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Original Scientific Paper

PERCUTANEOUS CORONARY INTERVENTION ON SAPHENOUS VEIN GRAFT IN SECOND GENERATION DRUG ELUTING STENT ERA

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SUMMARY – The aim of the study was to determine major adverse cardiac events (MACE) related to the percutaneous coronary intervention (PCI) on saphenous vein graft (SVG) with a second-generation drug eluting stents in patients with previous coronary artery bypass graft (CABG). The research was conducted as a unicenter retrospective observational study which analyzed consecutive patients of both genders who had PCI on SVG from January 1, 2016 until June 30, 2019. The aim was to investigate the occurrence of MACE defined as development of periprocedural myocardial infarction, acute heart failure in the first 24 hours after PCI, unstable angina after PCI, periprocedural stroke, contrast induced nephropathy, death, acute/subacute/late stent thrombosis, and target lesion revascularization. The study included 97 consecutive patients. MACE was recorded in 20.6% of patients, more often in patients with thrombolysis in myocardial infarction grade flow ≤2. High thrombus burden (HTB) was detected in 44.3% of patients and it significantly contributed to the development of MACE. In conclusion, PCI on SVG is a highly challenging procedure, especially in patients with an acute coronary syndrome. In patients who have HTB recorded in SVG, the usage of thrombus aspiration and distal protection device can reduce the frequency of no-reflow phenomenon and consequential MACE.

Keywords: *Saphenous vein graft; Percutaneous coronary intervention; Major adverse cardiac event; High thrombus burden*

Introduction

The possibility of saphenous vein graft (SVG) malfunction increases as the time from surgical revascularization passes. So far, research has shown that SVG malfunction occurs in 50% of the cases during the 10-year period, whereas it appears in 27% during the first year[1,2]. When compared to native coronary arteries, SVG is by far more susceptible to develop accelerated atherosclerosis due to intimal thickening which is an adaptive response to systemic circulation and surgical preparation of the vein[3]. SVG atherosclerotic lesions are concentric and diffuse with thinner fibrotic cap when compared to native coronary arteries, making them more vulnerable and liable to rupture[4].

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As a result of accelerated atherosclerotic progression in SVG and consequential malfunction, there is a need for repeated revascularization. Percutaneous coronary intervention (PCI) of native coronary artery has an advantage over PCI on SVG or repeated surgical revascularization. Often, PCI on native coronary artery is too complex. Therefore, PCI on SVG is opted for, even though it is considered riskier due to the higher frequency of the no-reflow phenomenon because of distal embolization with debris and thrombus masses from the site of the lesion[2,5].

The aim of the present study was to determine major adverse cardiac events (MACE) related to the PCI on SVG with a second-generation drug eluting stents (DES) in patients with previous coronary artery bypass graft (CABG).

Patients and Methods

The research was conducted as a unicenter retrospective observational study. It included patients of both genders older than 18 years, with previous CABG, who were hospitalized for coronary angiography due to suspicion of coronary artery disease progression, in the period from January 1, 2016 until June 30, 2019. All admitted patients underwent coronary angiography and graft angiography, and the findings showed that native coronary arteries were not adequate for PCI and that there was an indication for percutaneous SVG revascularization. PCI was performed *ad hoc* or as a staged procedure in the same or second elective hospitalization. PCI failure was defined as inability of treating lesions by stent implantation or balloon dilatation.

To assess SVG lesion and PCI characteristics, the following parameters were analyzed: access site, stenosis severity and thrombus burden in SVG, thrombolysis in myocardial infarction (TIMI) flow through SVG, TIMI myocardial perfusion grade (TMPG) both before and after the procedure, usage of a device for distal protection, stent implantation technique (predilatation/direct implantation), thrombus aspiration, and administration of glycoprotein IIb/IIIa inhibitors (GP IIb/IIIa). No-reflow was defined as TIMI flow 0.

