

SURGERY

SHORT-TERM AND LONG-TERM RESULTS OF BIMAMMARY BYPASS SURGERY IN PATIENTS WITH MULTIVESSEL CORONARY DISEASE AND TYPE 2 DIABETES MELLITUS AFTER PROPENSITY SCORE MATCHING

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ABSTRACT

Background. Among patients who have undergone coronary artery bypass surgery (CABG), the proportion of people with diabetes mellitus (DM) is about 40 %. To date, the problem of choosing the optimal method of surgical myocardial revascularization, which can provide the best result in this cohort, remains completely unresolved.

The aim of the study. To assess the in-hospital and long-term results of bimammary and traditional bypass surgery in patients with type 2 diabetes mellitus.

Methods. From September 2018 to December 2021, 176 CABG surgeries were performed in patients with coronary heart disease (CHD) and type 2 diabetes at the Federal Center for Cardiovascular Surgery (Krasnoyarsk). Group 1 (n = 45) included patients who underwent myocardial revascularization using two mammary arteries; group 2 (n = 131) included patients who underwent myocardial revascularization using traditional technique. After propensity score matching, 45 patients were selected into each group, comparable by basic preoperative characteristics.

Results. In group 1, cardiopulmonary bypass surgeries were performed in 23 (51.1 %) patients (group 1CPB), off-pump surgeries – in 22 (58.2 %) (group 1OP); in group 2, all patients underwent cardiopulmonary bypass surgeries. Hospital mortality was recorded in group 2 in 1 (2.2 %) case. Deep sternal infection developed in 1 (4.5 %) patient in group 1OP. Long-term survival in group 2 was 85.3 %, in group 1CPB – 83.3 % (p = 0.689), in group 1OP – 84.2 % (p = 0.739). 84.2 % of patients in group 2 and 100 % in groups 1CPB and 1OP had no cardiovascular events (p = 0.144 and p = 0.145, respectively).

Conclusion. Bimammary bypass surgery in patients with type 2 diabetes is a safe and effective method of surgical treatment of coronary artery disease in both short- and long-term period and may be the operation of choice in patients with multivessel disease. There were no differences in patient survival up to 45 months; bimammary revascularization was associated with 100 % absence of cardiac mortality.

Key words: coronary bypass surgery, bimammary bypass surgery, diabetes mellitus, deep sternal infection

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БЛИЖАЙШИЕ И ОТДАЛЁННЫЕ РЕЗУЛЬТАТЫ БИМАММАРНОГО ШУНТИРОВАНИЯ У ПАЦИЕНТОВ С МНОГОСОСУДИСТЫМ КОРОНАРНЫМ ПОРАЖЕНИЕМ И САХАРНЫМ ДИАБЕТОМ 2-ГО ТИПА ПОСЛЕ ПСЕВДОРАНДОМИЗАЦИИ

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РЕЗЮМЕ

Обоснование. Среди пациентов, перенёвших операцию коронарного шунтирования (КШ), доля лиц с сахарным диабетом (СД) составляет около 40 %. На сегодняшний день вопрос о выборе оптимального метода хирургической реваскуляризации миокарда, который обеспечит лучший результат у данной когорты, остаётся до конца нерешённым.

Цель исследования. Оценить госпитальные и отдалённые результаты бимаммарного и традиционного шунтирования у пациентов с сахарным диабетом 2-го типа.

Методы. С сентября 2018 г. по декабрь 2021 г. в ФГБУ «Федеральный центр сердечно-сосудистой хирургии» Минздрава России (г. Красноярск) проведено 176 операций КШ у пациентов с ишемической болезнью сердца (ИБС) и СД 2-го типа. Группа 1 (n = 45) состояла из пациентов, которым для реваскуляризации миокарда использовали две маммарные артерии; группа 2 (n = 131) – из пациентов, у которых реваскуляризация миокарда проводилась с использованием традиционной методики. После псевдорандомизации в каждую группу отобрано по 45 пациентов, сопоставимых по основным предоперационным характеристикам.

Результаты. В группе 1 операции в условиях искусственного кровообращения выполнены 23 (51,1 %) пациентам (1ИК), в условиях работающего сердца – 22 (58,2 %) (1РС); в группе 2 все операции проведены в условиях ИК. Госпитальная летальность зарегистрирована в группе 2 у 1 (2,2 %) пациента. Глубокая стерильная инфекция развилась у 1 (4,5 %) пациента в группе 1РС. Выживаемость в отдалённом периоде в группе 2 составила 85,3 %, в группе 1ИК – 83,3 % (p = 0,689), в группе 1РС – 84,2 % (p = 0,739). Свобода от кардиоваскулярных событий составила 84,2 % в группе 2 и по 100 % в группах 1ИК и 1РС (p = 0,144 и p = 0,145 соответственно).

Заключение. Бимаммарное шунтирование у пациентов с СД 2-го типа – безопасный и эффективный метод хирургического лечения ИБС как в ближайшем, так и в отдалённом периоде; может быть операцией выбора у пациентов с многососудистым поражением. В период до 45 месяцев не выявлено различий в выживаемости пациентов; бимаммарная реваскуляризация ассоциировалась с 100%-й свободой от кардиальной смертности.

Ключевые слова: коронарное шунтирование, бимаммарное шунтирование, сахарный диабет, глубокая стерильная инфекция

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INTRODUCTION

For many decades, coronary heart disease (CHD) has been the leading cause of death and disability among all cardiovascular diseases [1]. Although there have been advances in modern interventional cardiology associated with the use of the latest generation of drug-eluting stents, surgical myocardial revascularization in patients with complex multivessel coronary artery (CA) lesions is the preferential method of treatment, including patients with diabetes mellitus (DM) [2].

Coronary artery bypass grafting (CABG) is the most widely performed cardiac surgery worldwide, with isolated CABG procedures comprising more than half of all cardiac surgeries [3]. The modern level of coronary surgery allows performing operations with hospital mortality not exceeding 2–3 % [3]. The excellent long-term results obtained using the left internal thoracic artery (ITA) for revascularization of the anterior descending artery and the great saphenous vein for other target CAs, compared with the use of venous grafts alone, prompted the possibility of using the right ITA as well. The results of bimammary CABG surgery in numerous studies have demonstrated comparable hospital outcomes and better long-term results as opposed to the traditional bypass technique in patients with multivessel coronary lesions [4, 5]. Notwithstanding these encouraging results, this technique has not been widely used in the daily practice of cardiac surgeons since it requires high precision for the formation of coronary anastomoses and the associated increase in the duration of surgery, duration of the cardiopulmonary bypass (CPB), concerns about bleeding and severe sternal infectious complications as a result of decreased vascularisation of the sternum, especially in high surgical risk patients (diabetes mellitus, overweight, old age, chronic obstructive pulmonary disease (COPD)).

