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SHORT- AND LONG-TERM OUTCOMES OF PERCUTANEOUS CORONARY INTERVENTIONS OF HIGH-RISK VS. LOW-RISK LESIONS PERFORMED AT A HOSPITAL WITHOUT AN ON-SITE CARDIAC SURGERY UNIT

<i>Aim</i>	Widespread utilization of technology has led to the construction of a growing number of facilities with coronary angiography units and percutaneous coronary intervention (PCI) capability. Some of these centers do not have cardiovascular surgery (CVS) on site. Studies regarding the efficacy and safety of PCIs performed at these hospitals have been conducted. However, to date, high-risk procedures in this context have not been evaluated. The present study compares the outcomes of PCI procedures performed on high- and low-risk lesions groups in a center without CVS back-up.
<i>Material and methods</i>	A total of 999 patients treated with PCI with diagnoses other than ST elevation myocardial infarction were included in this study. Patients with SYNTAX scores 22 or higher, bifurcation lesions, chronic total occlusions, left main coronary artery lesions and saphenous graft lesions were classified as a high-risk group. In contrast, patients with SYNTAX scores lower than 22 were included in the low-risk group. Coronary lesions were classified as Type-A, B, and C. The 30-day major adverse cardiac events (MACE) and 1-year target vessel revascularization (TVR) rates were compared.
<i>Results</i>	There was no significant difference between the groups in terms of the rates of MACE (2 (0.9%) vs 5 (0.6%); p=0.64) and TVR (9 (4.2%) vs 25 (3.2%); p=0.52). Analysis regarding the lesion type also revealed no significant difference between the MACE and TVR rates (p=0.56 and p=0.43, respectively).
<i>Conclusions</i>	The findings in this study demonstrated that, similar to low-risk procedures, complex and high-risk coronary interventions can safely and effectively be conducted in hospitals without a CVS unit.
<i>Keywords</i>	Coronary artery disease; percutaneous coronary intervention; non-ST-elevated myocardial infarction
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Introduction

Percutaneous coronary intervention (PCI) has become the prime modality for the treatment of coronary artery disease (CAD). PCI for ST-segment elevation myocardial infarction (STEMI) patients in centers with or without surgical support is recommended by current guidelines. However, there are no clear recommendations of PCI for patients presenting with non-STEMI (NSTEMI) acute coronary syndrome (ACS) in centers without surgical support [1–3].

Guidelines have stated that centers performing less than 200 cardiovascular surgery (CVS) procedures a year might have worse CVS outcomes [3]. A growing number of hospitals with catheterization labs and an on-site surgery unit have been established. Establishing angiography and CVS units is both expensive and require educated staff. Some

centers do not have CVS capability. Some centers have CVS capability, but CVS procedures are not performed because the necessary number of CVS procedures is not reached.

These situations raise the question, “Should PCI for patients suffering ACS without STEMI be conducted in centers that lack CVS backup?” According to the guidelines of the American Heart Association/American College of Cardiology (AHA/ACC), PCI for the treatment of patients with STEMI is recommended in all hospitals with angiography units. For ACS patients without STEMI diagnosis, this recommendation is for those with class 2B heart failure [4, 5]. The Myocardial Revascularization Guideline of ESC has a specific recommendation for angiographic procedures performed at institutions without an on-site cardiac surgery unit, which states, “Procedures must be carried out in collaboration with hospitals that have CVS units” [3].

Evaluation of PCI, short and long-term mortality, and 1-year target vessel revascularization (TVR) rates in patients without a diagnosis of STEMI were performed in the MASS COMM, and CPORT-E trials. In terms of safety and efficacy, PCI procedures for patients without STEMI diagnosis performed in institutions without on-site CVS units were found to be not inferior to those performed at hospitals with on-site CVS units [6, 7]. However, in previous studies, patients considered to have high-risk lesions were excluded by the investigators, and their procedures were performed in institutions with on-site CVS units [7]. Hence, there has been no absolute consensus for examining this group of patients. Therefore, there has been a paucity of data on the safety and efficacy of PCI procedures performed on patients with high-risk lesions in hospitals without on-site CVS units.