All parameters were analyzed by two independent interventional cardiologists from the same high volume PCI center. After the procedure, the patients were followed up for the occurrence of MACE, which were defined as development of periprocedural myocardial infarction (MI), development of acute heart failure in the first 24 hours after PCI, unstable angina after PCI, periprocedural stroke, contrast induced nephropathy (CIN), death, acute/subacute/late stent thrombosis, and target lesion revascularization. Periprocedural complications of access site were followed by the Bleeding Academic Research Consortium (BARC) classification. The patients were tracked one year for the occurrence of MACE. Data on the cohort were acquired from the hospital electronic patient record system.

The study was performed respecting the tenets of the Declaration of Helsinki, and was approved by the local Ethics Committee.

Continuous variables were presented as mean values ± 1 standard deviation, while non-continuous variables were shown as frequencies. The significance between the two groups was determined depending on distribution and data type using Student's t-test, χ^2-test, ANOVA, and Mann-Whitney test. Binary logistic regression analysis was used to analyze relative risk for development of MACE. Cox regression analysis was used for hazard ratio prediction. The level of statistical significance was set at 0.05. Statistical analysis was performed with Statistical Package for Social Sciences version 17.0 (SPSS Inc., Chicago, Illinois, USA).

Results

The study included 97 patients, mean age 68.2±7.8 and 69.1% of males. Cohort characteristics are shown in Table 1. Acute coronary syndrome was detected in 59 (60.8%) patients; it manifested as ST-elevation myocardial infarction (STEMI) in 26 (26.8%), non-ST-elevation myocardial infarction (NSTEMI) in 24 (24.7%), and unstable angina pectoris (UAP) in 12 (12.4%) patients. Urgent coronary angiography was performed in all patients with STEMI (26/97), and in 5 patients with NSTEMI who were unstable. Patients who did not have acute coronary syndrome had elective procedure while 7 (7.2%) patients underwent coronary angiography after more than 72 hours of admission.

Table 1. General characteristics of patient cohort

General characteristic		N=97
Male		67 (69.1%)
Age (years)		68.2±7.8
BMI (kg/m^2)		28.1±4.1
Length of hospital stay (days)		7.3 (4-8)
Time from CABG (years)		12.1±5.8
Prior MI		63 (64.9%)
eCrCl (mL/min)		66.2±27.5
LVEF (%)		46.3±10.7
Heart failure classification at admission	Killip 1	73 (75.3%)
	Killip 2	23 (23.7%)
	Killip 3	1 (1%)
Risk factors	Hypertension	91 (93.8%)
	Diabetes mellitus	38 (39.2%)
	Hyperlipidemia	67 (69.1%)
	Smoking	33 (34%)
	Heredity	44 (45.4%)
HACS	Yes	59 (60.8%)
LIMA	Yes	61 (62.9%)
No. of SVG	1 SVG	14 (14.4%)
	2 SVG	56 (57.8%)
	3 SVG	26 (26.8%)
	4 SVG	1 (1%)
Occluded SVG without culprit	Patent SVG without culprit	42 (43.3%)
	1 occluded	46 (47.4%)
	2 occluded	1 (1%)
Culprit SVG	LAD	19 (19.6%)
	Diagonal	8 (8.2%)
	LCx	36 (37.1%)
	RCA	34 (35.1%)
Invasive strategy	Urgent (<2 h)	31 (32%)
	Early invasive strategy (2-24 h)	7 (7.2%)
	Invasive strategy (24-72 h)	14 (14.4%)
	Elective (>72 h for ACS and elective PCI)	45 (46.4%)

BMI = body mass index; CABG = coronary artery bypass graft; MI = myocardial infarction; eCrCl = estimated creatinine clearance (according to Cockcroft-Gault formula); LVEF = left ventricle ejection fraction; HACS = hospitalization due to acute coronary syndrome; LIMA = left internal mammary artery; SVG = saphenous vein graft; LAD = left anterior descending artery; LCx = left circumflex artery; RCA = right coronary artery

In 55 (56.7%) patients, radial access was used to perform PCI and there was no statistically significant difference compared to femoral access regarding coronary disease presentation (p=0.063). Patients with MI had a significantly higher thrombus burden when compared to elective and UAP patients (p=0.001). Thrombus aspiration was mostly used in patients with STEMI (p=0.028). GP IIb/IIIa inhibitors were used in 80% of patients with STEMI (p<0.0005). On average, 1.4±0.8 of DES were implanted in SVG. Hospital stay was longer in patients who had MI (p=0.034) (Table 2).