Among patients undergoing surgical myocardial revascularization, the proportion of patients with DM is about 40 % [6]. The question remains unresolved as to the optimal choice of the method of surgical intervention that can provide the best outcome for this category of patients. The presence of concomitant DM is associated with a risk of postoperative complications and poorer long-term survival after CABG. One of the main problems preventing the widespread implementation of bimammary bypass surgery in patients with DM remains the high risk of deep sternal infection as a result of the development of metabolic and severe microcirculatory disorders. The harvesting of only one left ITA can reduce the blood supply to half of the sternum by up to 90 %, while harvesting both ITAs can lead to devascularization of the entire sternum and prevent sternotomy wound healing [7]. As a result, the problem of CHD and DM comorbidity in patients requiring surgical myocardial revascularization is highly relevant. In view of the above-mentioned, it is necessary to evaluate the efficacy of bimammary CABG technique in comparison with the traditional technique of myocardial revascularization in order to reveal the advantages of surgical treatment by means of decreasing the surgery

time considering the reduction of the number of formed anastomoses, decreasing sternal infectious complications, mortality and decreasing major cerebrovascular events in patients with multivessel CA lesions and concomitant DM.

THE AIM OF THE STUDY

Analysis of the immediate and long-term results of bimammary and traditional coronary bypass surgery in patients with multivessel coronary lesions and concomitant diabetes mellitus.

METHODS

The analysis of the results of CHD surgical treatment in 176 patients with multivessel coronary lesions and compensated type 2 DM, who underwent isolated CABG in the period from 2018 to 2021 in the cardiac surgery department No. 1 of the Federal Center for Cardiovascular Surgery (Krasnoyarsk) was performed. Indications for CABG were in compliance with the 2018 ESC/EACTS (European Society of Cardiology/European Association for Cardio-Thoracic Surgery) guidelines for myocardial revascularisation. The study was performed as a retrospective, prospective, single-center, controlled study. The retrospective part of the study is represented by hospital outcomes and the prospective part is represented by long-term outcomes. Two groups of patients were formed: group 1 ($n = 45$) (study group) included patients who underwent myocardial revascularisation using both ITAs; group 2 ($n = 131$) (control group) included patients who underwent revascularisation using the traditional method of coronary artery bypass surgery (TCABG), namely, by anastomosis between the left ITA and the anterior descending artery; the other affected CAs were bypassed using the great saphenous vein. All patients underwent complete revascularisation according to the SYNTAX study criteria, including the 2018 ESC/EACTS guidelines for myocardial revascularisation: revascularisation of epicardial vessels with a diameter of at least 1.5 mm and lumen stenosis in the lesion area of 50 % or more. In diffuse CA atherosclerosis, the distal anastomosis was sought to be formed in the least altered area. The study was conducted in accordance with the standards of good clinical practice and the principles of the World Medical Association Declaration of Helsinki. The study protocol was approved by the bioethical committee of the Federal Center for Cardiovascular Surgery (Krasnoyarsk) (minutes No. 3 dated July 06, 2021). Inclusion criteria: patients aged 35 to 80 years with angina pectoris of functional class II and higher (according to the criteria of the Canadian Cardiovascular Society (CCS) with concomitant type 2 DM and having haemodynamically significant lesions of 2 or more CA or isolated lesion of the left coronary artery trunk more than 50 %. Exclusion criteria: age of patients older than 80 years; concomitant cardiac or aortic pathology requiring one-stage surgical correction; single-vessel lesion suitable for CA stenting; previous cardiac

surgery. The primary endpoints of the study were hospital mortality and mortality in the remote postoperative period; mortality from cardiac causes in the remote period; myocardial infarction (MI); acute cerebrovascular accident (ACVA) in the early and remote postoperative periods; deep sternal infection during hospitalization; repeat revascularization in the remote period; freedom from major cardiovascular events (death from cardiac causes + freedom from MI + freedom from ACVA + freedom from repeat revascularization). Secondary endpoints of the study were the clinic of recurrent angina pectoris. The main preoperative clinical indicators are summarised in Table 1.

The groups were comparable in terms of age ($p = 0.295$), gender ($p = 0.561$), and body mass index ($p = 0.856$). No differences were found for comorbidities: arterial hypertension ($p = 0.432$), chronic kidney disease (glomerular filtration rate less than 60 mL/min/1.73m²; $p = 0.130$), COPD ($p = 0.662$); the groups were similar in nicotine addiction in patients ($p = 0.07$). The functional class of angina pectoris was assessed according to the CCS classification. Most patients from both groups had functional class III angina pectoris. In group 1, the prevalence of heart failure was mainly of functional class III (57.8 %), in group 2 – of functional class II (51.1 %) according to the classification of the New York Heart Association (NYHA).

The groups were comparable in terms of haemodynamically significant (stenosis greater than 60 %) lesions in the brachiocephalic artery system (BCA) ($p = 0.513$); the number of patients with severe calcinosis of the ascending aorta was statistically significantly higher in the bimammary CABG group ($p = 0.001$); the groups were identical in terms of the number of haemodynamically significant CA lesions ($p = 0.629$). Echocardiography (EchoCG) findings revealed no differences between groups in left ventricular contractile function ($p = 0.266$). According to the EuroScore II postoperative complications risk scale, the risk of adverse outcome was statistically significantly higher in group 1 ($p = 0.016$).

In an attempt to minimise systematic errors, which could lead to misinterpretation of the results, and to maximise equivalence of the two groups with each other, a computer-generated equating of the groups was performed by adjusting the raw data using the pseudorandomization method. This statistical method allowed the formation of a study control group with minimal variation in baseline parameters coded into the various intervening factors (confounders) that were included in the propensity score matching model ("Propensity Score Matching"). The following parameters that may have influenced the outcomes of surgical interventions were used to minimize variation in preoperative data: age; sex; body mass index; smoking; chronic kidney disease (glomerular filtration rate less than 60 mL/min/1.73 m²); COPD; lower limb atherosclerosis; hypertension; left ventricular ejection fraction; myocardial infarction; and history of percutaneous coronary interventions. The Nearest Neighbor Matching method with a calibre value of 0.85 was used, with no prior discarding of unsuitable patients in the groups, with a given 1:1 ratio of the groups to be searched. RStudio

software (version 2022.02.0, build 443, USA) was used to perform propensity score matching. After performing propensity score matching, both groups were equalized according to baseline characteristics, selecting 45 patients in each group. The groups were comparable in terms of baseline characteristics (Table 1). The majority of patients in both groups had insulin-independent DM. The groups were predominantly male patients ($p = 0.460$), most of them were elderly (over 60 years) ($p = 0.571$), obese (body mass index over 30) ($p = 0.997$), good left ventricular contractile function (ejection fraction over 50 %) ($p = 0.405$). There were 4 (8.9 %) patients in group 1 with left ventricular ejection fraction less than 40 % and 2 (2.2 %) patients in group 2. In both groups, according to the results of preoperative coronary angiography, patients with multiple (more than two) CA lesions predominated. Calcinosis of the ascending aorta was statistically significantly more common in patients from the bimammary CABG group (group 1) ($p = 0.007$); accordingly, the risk of surgical complications was statistically significantly higher in this group ($p = 0.012$).

The criteria for selection of the bimammary CABG technique was the surgeon's preference based on experience with this technique, as well as the absence of an adequate quality VSM (vena saphena magna) conduit. The use of bimammary CABG in patients with DM was considered individually, with such criteria as patient's age, body mass index, and severity of concomitant pathology being considered.