The current study aimed to compare the efficacy and safety PCI procedures for high-risk lesions vs those for low-complex lesions when performed at an institution without on-site a CVS unit for NSTEMI ACS patients relative to the patients' risk profiles.

Material and methods

All study procedures involving human participants were in accordance with the ethical standards of the institutional and national research committees and with the 1975 Helsinki declaration and its later amendments or with comparable ethical standards.

This study was designed as a retrospective, single-center study. We do not have a CVS unit on-site, and the nearest such facility is approximately 200 km distant. On average, more than 1,000 coronary angiograms are performed annually, with all cardiologists performing at least 100 procedures per year. Required permissions were obtained from The Ministry of Health and were in accordance with the ESC guideline recommendations. All procedures were performed in collaboration with an institute that has a CVS unit on-site.

Patients treated between 2016 and 2020 by PCI with diagnoses other than STEMI were included. The majority (>80%) of the procedures were performed via the femoral route. After ticagrelor or prasugrel loading doses had been given to patients presenting with ACS, maintenance therapy was continued for 1 yr. For the patients who presented with stable angina pectoris (SAP), maintenance treatment was continued in the same way for 1 yr after the clopidogrel loading dose. Acetylsalicylic acid was added to the treatment of both groups.

The decision for referral to surgery for coronary artery bypass graph (CABG) and the SYnergy between percutaneous coronary intervention with TAXus and cardiac surgery (SYNTAX) score calculation [8, 9] were performed and recorded by two experienced cardiologists.

Patients were classified according to their age, gender, clinical presentation, procedures performed, SYNTAX score, and lesion characteristics. 30-day mortality, stent thrombosis, and complications requiring surgical intervention, i.e., 30-day major adverse cardiac events (MACE), were identified as safety endpoints. The efficacy endpoint of the study was determined as indication for reintervention of the same artery for 1 yr, also called 1-year target vessel revascularization (TVR).

The patients were subdivided according to the SYNTAX scores and lesion characteristics. Patients with SYNTAX scores 22 and higher, bifurcation procedures requiring double stent techniques, chronic totally occluded lesions (CTO), left main coronary artery lesions, and saphenous graft lesions were classified as the high-risk, primary group (Group 1). In contrast, the participants who had SYNTAX scores lower than 22 and no high-risk criteria constituted the low-risk, secondary group (Group 2). Additionally, lesions were classified as Type A, B (B1, B2), and C with regard to lesion characteristics and in coherence with the ACC/AHA guideline recommendations [10].

Categorical variables between the two groups were compared using the Chi-square and Fischer's exact tests. These data were represented as numbers and percentages. The t-test was used to evaluate differences among normally distributed, continuous variables, and the Mann-Whitney-U test was used for variables with non-normal distributions. Data with normal distributions are presented as mean±SD, whereas data with non-normal distributions are presented as median and interquartile range (IQR). Univariate logistic regression analysis was performed for all contributing factors that may have an effect on the 1-year TVR rate. Variables with p value <0.1 after univariate analysis were subjected to multivariate regression analysis. These results were summarized by the odds ratio and 95% confidence interval.

Results

999 patients were found eligible for the study after excluding those with STEMI, cardiogenic shock, cardiac arrest, and those that could not be contacted. The mean age of the patients was 61.7±11.5. There were 716 (71.6%) male and 283 (28.3%) female participants. Regarding the diagnosis, 669 (67%) patients had NSTEMI, and 330 (33%) had SAP. The median SYNTAX score was 9 (6–15). The distribution of culprit lesions as related to lesion type was: type-A lesion, 146 (14.6%); type-B, 392 (39.2%); type-C, 461 (46.1%). 28 (2.8%) of the patients had 3-vessel disease. The number of ad hoc PCIs was 839 (84%) for a single vessel, 148 (14.8%) for two vessels, and 12 (1.2%) for three vessels. Bare-metal stents (BMS) were implanted in 77 (7.7%) patients, whereas 919 (92%) were treated