In 6 (6.2%) patients, BARC 2 bleeding was recorded regardless of the type of invasive strategy (p=0.48). Retroperitoneal hematoma was recorded in 1 elective patient, whereas hematoma of the access site was recorded in 5 patients. All complications were conservatively treated. All complications were recorded in patients with femoral access (6/42; 14.2%). No-reflow phenomenon during PCI after stent implantation was significantly more often recorded in patients with STEMI (23.1%) and NSTEMI (17.4%) as compared to elective patients, where this phenomenon was recorded in only 2.9% (p=0.039) of cases. No-reflow phenomenon was not recorded in patients with UAP. At the end of the procedure, TIMI flow ≤2 was more often recorded in patients with STEMI (50.0%) and NSTEMI (26.1%) as compared to elective patients (11.4%) and those with UAP (8.3%) (p=0.003).

MACE were more often recorded in patients with no-reflow phenomenon (54.5%) than in patients without no-reflow phenomenon (16.5%) (p=0.009). MACE were more common in patients with TIMI flow ≤2 (37.5%) as compared to those whose TIMI flow was >2 (15.3%) (p=0.039). High thrombus burden (HTB) was detected in 43 (44.3%) patients, and this contributed to the statistically higher number of MACE (14/43; 32.6%) (p=0.012). Filter wire protection was used in 6/43 (14.0%) patients with HTB. There was no significant difference in MACE between patients in whom filter wire was used (2/6; 33.3%) and those in whom filter wire was not used (12/37; 32.4%). HTB patients who were treated with filter wire protection had better TIMI flow and TMPG at the end of the procedure (Table 3), however, without significant difference when compared to patients where filter wire protection was not used (p=0.241). Heart

Table 2. General characteristic of saphenous vein graft PCI

PCI characteristic	Coronary disease type					p value
	Elective	STEMI	NSTEMI	UAP	Sample	
Radial access	19 (54.3%)	12 (46.2%)	13 (54.2%)	11 (91.7%)	55 (56.7%)	0.063
Femoral access	16 (45.7%)	14 (53.8%)	11(45.8%)	1 (8.3%)	42 (43.3%)	
Crossover radial to femoral	8 (22.9%)	2 (7.7%)	2 (8.3%)	1 (8.3%)	13 (13.4%)	0.238
HTB	8 (22.9%)	18 (69.2%)	14 (58.3%)	3 (25%)	43 (44.3%)	0.001
Filter wire	2 (5.7%)	1 (3.8%)	2 (8.3%)	1 (8.3%)	6 (6.2%)	0.909
Predilatation	28 (82.4%)	21 (80.8%)	16 (66.7%)	8 (66.7%)	73 (76%)	0.424
Thrombus aspiration	2 (5.7%)	7 (26.9%)	2 (8.3%)	0 (0%)	11 (11.3%)	0.028
Direct implantation	4 (11.8%)	5 (19.2%)	7 (29.2%)	4 (33.3%)	20 (20.8%)	0.274
Postdilatation	20 (62.5%)	9 (39.1%)	13 (56.5%)	7 (63.6%)	49 (55.1%)	0.331
PCI failure	3 (8.6%)	0 (0%)	2 (8.3%)	0 (0%)	5 (5.2%)	0.525
Amount of contrast (mL)	260 (200-335)	225 (160-270)	220 (155-305)	210 (155-310)	256.49 ±109.73	0.321
Radiation dose (mGy)	801 (546-1294.5)	1121(580-1707)	804 (521.5-1420)	967 (556-1650.5)	923 (551-1500.5)	0.665
GP IIb/IIIa	4(11.8%)	20 (80%)	7 (29.2%)	5(41.7%)	36 (37.9%)	<0.0005
Hospital stay (in days)	5 (4-8)	6 (3-8)	7 (6-9)	4.5 (2-6.5)	6 (4-8)	0.034
Length from CABG (years)	12 (9-14)	10 (7-14)	11 (7.5-16.5)	15 (13.5-19)	12.11 ±5.81	0.023