The criteria for choosing OP CABG (Off-Pump Coronary Artery Bypass Graft) were: the surgeon's experience in conducting bimammary multivessel CABG; hemodynamically significant BCA lesion; severe calcinosis of the ascending aorta.

Most patients were monitored for bypass patency following completion of the main stage of surgery. Ultrasound flowmetry (Medistim Mira Q, Norway) using transducers of different diameters was used to assess the bypass patency functioning; the volume velocity of blood flow through the shunt (Q) (the norm is at least 15–20 mL/min) and pulse index (Pi) (not more than 5) were estimated.

All surgeries were performed using the ITA skeletonization technique, and no other arterial conduits were used for revascularization of the affected CAs. The technique of bimammary CABG was used in two modifications: "*in situ*" – each ITA was excised distally before bifurcation and an anastomosis with the affected CA was formed; composite bypass surgery – the right ITA after mobilization was excised proximally to its branching from the right subclavian artery and distally to its branching and sewn into the left ITA (Y-graft). The use of the composite-sequential bypass surgery technique allowed to form more than 2 distal anastomoses, thereby enabling the surgeon to perform complete myocardial revascularization in patients with 3 or more CA lesions. The choice of bimammary CABG method was determined based on the number of target arteries and lesion topography. More details describing the technical aspects of surgical myocardial revascularization using both ITAs can be found in our previous publications [4]. TCABG was performed using the left ITA, separated

TABLE 1
PREOPERATIVE CLINICAL CHARACTERISTICS OF PATIENTS

Parameters	Before propensity score matching			After propensity score matching		
	Group 1 (<i>n</i> = 45)	Group 2 (<i>n</i> = 131)	<i>p</i>	Group 1 (<i>n</i> = 45)	Group 2 (<i>n</i> = 45)	<i>p</i>
IDDM, <i>n</i> (%)	11 (24.4 %)	21 (16 %)	–	11 (24.4 %)	8 (17.8 %)	–
NIDDM, <i>n</i> (%)	34 (75.5 %)	110 (84 %)	–	34 (75.5 %)	37 (82.2 %)	–
Glycated hemoglobin level						
M ± SD	7.5 ± 0.37	7.5 ± 0.41	0.762	7.5 ± 0.37	7.6 ± 0.43	0.568
Me [Q1; Q3]	7.5 [7.4; 7.7]	7.5 [7.4; 8.0]		7.5 [7.4; 7.7]	7.5 [7.5; 8.0]	
6–8.4 %, <i>n</i> (%)	44 (97.8 %)	129 (98.5 %)		44 (97.8 %)	43 (95.6 %)	
8.5–10 %, <i>n</i> (%)	1 (2.2 %)	2 (1.5 %)		1 (2.2 %)	2 (4.4 %)	
Age, years						
M ± SD	62.3 ± 7.1	63.3 ± 6.8	0.295	62.3 ± 7.1	63.3 ± 4.3	0.571
Me [Q1; Q3]	62 [60.2; 64.5]	64 [62.1; 64.5]		62 [60.2; 64.5]	64 [61.2; 65]	
45–59 years, <i>n</i> (%)	9 (20.0 %)	24 (18.3 %)		9 (20.0 %)	8 (17.8 %)	
60–74 years, <i>n</i> (%)	33 (73.3 %)	97 (74.0 %)		33 (73.3 %)	35 (77.8 %)	
> 74 years, <i>n</i> (%)	3 (6.7 %)	10 (7.6 %)		3 (6.7 %)	2 (4.4 %)	
Male, <i>n</i> (%)	33 (73.3 %)	90 (68.7 %)	0.561	33 (73.3 %)	36 (80 %)	0.460
BMI, kg/m ²						
M ± SD	31.3 ± 5.4	31.1 ± 4.8	0.856	31.3 ± 5.4	31.2 ± 4.4	0.997
Me [Q1; Q3]	32 [27.5; 35.2]	32 [28.1; 34.7]		32 [27.5; 35.2]	32 [28.7; 34]	
Persistent smoking, <i>n</i> (%)	10 (22.2 %)	15 (11.5 %)	0.075	10 (22.2 %)	10 (22.2 %)	0.998
Arterial hypertension, <i>n</i> (%)	44 (97.8 %)	130 (99.2 %)	0.432	44 (97.8 %)	45 (100 %)	0.328
Chronic kidney disease (GFR < 60 ml/min/1.73 m ²), <i>n</i> (%)	22 (48.9 %)	81.6 (61.8 %)	0.130	22 (48.9 %)	13 (73.3 %)	0.051
COPD, <i>n</i> (%)	2 (4.4 %)	4 (3.05 %)	0.662	2 (4.4 %)	2 (4.4 %)	0.990
Obesity (BMI > 30), <i>n</i> (%)	29 (64.4 %)	81 (64.4 %)	0.757	29 (64.4 %)	26 (57.8 %)	0.522
Angina pectoris according to CCS, <i>n</i> (%)						
functional class II	11 (24.4 %)	50 (38.2 %)	–	11 (24.4 %)	22 (48.9)	–
functional class III	31 (68.9 %)	62 (47.3 %)	–	31 (68.9 %)	15 (33.3)	–
functional class IV	3 (6.7 %)	10 (7.6 %)	–	3 (6.7 %)	4 (8.9)	–

TABLE 1 (continued)

Heart failure according to NYHA, <i>n</i> (%)						
functional class II	19 (42.2 %)	67 (51.1 %)	–	19 (42.2 %)	25 (55.6 %)	–
functional class III	26 (57.8 %)	60 (45.8 %)	–	26 (57.8 %)	20 (44.4 %)	–
BCA atherosclerosis (more than 60 %), <i>n</i> (%)	8 (17.8 %)	18 (13.7 %)	0.513	8 (17.8 %)	5 (11.1 %)	0.374
Calcification of the aorta, <i>n</i> (%)	11 (24.4 %)	2 (1.5 %)	0.001	11 (24.4 %)	2 (4.4 %)	0.007
Number of CA lesions, <i>M</i> ± <i>SD</i>	2.8 ± 0.6	2.7 ± 0.5	0.629	2.8 ± 0.6	2.8 ± 0.6	0.970
2 CA, <i>n</i> (%)	14 (31.1 %)	39 (29.8 %)	–	14 (31.1 %)	12 (26.7 %)	–
3 CA, <i>n</i> (%)	25 (55.6 %)	85 (64.9 %)	–	25 (55.6 %)	30 (66.7 %)	–
4 CA, <i>n</i> (%)	6 (13.3 %)	5 (3.82 %)	–	6 (13.3 %)	2 (4.44 %)	–
5 CA, <i>n</i> (%)	–	2 (1.53 %)	–	–	1 (2.22 %)	–
Left ventricular ejection fraction, %						
<i>M</i> ± <i>SD</i>	51.3 ± 7.6	52.8 ± 9.2		51.3 ± 7.6	52.3 ± 7.2	
Me [Q1; Q3]	52 [49; 53.5]	54 [49; 54.3]		52 [49; 53.5]	54 [50.1; 54.4]	
< 40 %, <i>n</i> (%)	4 (8.9 %)	11 (8.4 %)	0.266	4 (8.9 %)	2 (4.4 %)	0.405
40–49 %, <i>n</i> (%)	10 (22.2 %)	28 (21.4 %)		10 (22.2 %)	10 (22.2 %)	
> 50 %, <i>n</i> (%)	31 (68.9 %)	92 (70.2 %)		31 (68.9 %)	33 (73.3 %)	
EuroSCORE II assessment						
<i>M</i> ± <i>SD</i>	2.9 ± 1.7	3.2 ± 9.7		2.9 ± 1.7	4.7 ± 16.4	
Me [Q1; Q3]	2.6 [2.5; 3.5]	2.1 [1.5; 4.8]	0.016	2.6 [2.5; 3.5]	2.1 [0.2; 9.6]	0.012