Table 1. Comparison of demographic, angiographic, and follow-up data

Variable	Total patients	Group 1	Group 2	p value
Number of patients	999	214	785	
Age	61.7±11.5	64.9±10.9	60.8±11.5	<0.001
Male gender	716 (71.6%)	152 (71%)	564 (71.8%)	0.86
NSTEMI diagnosis at presentation	669 (67%)	149 (69.6%)	520 (66.2%)	0.36
History of CAD	320 (32%)	101 (47.2%)	219 (27.9%)	<0.001
3-vessel disease	28 (2.8%)	7 (3.3%)	21 (2.7%)	0.64
SYNTAX score	9 (6–15)	24 (22.50–28)	9 (5–12)	<0.001
Lesion type	A: 146 (14.6%); B: 392 (39.2%); C: 461 (46.1%)	A: 10 (4.7%); B: 51 (23.8%); C: 153 (71.8%)	A: 136 (17.3%); B: 341 (43.4%); C: 308 (39.2%)	<0.001
Number of arteries intervened during the same procedure	1: 839 (84%); 2: 148 (14.8%); 3: 12 (1.2%)	1: 140 (65.4%); 2: 65 (30.4%); 3: 9 (4.2%)	1: 699 (89%); 2: 83 (10.6%); 3: 3 (0.4%)	<0.001
Number of DES	919 (92%)	190 (88.8%)	729 (93.2%)	0.04
30-day MACE	7 (0.7%)	2 (0.9%)	5 (0.6%)	0.64
1-year TVR	34 (3.4%)	9 (4.2%)	25 (3.2%)	0.52

Data are mean±SD, number (percentage), or median (interquartile range). BMS, bare-metal stent; CAD, coronary artery disease; DES, drug-eluting stent; MACE, major adverse cardiac event; NSTEMI, non-ST segment elevation myocardial infarction; SAP, stable angina pectoris; TVR, target vessel revascularization.

Table 2. Other factors that potentially contributed to 30-day MACE and 1-year TVR rates

Parameter	30-day MACE	p value	1-year TVR	p value
Type-A lesion	2 (1.4%)	0.27	3 (2.1%)	0.24
Type-B lesion	2 (0.05%)	0.43	12 (3.1%)	0.38
Type-C lesion	3 (0.07%)	0.58	19 (4.1%)	0.16
DES	1 (1.3%)	0.43	7 (9.1%)	0.01
BMS				

DES, drug-eluting stent; BMS, bare metal stent.

with drug-eluting stents (DES) and 3 (0.3%) with balloon only angioplasty. A 30-day MACE occurred in 7 (0.7%) patients; a 1-year TVR was performed in 34 (3.4%) patients. Angiographic, demographic, and follow-up data of all patients are summarized in Table 1.

The patients were subdivided according to their risk profile. Mean age (64.9±10.9 vs 60.8±11.5; p<0.001) and history of coronary artery disease (101 (47.2%) vs 219 (27.9%); p<0.001) were significantly higher in the high-risk group. Patients in the high-risk group had more complex lesion features than low-risk group. For the high-risk group,

the lesion types included: A, 10 (4.7%); B, 51 (23.8%); C, 153 (71.8%) vs A, 136 (17.3%); B, 341 (43.4%); C, 308 (39.2%) for the low risk group, for all types p<0.001). The rate of DES implantation (190 (88.8%) vs 729 (93.2%); p=0.04) and the number of coronary arteries intervened during a single procedure (1, 140 (65.4%); 2, 65 (30.4%); 3, 9 (4.2%) vs 1, 699 (89%); 2, 83 (10.6%), 3, 3 (0.4%), respectively, for all p<0.001) were significantly higher in the group of high-risk patients. There was no significant difference between the groups regarding the 30-day MACE rate (2 (0.9%) vs 5 (0.6%); p=0.64) and the 1-year TVR rate (9 (4.2%) vs 25 (3.2%); p=0.52). These results are summarized in Table 1.

Analysis of all patients revealed no significant correlation between 30-day MACE rate or the 1-year TVR rate and culprit lesion types (p=0.56 and p=0.43, respectively). Although the rate of 30-day MACE did not significantly differ regarding the stent type used, the 1-year TVR rate was significantly higher in BMS patients compared to the DES group (DES, 27 (2.9%) vs BMS, 7 (9.1%); p=0.01). Table 2 summarizes other factors that potentially contributed to 30-day MACE and 1-year TVR rates.