PCI = percutaneous coronary intervention; STEMI = ST elevated myocardial infarction; NSTEMI = non-ST elevated myocardial infarction; UAP = unstable angina pectoris; GP IIb/IIIa = glycoprotein IIb/IIIa inhibitors; HTB = high thrombus burden; CABG = coronary artery bypass graft

failure after the procedure was more often in patients with STEMI (26.9%) and NSTEMI (16.7%) when compared to elective patients (2.9%) and UAP patients (13.4%) (p=0.047). Intrahospital mortality was 4.1%, while there were no lethal outcomes during the 1-year follow up. During the 1-year follow up, stent thrombosis was more often recorded in patients with STEMI (p=0.038) (Table 3).

Logistic regression analysis yielded several independent predictors of intrahospital MACE. Patients with HTB had a 4 times higher risk of MACE (odds ratio (OR) 3.86; 95% confidence interval (CI) 1.35-11.17; p=0.013). Increasing TMPG value by 1 reduced the risk of MACE by 44% (OR 0.56; 95% CI 0.34-0.93; p=0.024). No-reflow phenomenon during the procedure increased the risk of MACE 6 times (OR 6.09; 95% CI 1.63-22.74; p=0.007). Patients who had TIMI ≤2 at the end of the procedure had an almost 3.5 times higher risk of MACE (OR 3.33; 95% CI 1.69-9.48; p=0.024). Cox regression analysis indicated that TMPG at the end of PCI affected MACE (p=0.003). TMPG hazard ratio after PCI was 0.493 (0.31-0.78). Increasing TMPG by 1 after PCI lowered the risk of MACE by 51%.

Discussion

Coronary artery bypass graft success depends on long-term patency of arterial and venous grafts. In the majority of patients, left internal mammary artery (LIMA) is used for left anterior descending artery revascularization, whereas SVG is mostly used for revascularization of other coronary arteries. Various

Table 3. Distribution of MACE according to coronary disease type and TIMI flow, and TMPG after PCI according to usage of filter wire protection

PCI characteristic	Coronary disease type					p value
	Elective	STEMI	NSTEMI	UAP	Sample	
MACE	6 (17.1%)	8 (30.8%)	5 (20.8%)	1 (8.3%)	20 (20.6%)	0.391
Periprocedural MI	3 (8.6%)	0 (0%)	1 (4.2%)	0 (0%)	4 (4.1%)	0.336
UAP after PCI	0 (0%)	0 (0%)	1 (4.2%)	0 (0%)	1 (1%)	0.380
Heart failure after PCI	1 (2.9%)	7 (26.9%)	4 (16.7%)	1 (8.3%)	13 (13.4%)	0.047
Intrahospital death	0 (0%)	3 (11.5%)	1 (4.2%)	0 (0%)	4 (4.1%)	0.131
CIN	1 (2.9%)	3 (11.5%)	0 (0%)	0 (0%)	4 (4.1%)	0.151
CIN and CVVHDF	0 (0%)	2 (7.7%)	0 (0%)	0 (0%)	2 (2.1%)	0.753
Intrahospital stent thrombosis	0 (0%)	1 (3.8%)	0 (0%)	0 (0%)	1 (1%)	0.480
Stent thrombosis during 1-year follow-up	0 (0%)	3 (11.5%)	0 (0%)	0 (0%)	3 (3.1%)	0.038
Re-PCI on SVG (TLR)	2 (5.7%)	2 (8.7%)	2 (9.1%)	0 (0%)	6 (6.5%)	0.731
Filter wire	TIMI flow after PCI in patients with HTB					
	TIMI 0	TIMI 1	TIMI 2	TIMI 3		
Without fw protection	5 (13.5%)	7 (18.9%)	10 (27%)	15 (40.5%)		0.241
With fw protection	0 (0%)	0 (0%)	1 (16.7%)	5 (83.3%)		
	TMPG after PCI in patients with HTB					
	TMPG 0	TMPG 1	TMPG 2	TMPG 3		
Without fw protection	5 (13.5%)	7 (18.9%)	11 (29.7%)	14 (37.8%)		0.197
With fw protection	0 (0%)	0 (0%)	1 (16.7%)	5 (83.3%)		