Note. IDDM – insulin-dependent diabetes mellitus; NIDDM – non insulin dependent diabetes mellitus; GFR – glomerular filtration rate.

by a skeletonization technique for bypass surgery of the anterior descending artery and a VSM (vena saphena magna) conduit for revascularization of the remaining target CAs. Autovenous conduits were harvested in an open manner using the skeletonization technique.

The RStudio program (version 2022.02.0, build 443, USA) was used for statistical analysis. To identify the type of mean values distribution of the studied indicators, the Shapiro – Wilk test was performed between the groups. No normal distribution of the mean was revealed for each of the indicators; thereby further non-parametric statistics were used. The Wilcoxon-rank sum test was used to analyze continuous variables of independent groups, categorical variables were assessed using the Pearson's χ^2 test. 0.05 was chosen as the reference value of the statistical significance level of *p*. The data are presented in the table in two versions:

the mean value together with the standard deviation value and the median value together with the 25 and 75 % quartile values. The values of the categorical variables are also presented by discrete values as the absolute number of patients and their percentage of the total number of patients in the group. Survival and cardiovascular events in the long-term period were analyzed using the Kaplan – Meier method. *p* < 0.05 was considered to indicate statistical significance for the primary outcome.

HOSPITAL OUTCOMES

According to the results of this study, in group 1, 23 (51.1 %) surgeries were performed in CPB (group 1CPB) and 22 (49.9 %) surgeries were performed in OP (group 1OP).

Further comparative analysis was performed between group 2 and groups 1CPB and 1OP. The main postoperative results are summarized in Table 2.

Group 2 was comparable to groups 1CPB and 1OP in terms of the total duration of surgery ($p = 0.431$ and $p = 0.142$, respectively); we saw no intergroup differences in the number of distal anastomoses formed either ($p = 0.263$ and $p = 0.901$, respectively). Although no proximal anastomoses were formed when performing the bimammary CABG technique, aortic occlusion time and CPB duration were statistically significantly higher than in group 2 ($p = 0.05$ and $p = 0.05$, respectively). The rationale for this is that bimammary cardiac revascularisation and sequential anastomosis techniques require the surgeon to be very precise in shunt formation and, consequently, the duration of the surgical procedure. In group 1CPB, extubation of patients in the intensive care unit (ICU) occurred later than in group 2 ($p = 0.022$), but was comparable in duration to group 1OP ($p = 0.114$). Drainage losses during the first day in the ICU were comparable between the groups ($p = 0.214$ and $p = 0.243$, respectively). Diagnostic coronary artery bypass grafting in the early postoperative period

was performed in group 1CPB in 1 (4.3 %) patient, in group 2 – in 1 (2.2 %) patient ($p = 0.645$) due to ischemic changes recorded on the electrocardiogram (ECG) and EchoCG. In group 1CPB, the bypass patency was intact; in group 2, a kink of the autovenous bypass to the right CA with stenosis of the conduit lumen up to 80 % was revealed, and a re sternotomy was performed as an emergency procedure to correct the kink. According to EchoCG data, no statistically significant difference was found between group 2 and groups 1CPB and 1OP in left ventricular contractility before hospital discharge ($p = 0.932$ and $p = 0.241$, respectively). Following the results of flowmetric study in both subgroups of bimammary CABG, the volumetric blood flow velocity (Q) was statistically significantly higher than in the traditional CABG group ($p < 0.001$ and $p < 0.001$, respectively), but the indices were within the reference values in all groups; the pulse index (Pi) was comparable between group 2 and groups 1CPB and 1OP ($p = 0.474$ and $p = 0.526$, respectively), the mean indices were within the normal range.

Analyses of major hospital complications are summarised in Figure 1. Hospital mortality was only 1 (2.2 %) case in group 2 ($p = 0.491$ and $p = 0.503$, respectively) and

TABLE 2
INTRAOPERATIVE AND HOSPITAL OUTCOMES

Parameters	Group 1CPB (<i>n</i> = 23)	<i>p</i>	Group 2 (<i>n</i> = 45)	<i>p</i>	Group 1OP (<i>n</i> = 22)
Duration of CPB, min					
Me [Q1; Q3]	78 [67; 99.7]	0.05	78 [74.4; 89.1]	–	–
M ± SD	83.3 ± 37.8		81.7 ± 24.4		–
Duration of aortic occlusion, min					
Me [Q1; Q3]	58 [45; 67.9]	0.05	48 [44.8; 53]	–	–
M ± SD	56.4 ± 26.4		48.9 ± 13.6		–
Duration of surgery, min					
Me [Q1; Q3]	220 [201; 229]	0.431	201 [200; 222]	0.142	189 [178; 211]
M ± SD	215 ± 32.9		211 ± 36.5		194 ± 37.2
Number of distal anastomoses					
Me [Q1; Q3]	2.9 ± 0.6	0.263	2.7 ± 0.5	0.901	2.7 ± 0.6
M ± SD	3 [2.6; 3.1]		3 [2.5; 2.8]		3 [2.4; 3]
2 anastomoses, <i>n</i> (%)	6 (26.1 %)	–	15 (33.3 %)	–	8 (36.4 %)
3 anastomoses, <i>n</i> (%)	14 (60.9 %)	–	29 (64.4 %)	–	12 (54.5 %)
4 anastomoses, <i>n</i> (%)	3 (13 %)	–	1 (2.2 %)	–	2 (9.1 %)

TABLE 2 (continued)