30-day MACE and TVR rates were similar regarding the clinical presentation of the patients (p=0.43 and p=0.85, respectively). In the comparison of the NSTEMI and SAP groups, CTO and PCI (NSTEMI, 0.6% vs SAP, 3.3%; p=0.002) and history of CAD (NSTEMI, 27.7% vs SAP, 40.9%; p<0.001) were higher in patients in the SAP group.

Table 3. Comparisons regarding the clinical presentation

Variable	NSTEMI	SAP	p value
Number of patients	669 (67%)	330 (33%)	-
Male gender	473 (70.7%)	243 (73.6%)	0.18
SYNTAX Score	10 (6-16)	8 (5-13.25)	< 0.001
Number of vessels PCI on the same procedure	1: 559 (83.6%); 2: 100 (14.9%); 3: 10 (1.5%)	1: 280 (84.8%); 2: 48 (14.5%); 3: 2 (0.6%)	0.46; 0.42; 0.42
CAD history	185 (27.7%)	135 (40.9%)	< 0.001
Bifurcation lesions	27 (4%)	16 (4.8%)	0.32
CTO PCI	4 (0.6%)	11 (3.3%)	0.002
CABG history	46 (6.9%)	17 (5.2%)	0.18
Type-A lesion	92 (13.8%)	54 (16.4%)	0.15
Type-B lesion	270 (40.4%)	122 (37%)	0.16
Type-C lesion	307 (45.9%)	154 (46.7%)	0.43
3-vessel disease	18 (2.7%)	10 (3%)	0.45
DES	624 (93.3%)	295 (89.4%)	0.08
Group 1 (high-risk)	149 (22.3%)	65 (19.7%)	0.19
30-day MACE	6 (0.9%)	1 (0.3%)	0.43
1-year TVR	22 (3.3%)	12 (3.6%)	0.85

Data are number (percentage). CABG, coronary artery bypass graft; CAD, coronary artery disease; CTO, chronic totally occluded lesion; DES, drug-eluting stent; MACE, major adverse cardiac event; PCI, percutaneous coronary intervention; TVR, target vessel revascularization.

Table 4. Univariate and multivariate regression analysis for 1-year TVR

Parameters	Univariate analysis			Multivariate analysis		
	Odds ratio	%95 CI	p value	Odds ratio	%95 CI	p value
Age	1.003	0.974–1.034	0.82	-	-	-
Gender	1.101	0.508–2.390	0.80	-	-	-
Clinic on admission	0.901	0.440–1.844	0.77	-	-	-
Number of vessels PCI	2.018	1.063–3.830	0.03	1.372	0.615–3.060	0.44
CAD history	0.754	0.372–1.525	0.43	-	-	-
Bifurcation lesions	3.166	1.063–9.429	0.03	2.063	0.567–7.502	0.27
CABG history	1.080	0.253–4.611	0.91	-	-	-
A type lesion	0.556	0.168–1.844	0.33	-	-	-
B type lesion	0.840	0.411–1.717	0.63	-	-	-
C type lesion	1.499	0.753–2.984	0.24	-	-	-
Group (high-risk vs low risk lesions)	1.335	0.613–2.904	0.46	-	-	-
SYNTAX score	1.039	0.997–1.082	0.06	1.022	0.979–1.066	0.32
BMS	3.304	1.389–7.855	0.007	3.996	1.660–9.621	0.002

BMS, bare metal stent; CABG, coronary artery bypass graft; CI, confidence interval PCI, percutaneous coronary intervention.

The SYNTAX score was higher in the NSTEMI group. No statistical difference was detected between the other factors (Table 3).

The regression analyzes of the factors that may affect 1-year TVR showed that BMS stenting improved the 1-year TVR rate. The results of univariate and multivariate regression analyzes are summarized in Table 4.