MACE = major adverse cardiac events; STEMI = ST elevated myocardial infarction; NSTEMI = non-ST elevated myocardial infarction; UAP = unstable angina pectoris; MI = myocardial infarction; PCI = percutaneous coronary intervention; CIN = contrast induced nephropathy; CVVHDF = continuous venovenous hemodiafiltration; SVG = saphenous vein graft; HTB = high thrombus burden; TLR = target lesion revascularization; TIMI flow = thrombolysis in myocardial infarction flow; TMPG = TIMI myocardial perfusion grade; fw = filter wire

studies examined long-term SVG patency, and the results showed that almost 50% of these grafts occluded in the period of 10 years after the surgery. In that period, LIMA patency is 90%-95%[1,2]. In current practice, almost 80% of grafts which are used for revascularization are SVG mainly because they are easier to prepare and use in revascularization[6].

When it comes to SVG malfunction, there is a dilemma whether to apply CABG re-surgery or try recanalization with PCI. Patient subgroup analysis from AWSOME study and register showed that patients that were referred to a CABG re-do had a significantly higher periprocedural mortality rate when compared to patients with PCI[7]. In patients who present with acute coronary syndrome triggered by culprit lesions on SVG, revascularization of native coronary artery is always the first option, and if this is not feasible or there is a high risk, the culprit lesion on SVG is revascularized[1,2]. Re-do CABG is shown to be very risky with a 2 to 4 times higher mortality rate and consequently, today, is rarely used in practice and PCI is preferred[8,9]. It is important to emphasize that up-to-date research implies that PCI on SVG is a riskier procedure in contrast to PCI on native vessels.

Pucelikova *et al.* recorded a high percentage of MACE during 1-year follow-up. The percentage

of death, MI and repeated revascularization was high, 30.5%[10]. In our study, almost one third of the patients had urgent coronary angiography to achieve fast reperfusion. MACE occurrence was high and it was 20.5%. In their research, Welsh *et al.* compared the characteristics of 128 patients with MI and prior CABG with 5,617 patients without prior CABG. They report that CABG patients with culprit lesion on SVG had a higher mortality rate within 90 days after coronary event (11.9% *vs.* 4.6%)[11]. In our study, 4 patients died, i.e., 4.1% of the sample. It is important to emphasize that all lethal outcomes were recorded in patients with MI, with the mortality rate of 8%. Intrahospital mortality was higher in STEMI patients (11.5%) when compared to NSTEMI patients (4.2%). PCI on SVG correlates with a higher periprocedural complication rate mainly because of the higher possibility of distal embolization of atheroma debris, which can lead to no-reflow phenomenon and periprocedural MI[12,13].