ALV (artificial lung ventilation) duration, h					
Me [Q1; Q3]	7 [6.2; 8.5]	0.022	9 [8.4; 11.5]	0.114	7 [6.7; 9.7]
M ± SD	9.9 ± 5.1		9.9 ± 5.1		8.2 ± 3.3
Blood loss, ml					
Me [Q1; Q3]	250 [193; 397]	0.214	300 [287; 385]	0.243	200 [187; 333]
M ± SD	295 ± 236		336 ± 163		260 ± 164
Stay in ICU, days					
Me [Q1; Q3]	2 [2.05; 3.1]	0.756	2 [1.8; 3.8]	0.375	2 [1.8; 2.6]
M ± SD	2.6 ± 1.2		2.8 ± 3.5		2.2 ± 0.8
Inpatient stay, days					
Me [Q1; Q3]	11 [8.9; 18.7]	0.932	11 [9.9; 17.3]	0.214	10 [9.1; 16.3]
M ± SD	10 ± 11.2		13.6 ± 12.3		12.7 ± 8.1
Coronary bypass angiography, <i>n</i> (%)	1 (4.3)	0.645	1 (2.2)	–	–
Left ventricular ejection fraction, %					
Me [Q1; Q3]	53 [50.4; 54.6]	0.932	53 [49.8; 55.9]	0.241	51 [46.2; 53.3]
M ± SD	52.5 ± 4.9		52.8 ± 10.2		49.8 ± 8
Flowmetry parameters					
Q, ml/min					
Me [Q1; Q3]	72 [64.2; 77.3]	< 0.001	47 [42.5; 56.5]	< 0.001	60.5 [56.1; 70.2]
M ± SD	70.7 ± 11.2		49.5 ± 11		63.1 ± 12
Pi					
Me [Q1; Q3]	1.9 [1.3; 3.7]	0.474	3 [2.5; 3.2]	0.526	2.1 [1.9; 2.5]
M ± SD	2.5 ± 2.8		2.9 ± 0.7		2.2 ± 0.6

was associated with the development of acute mesenteric thrombosis. Acute perioperative myocardial infarction was observed only in group 2 in 2 (4.4 %) patients ($p = 0.322$ and $p = 0.334$). The first case was associated with impaired patency of the autovenous conduit, and the second case was associated with ischaemic changes observed during ECG at the initial stage of surgery as a result of the severity of the coronary lesion. Acute cerebrovascular accident resulted in postoperative complications in only 1 (4.5 %) patient in the 1OP group ($p = 0.307$). An initially severe

lesion of the carotid arteries appeared to be the probable cause. Bleeding requiring re sternotomy developed in 1 (4.3 %) case in group 1CPB and 3 (6.7 %) patients in group 2 ($p = 0.714$), with no active bleeding sources identified in either case; none of the cases in group 1OP had this complication ($p = 0.236$). Group 2 and groups 1CPB and 1OP were comparable in the development of superficial wound infection ($p = 0.231$ and $p = 0.227$, respectively). Severe mediastinitis developed in 1 (4.5 %) case in group 1OP ($p = 0.328$) – in a patient with insulin-dependent type 2 DM.

LONG-TERM RESULTS

The median duration of follow-up was 30.8 months (range from 14 to 45 months). 86.7 % of the total number of patients were examined in the long-term period. We were unable to follow-up 4 (8.9 %) patients from group 2, 5 (21.7 %) patients from group 1CPB and 3 (13.6 %) patients from group 1OP. Kaplan – Meier

survival curves demonstrated 1-year, 2-year, and 3-year survival rates for all-cause mortality: 100 %, 88.9 %, and 83.3 %, respectively, in group 1CPB; 100 %, 84.2 %, and 84.2 %, respectively, in group 1OP; 95.1 %, 92.7 %, and 85.3 %, respectively, in group 2. A Kaplan – Meyer survival curve analysis of survival estimates revealed no statistically significant advantage in overall survival between the 1CPB and 2 ($p = 0.689$) and 1OP and 2 ($p = 0.739$) groups

