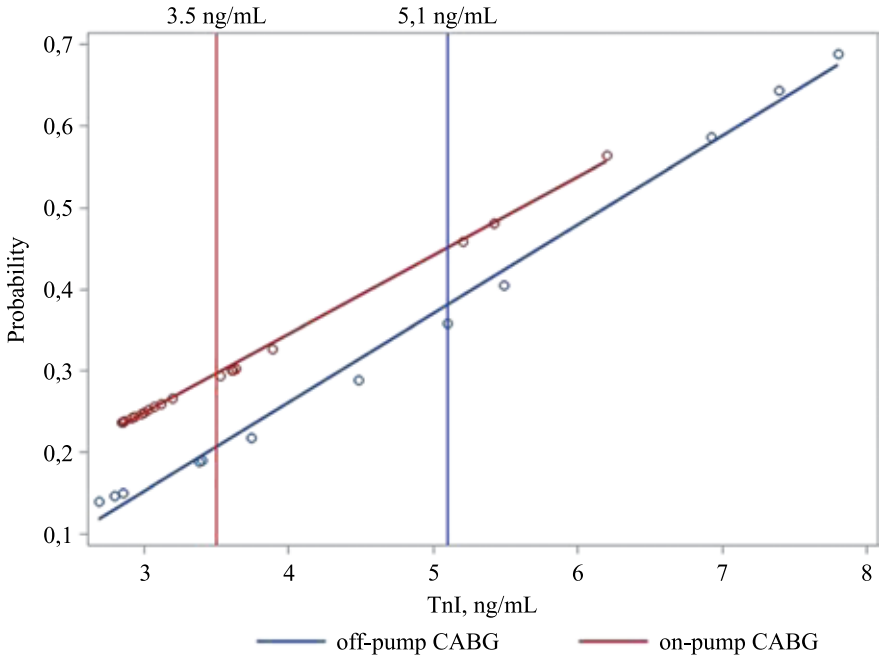

Fig. 6. Probability of CI falling below 2.2 on day 4 after CABG at different troponin I thresholds. The vertical lines indicate troponin I thresholds above which the probability of the CI falling below 2.2 should be considered as clinically significant

3.5 ng/mL in the off-pump, on-pump, and pump-assisted CABG groups, respectively.

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The authors declare no conflict of interest.

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