In their meta-analysis of 22 observational studies, Farag *et al.* compared PCI on SVG and PCI on native coronary arteries. They concluded that PCI on native coronary artery had less MACE, all mortality causes, MI, and target vessel revascularizations[14]. Paul *et al.* published the biggest meta-analysis which was focused on the efficiency of a distal protection device. This analysis included 52,893 patients and showed that MACE rate and all mortality causes were even irrespective of the use of a distal protection device[15]. According to the latest ESC guidelines for myocardial revascularization, usage of distal protection device is downgraded to class IIa from class I[8]. Nonetheless, distal protection device prevents microembolization and can be useful in patients with HTB. In our research, FilterWire EZ (Boston Scientific, USA) was used for distal protection in 6/97 (6.2%) patients. The usage of filter wire protection did not show huge benefit in intrahospital adverse event prevention. Filter wire was exclusively used in patients with HTB, 6/43 (14%). Even though there was no difference in the MACE rate, it was noticed that when filter wire was used there was no-reflow phenomenon or TIMI <2 detected, whereas TMPG was higher.

The TOTAL study showed the presence of HTB in native coronary vessels in STEMI patients to be an independent predictor of fatal outcome[16]. The presence of HTB in SVG is not rare and it is challenging to treat. The most commonly used techniques during PCI for high thrombus burden are thrombus aspiration and/or distal protection, as well as a combination of the two. All of these methods have their pros and cons. One of the risks that might occur when thrombus aspiration is used is cerebrovascular insult, and when it comes to distal protection, it is sometimes challenging to remove the device from SVG, which can compromise implanted stent[15-17]. In our study, 44.3% of the patients had HTB; HTB was more frequent in patients with STEMI (69.2%) and NSTEMI (58.3%) when compared to elective patients (22.9%) and those with UAP (25%). The treatment of these patients was more demanding considering the higher usage of thrombus aspiration and distal protection device, as well as the high presence of GP IIb/IIIa inhibitors, which were administered to 80% of STEMI patients. It was observed that the presence of HTB caused a 4 times higher risk of MACE, whereas no-reflow phenomenon during the procedure caused 6 times higher risk of MACE.

In conclusion, PCI on SVG is a highly challenging procedure, especially in patients with acute coronary syndrome. Very often, PCI on SVG is the only possible way to restore fast reperfusion in the infarcted area. In patients who have HTB recorded in SVG, the usage of thrombus aspiration and distal protection device can reduce the frequency of no-reflow phenomenon and consequential MACE.

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Sažetak

PERKUTANA KORONARNA INTERVENCIJA NA GRAFTU VENE SAFENE U ERI LIJEKOM OBLOŽENIH STENTOVA DRUGE GENERACIJE

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Cilj ove studije bio je utvrditi velike neželjene srčane događaje (MACE) povezane s perkutanom koronarnom intervencijom (PCI) na graftu vene safene (SVG) s drugom generacijom lijekom obloženih stentova kod bolesnika s prethodnom operacijom koronarne premosnice (CABG). Istraživanje je provedeno kao retrospektivna opservacijska studija u jednom centru, koja je analizirala uzastopne bolesnike obaju spolova kojima je izvedena PCI na SVG od 1. siječnja 2016. do 30. lipnja 2019. godine. Studija je istraživala pojavu MACE definirane kao razvoj periproceduralnog infarkta miokarda, akutna srčana insuficijencija unutar prvih 24 sata nakon PCI, nestabilna angina nakon PCI, periproceduralni moždani udar, kontrastom izazvana nefropatija, smrt, akutna/subakutna/kasna tromboza stenta i revaskularizacija ciljne lezije. Studija je uključila 97 uzastopnih bolesnika. MACE je utvrđen kod 20,6% bolesnika, češće u bolesnika s TIMI protokom ≤2. Visok rizik od tromba (HTB) utvrđen je kod 44,3% bolesnika i značajno je doprinosio razvoju MACE. U zaključku, PCI na SVG je veoma izazovan zahvat, naročito kod bolesnika s akutnim koronarnim sindromom. Kod bolesnika koji imaju utvrđen HTB na SVG primjena aspiracije tromba i uređaja za distalnu zaštitu može smanjiti učestalost fenomena *no-reflow* i posljedičnih MACE.

Ključne riječi: *Presadak vene safene; Perkutana koronarna intervencija; Veliki neželjeni srčani događaji; Visok rizik od tromba*