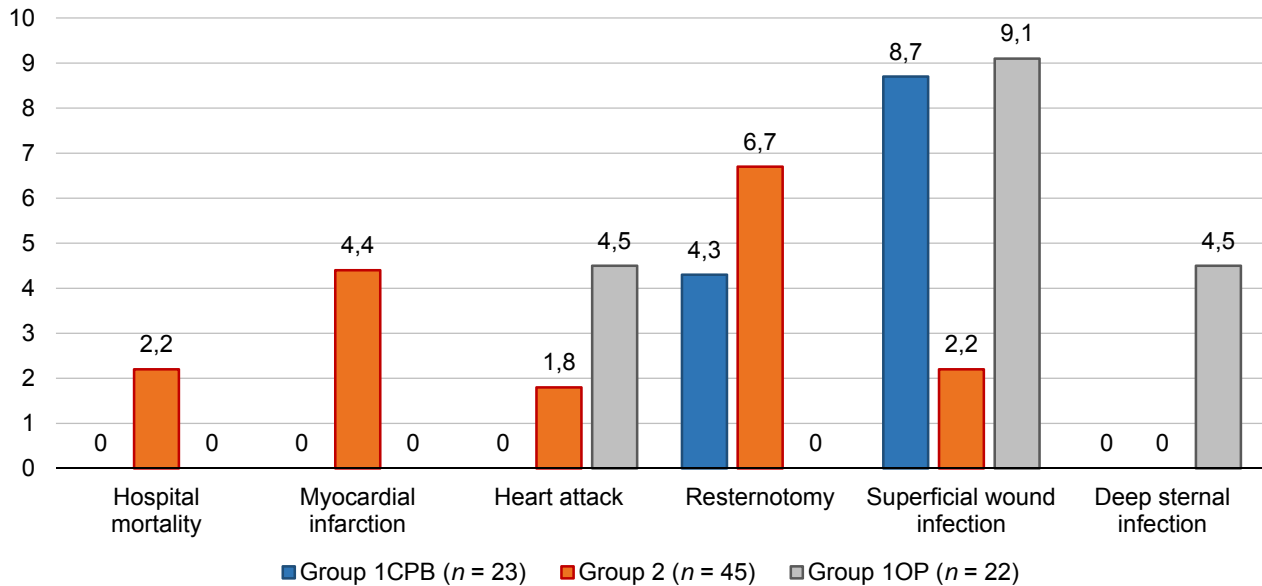


FIG. 1.
Complications in the postoperative period

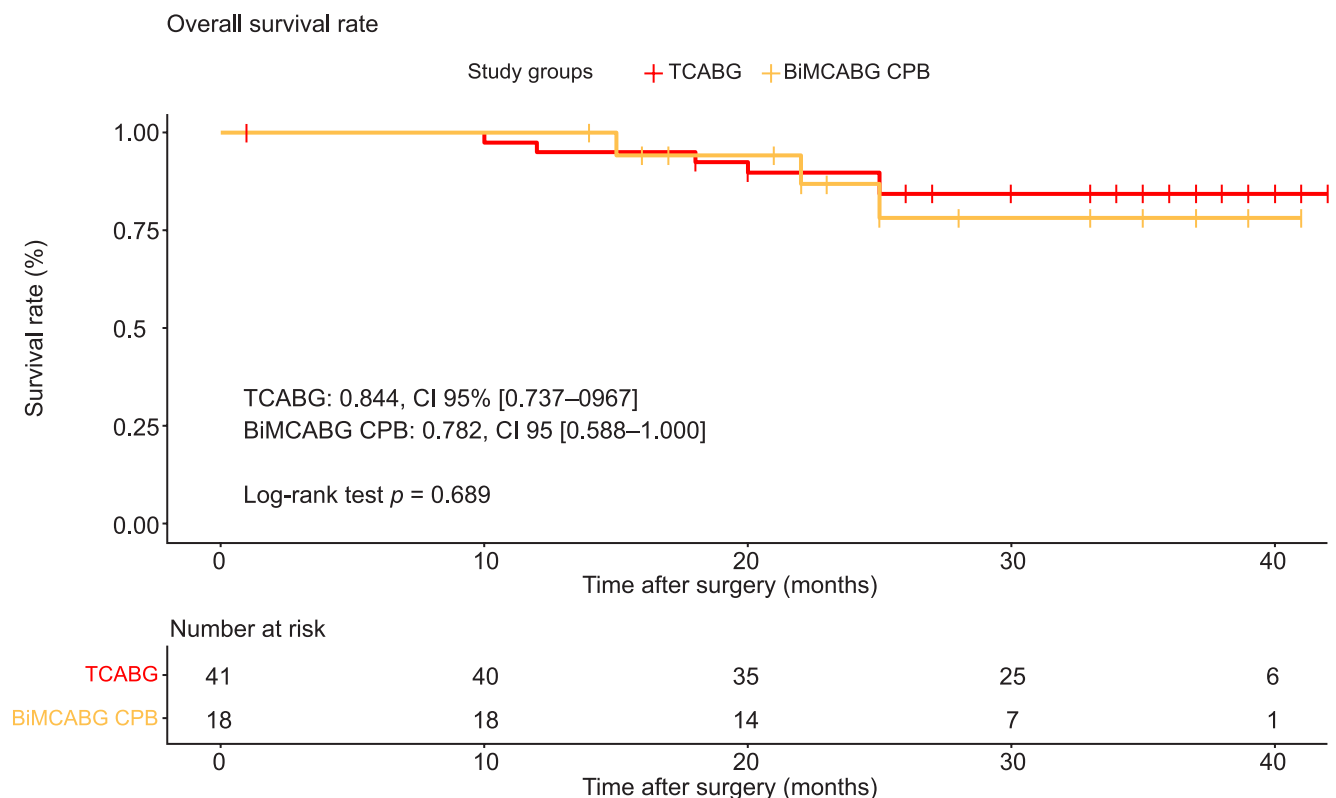


FIG. 2.
Kaplan – Meier all-cause survival curves between group 1CPB (cardiopulmonary bypass surgeries) and group 2

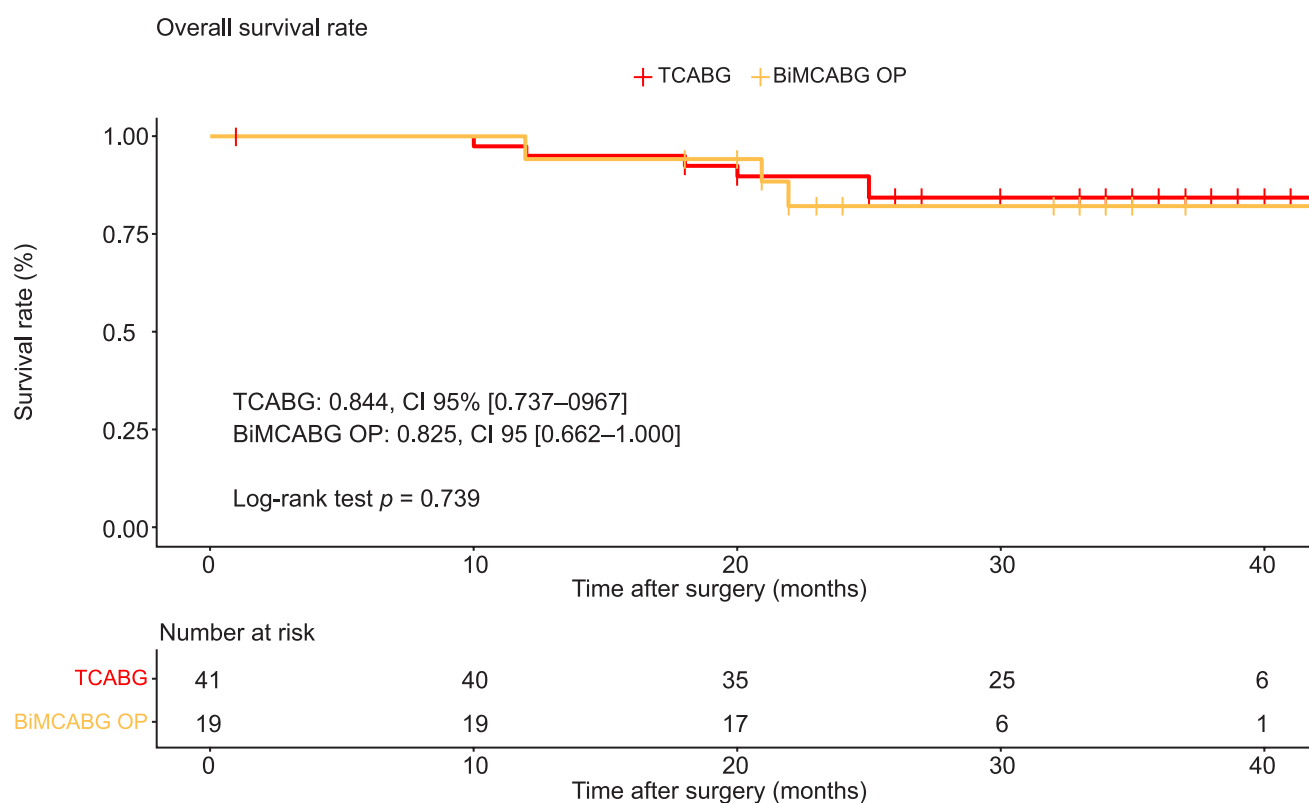


FIG. 3.

Kaplan – Meier all-cause survival curves between group 1OP (off-pump surgeries) and group 2

(Fig. 2, 3). But it is important to note that in the bimammary CABG groups, freedom from cardiac mortality was 100 %, while in group 2, in 50 % of cases (3 patients), mortality was associated with the development of acute myocardial infarction, in other cases with complications of COVID-19. In group 1CPB, in 1 case patient died from complications of oncological disease, in 2 cases – from complications of COVID-19. In group 1OP, one patient died from complications of oncological disease, the second patient died from complications of COVID-19, and the third patient died from an accident.

In groups 1CPB and 1OP, the freedom from myocardial infarctions in the long-term period was 100 %, while in group 2 it was 97.6 % ($p = 0.683$ and $p = 0.683$, respectively): in 1 patient, myocardial infarction developed against the background of occlusion of the autovenous bypass to the right coronary artery basin.

Freedom from acute cerebral complications in group 2 was 97.6 %: in 1 patient the long-term postoperative period was complicated by the development of acute cerebral circulatory disturbance of ischaemic type. No such complications were observed in the 1PCB and 1OP groups ($p = 0.547$ and $p = 0.500$, respectively).

Freedom from repeated revascularization in the group 2 was 97.6 %, in groups 1CPB and 1OP – 100 % ($p = 0.564$ and $p = 0.645$, respectively). In group 2, bypass dysfunction was revealed in 2 patients. An occlusion of the conduit from the midline was revealed in one case, however, a conservative medical therapy as a result of the depleted distal native channel beyond the anastomosis site

was recommended. The second patient required stenting of the right CA as a consequence of recurrence of angina pectoris, the CBA revealed occlusion of the autovenous bypass to the proximal posterior interventricular artery.