Discussion

The effects of PCI on 30-day MACE and 1-year TVR rates, stated as the purpose of the study, were found similar between the groups. At this point, we consider high-risk procedures safe and effective, as is low-risk PCI in a center without CVS capability. The sub-analysis regarding lesion characteristics demonstrated no significant difference for

30-day MACE and 1-year TVR rates. Members of the high-risk group were older and had more type-C lesions compared to the low-risk patients. The stent type used in PCI directly correlated with the 1-year TVR.

No scoring system for lesion characteristics and procedural risks was used in previous trials. However, naturally it was considered that the results were related to the lesion type intervened and to the procedural risk. The dominance of male patients in the general patient population was accepted as a normal consequence, considering that male gender is a risk factor for CAD. The number of patients with 3-vessel disease was lower than in other studies e.g., 28% in the CPORT-E study. Direct comparison with those studies is challenging since SYNTAX scores were not provided. The number of patients who underwent coronary angiography and were referred to surgery during the study period was 156, and the mean SYNTAX score of this group was 29.01 ± 7.54 . SYNTAX scores of the patients indicated that guideline-directed, accurate decisions had been made [1, 2]. The majority of patients underwent ad hoc single vessel PCI (84%); 14.8% received two-vessel PCI, and 1.2% underwent 3-vessel PCI. The rate of ad hoc PCI for multiple vessels was 16% in the current trial, 21% in the CPORT-E trial, and 15.7% in the MASS COMM trial [6, 7].

Seventy-seven (7.7%) patients were treated with BMS, and all the lesions treated with BMS had diameters ≥ 3.5 mm. A higher rate of TVR was indicated for patients treated with BMS (BMS, 9.1%; DES, 2.9%;, $p=0.01$). The rate of BMS was lower compared to previous studies, i.e., 19.9% in CPORT-E and 32.6% in MASS COMM trials. Steinberg et al. compared BMS and DES implantation for arteries ≥ 3.5 mm in diameter and found no difference in short-term MACE and 1-year TVR rates (8.5% and 7.7%, respectively; $p=0.80$) [11]. However, according to the results of a meta-analysis of three previous trials that compared second-generation DES and BMS for vessels >3.5 mm in diameter, the second-generation DES was found to be superior in terms of the 1-year TVR rate [12]. Similar results were achieved in our study from routine second-generation DES implantation.

MACE rates of all patient groups were found to be lower than in previous studies. i.e., 0.7% in this study. 12.1% in the CPORT-E trial, 9.5% in the MASS COMM trial. 1-year TVR rates were 3.4% in our study, 6.1% in the CPORT-E trial, 5.6% in the MASS COMM trial [6, 7].

30-day MACE and TVR rates were similar with regard to the clinical presentation of the patients. However, NSTEMI-ACS is a risk factor for mortality. When this situation was examined, in the group that underwent PCI, only 6 (0.3%) of the NSTEMI patients and 1 (0.9%) SAP patient experienced a 30-day MACE. One reason why 30-day mace was similar for NSTEMI and SAP may be that a small number of patients had MACE. One of the reasons for the similar MACE and TVR rates in patients with ACS and SAP may have been due to new antithrombotic drugs, such as ticagrelor and prasugrel.

Group analyses demonstrated a significantly higher mean age of the high risk group, which was related to higher rates of CAD prevalence and significance with increasing age. The incidence of type C lesions was greater in the high-risk group, and this could be interpreted as evidence that the severity of CAD augments the complexity of the lesions. Another contributing factor might be the inclusion of CABG graft interventions in this group. Likewise, the number of patients who underwent multivessel PCI was higher in the high-risk group, and this was considered to be the result of diffuse arterial disease. Both patient groups had similar outcomes regarding the 30-day MACE and 1-year TVR rates. Thus, we conclude that these results support the thesis that high-risk PCI procedures, as with low-risk procedures, can safely be conducted in institutions without an on-site cardiac surgery unit.

Conclusions

Outcomes of high-risk PCI interventions were similar to those of low-risk PCI interventions. Therefore, the possibility for the safe, effective utilization of complex, high-risk PCI procedures in institutions without cardiac surgery backup is supported by this study.

Limitations

This was a cross-sectional and single center study. We were not able to use optical coherence tomography or intravascular ultrasound at our center. These tests may have further explained the stent site.

No conflict of interest is reported.

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