The patency of the left and right ITA for up to 45 months in all groups was 100 %, the patency of venous bypass was lower and was 96.1 %.

Absence from recurrent angina pectoris was observed in 94.1 % of cases in group 2, in 100 % and 87.5 % in groups 1CPB and 1OP ($p = 0.450$ and $p = 0.208$), respectively. The results of multi-layer spiral computed tomography of CA in group 1OP revealed no impairment of bypass patency; the probable cause of recurrent angina was associated with the progression of atherosclerosis in the native coronary bed. Both cases in group 2 were caused by dysfunction of the autovenous bypass.

Freedom from cardiovascular events (MACCE, major adverse cardiac and cerebrovascular event) (death from cardiac causes + freedom from MI + freedom from ACVA + freedom from repeat revascularization) in groups using two ITAs was 100 %, in group 2 – 84.2 %, but no statistically significant difference was obtained ($p = 0.144$ and $p = 0.145$).

In assessing the functional classes of heart failure (according to NYHA) during the long-term period in the patients who underwent surgery, we did not see statistically significant differences in the intergroup study ($p = 0.429$ and $p = 0.484$, respectively), but in the intragroup analysis, when comparing the preoperative data and the results in the long-term period, there was a statistically

significant decrease in the functional classes of heart failure in each of the groups: in group 1CPB $p < 0.005$; in group 1OP $p < 0.001$; in group 2 $p < 0.001$.

DISCUSSION

The number of DM patients undergoing CABG is steadily increasing worldwide. A higher propensity for progression of multifocal atherosclerosis, a higher incidence of extensive peripheral and visceral arterial lesions, and a higher risk of perioperative mortality are also associated with the type 2 DM existence. It is currently very important to optimize clinical outcomes in patients with concomitant DM undergoing CABG.

The use of the skeletonization technique of both ITAs in this study did not increase the incidence of both superficial wound infection ($p = 0.23$ and $p = 0.22$) and deep sternal complications ($p = 0.47$ and $p = 0.42$). It may safely be used for myocardial revascularization in patients with multivessel coronary lesions and type 2 DM. This view is shared by a number of authors. In the study by U. Benedetto et al. it was demonstrated that the number of sternal complications does not increase when both ITAs are harvested by the skeletonization technique and is comparable with the use of the left ITA through the preservation of collateral blood flow in the sternum (odds ratio (OR) – 1.00; 95% confidence interval (95% CI): 0.65–1.53) [8]. Also no difference in the incidence of deep sternal infection in patients with bimammary and conventional bypass surgery was obtained in the study conducted by D.J. LaPar et al. (0.4 % vs. 0.2 %; $p = 0.48$) [9]. In contrast, in a study by Japanese colleagues, the incidence of deep sternal infection in patients with type 2 DM was higher in the group that used the bimammary CABG technique (2.7 % vs. 1.2 %; $p > 0.05$), with no information about the method of ITA harvesting being reported in the study [10]. A review article covering the literature between 1970 and 2017 advised that deep sternal infection is a multifactorial problem and the use of ITA skeletonization technique does not affect the development of infectious complications [11]. The ART (The Arterial Revascularization Trial), the only randomized multicentre study to date, assessed the results of surgery using bimammary and traditional CABG technique: about 50 % of patients had DM, and more than 40 % of all surgeries were performed without CPB [12]. The study results revealed that hospital mortality was comparable between groups (relative risk (RR), 0.96 (0.79–1.17); $p = 0.9$), but the incidence of sternal reconstruction was higher in patients where both ITAs were used (OR=2.91; 95% CI: 1.42–5.95; $p = 0.002$). However, the study does not emphasise the techniques of conduit isolation. The authors suggest that an individualized approach is needed to apply the bimammary CABG technique in patients with DM. A contraindication to the harvesting of both ITAs, according to the authors, is insulin-dependent DM, especially in overweight female patients. Relative contraindications include age over 70 years. Despite the ongoing debate about the role

of ITA skeletonization in preventing sternal infection, most authors believe that this technique remains the main one in the prevention of infectious complications, including this technique being the main one in the latest recommendations for myocardial revascularisation.

Major hospital outcomes were comparable between the study groups: hospital mortality was only observed in group 2 in 1 (2.2 %) patient ($p = 0.49$ and $p = 0.50$, respectively): the patient died of acute intestinal ischaemia. Acute perioperative myocardial infarction also developed in 2 patients of group 2 (4.4 %) ($p = 0.32$ and $p = 0.33$, respectively): in one case it was associated with kinking of the autovenous bypass, in the second case – with the initial severe coronary lesion, multiple CA stenting, pronounced calcinosis in the arterial walls complicating the formation of anastomoses. Acute cerebrovascular accident was observed in one case (4.5 %) in the 1OP group ($p = 0.31$ and $p = 0.30$, respectively).

These results were similar to ours in the study of L. Di Bacco et al., which included 268 patients with CHD and concomitant DM, of whom half of the patients were underwent surgery using bimammary CABG technique. No statistically significant difference was observed between groups for hospital mortality ($p = 0.89$), acute perioperative myocardial infarction ($p = 0.86$), neurological complications ($p = 0.98$), and re sternotomies for acute bleeding ($p = 0.32$). The authors of the study have come to the conclusion that the use of bimammary CABG technique does not worsen hospital outcomes in patients with CHD and concomitant DM and may be the operation of choice in this cohort of patients [13]. Alternately, in a study by A.M. Calafiore et al. the use of one ITA versus the use of two ITAs was associated with statistically significantly higher hospital mortality from all cardiac causes ($p = 0.015$) [14]. In the work of D. Pevni et al. hospital mortality was similar in both groups (2.6 % and 3.0 %; $p = 0.113$), but in the bimammary CABG group there was an increase in the incidence of heart attack in the early postoperative period (4.87 % vs. 2.13 %; $p = 0.003$), despite the fact that the «no touch aorta» technique was used [15].

According to the results of this study, the groups were comparable in terms of the number of distal anastomoses formed: in group 2 – 2.7 ± 0.5 , in group 1CPB – 2.9 ± 0.6 ($p = 0.26$), in group 1OP – 2.7 ± 0.6 ($p = 0.90$). A non-significant statistical difference was obtained in the duration of CPB and aortic cross-clamping time ($p = 0.05$); this difference can be associated with the high precision of bimammary myocardial revascularisation and the technique of distal anastomosis formation. Extubation of patients in the group 2 occurred later than in group 1CPB ($p = 0.02$), but no difference in clinical picture between the groups was observed. In the study by B. Gansera et al. [16], the mean number of distal anastomoses formed using both ITAs was higher than ours, but in an intergroup comparison of the number of distal anastomoses formed, the studies were comparable (3.3 ± 0.8 vs. 3.2 ± 0.9 , respectively; $p = 0.921$), which is consistent with our results. In the study by A. Iribarne et al. including 430 patients with CHD and concomitant DM who underwent surgical myocardial

revascularisation (217 TCABG and 213 bimammary CABG), no group difference was obtained in the number of affected CAs and the number of distal anastomoses performed ($p < 0.503$). The groups were similar in terms of CPB duration ($p = 0.177$), however, aortic cross-clamping time was statistically significantly higher in the bimammary CABG group ($p < 0.001$), which is similar to our results, except that patients were extubated earlier in the group using both ITAs ($p = 0.049$) [17].

The consistency of the bypasses was analyzed by means of a flowmetric study. Flowmetry results of the formed bypasses revealed a statistically significant difference between groups 2 and CPB, as well as 1OP in linear blood flow velocity (Q) at the formed bypass ($p < 0.001$ and $p < 0.001$, respectively). Linear blood flow velocity was higher in the bimammary CABG groups, but the groups were completely comparable in terms of pulse index (Pi) ($p = 0.47$ and $p = 0.52$, respectively). The results of the study revealed that, despite the difference in linear blood flow velocity, this hydrodynamic parameter was within the reference limits in all groups. Statistically significant difference in Q parameter can be associated with the fact that in the bimammary CABG group in most cases composite and composite-sequential bypass surgery technique was used, and comparable intergroup results in Pi parameter can be explained by the fact that in all patients revascularisation was performed with hemodynamically significant lesions in CA with a satisfactory distal bed behind the lesion. In case of composite and composite-sequential bypass surgery, hydrodynamic parameters in bypasses with rhomboidal anastomoses were statistically significantly higher than in parallel anastomosis technique, which is associated with higher pulse blood flow velocity along the conduits through the anastomosis area and lower probability of bypass deformation in this area [18]. In the study by D. Glineur et al. the 7-year results of bimammary bypass surgery depending on the bypass configuration were assessed; no statistically significant difference in long-term survival in patients was revealed ($p = 0.3$), but the composite bypass technique was associated with a lower incidence of cardiovascular events ($p = 0.01$) and repeat revascularisations ($p = 0.009$) [19]. Concurrently, the results of the PREVENT IV study demonstrated that the use of composite-sequential technology was associated with poorer bypass patency and consequently worse clinical outcomes compared with the use of linear bypasses (OR = 1.24; 95% CI: 1.03–1.48) [20].

The long-term patient survival in this study (median follow-up, 30.8 months) was comparable between the bimammary and traditional CABG groups ($p = 0.689$ and $p = 0.739$, respectively), which correlates with the results of other studies. In a study by A. Iribarne et al. the survival rate of patients in the long-term period (median follow-up was 9.5 years) after bimammary bypass surgery was statistically significantly higher (OR = 0.75; 95% CI: 0.57–0.98; $p < 0.034$) [17]. At the opposite end of the spectrum, in the study performed by B. Gansera et al. revealed no difference in survival between the groups: 5-, 10-, and 14-year survival rates were 93.4 %, 76.6 %,

and 67.5 % in the bimammary bypass surgery group and 89.5 %, 81.5 %, and 32.8 % in the traditional CABG group ($p = 0.288$), respectively [16]. Cardiac-related mortality was 30.8 % in the TCABG group and 30.0 % in the bimammary CABG group. Analyzing them by causes of mortality in this study, we revealed that in the TCABG group, 50 % of mortality was associated with the development of myocardial infarctions, whereas in the bimammary bypass surgery subgroups, patient mortality was not associated with cardiac pathology. An important point to be mentioned is that in the aforementioned studies, the follow-up period was longer than in our work. The survival advantage in patients after bimammary CABG is observed after 7 years of follow-up, as reported by a number of researchers [21]. A shorter follow-up period in the long-term period may have been the reason for the lack of differences in our study.

Analysis of the MACCE development incidence in the long-term postoperative period revealed no advantages of one surgical technique over the other, despite the fact that, indeed, these complications were absent in the bimammary CABG groups. Freedom from MACCE in the group 2 was 84.2 %, in groups 1CPB and 1OP – 100 % ($p = 0.144$ and $p = 0.145$, respectively). Similar results were obtained in a recent publication that assessed the impact of multiple arterial bypass surgery versus traditional CABG in a retrospective analysis of 10-year outcomes in patients with DM from the ART study. In a cohort of DM patients, the incidence of MACCE was actually higher in the TCABG group (35.4 %) (28.9%; OR=0.80; 95% CI: 0.61–1.03), but the subgroup interaction effect was not significant ($p = 0.93$); even adjustment for potentially distorting factors had little effect on the results: the adjusted OR for MACCE was 0.80 (95% CI: 0.61–1.05; $p = 0.93$) [22]. Conversely, the study by L. Di Bacco et al. revealed that the use of arterial conduits provides significantly better results compared to traditional revascularization in terms of freedom from major cardiac and cerebrovascular events (77 ± 6.0 % vs. 53 ± 5.8 %, respectively; $p < 0.001$) [13].

This study demonstrated that the use of the bimammary bypass surgery technique in patients with multivessel CA lesions and type 2 DM is comparable to the in-hospital and mid-term outcomes of traditional myocardial revascularization techniques. The use of bimammary CABG in off-pump surgeries should be considered as an operation of choice in patients with significant lesions of brachiocephalic and visceral arteries, in patients with low contractile function of the left ventricular myocardium. The ITAs skeletonization technique did not increase the number of infectious complications in the surgical area, and comparable results were obtained with the group where a single ITA was used, which may indicate the high efficiency and safety of this conduit harvesting technique. Considering the fact that the simultaneous use of both ITAs did not increase the number of hospital complications, we believe that the use of this strategy to revascularize myocardium in patients with type 2 DM should be considered on an individual basis, with the consideration of such factors as the severity of the underlying and concomitant disease, age, sex, and body mass index of the patient.

In the long-term period, no statistically significant difference was observed between the groups in terms of mortality and cerebrovascular events, but the use of bimammary myocardial revascularization technique was associated with 100 % freedom from cerebrovascular events and cardiac mortality in this study.

Study limitations

A limitation of the study is its single-centre nature, the small sample of patients and the fact that surgeries were performed by multiple surgeons. This study is retrospective and does not have the same power as prospective randomized multicentre studies with large patient sample.

CONCLUSION

Bimammary bypass surgery may be a suitable option for surgical myocardial revascularization for patients with type 2 DM either in CPB or OP cases. Bimammary CABG in off-pump surgeries should be considered as the surgery of choice in patients with hemodynamically significant lesions of the brachiocephalic and visceral arteries. No differences in overall survival were observed during the period from 14 to 45 months in the groups of bimammary and traditional coronary bypass surgery in patients with type 2 diabetes mellitus; in the groups using two ITAs for myocardial revascularization, cardiac cause of death was not revealed in any of the cases, which may indicate the high efficacy of this technique of CHD surgical treatment. The use of the bimammary myocardial revascularization technique was associated with complete freedom from major cardiovascular complications. Further analyses of longer-term outcomes will be required to assess the efficacy of bimammary coronary bypass surgery in patients with type 2 DM.

Conflict of interest

The authors of this article declare no conflicts of interest.

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