

Comparison of Clinical Outcomes in Patients Who Underwent Bare Metal Coronary Stenting Versus Coronary By-pass Surgery

Koroner Baypas Cerrahisi ve Çıplak Metal Stent Uygulanan Hastaların Klinik Sonlanımlarının Karşılaştırılması

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ABSTRACT

Introduction: We aimed to compare the effects of coronary lesion complexity assessed by SYNTAX (Sx) score on the clinical outcomes in patients who have received BMS versus undergone coronary bypass grafting.

Patients and Methods: Our study population consisted of 459 consecutive patients received bare metal stents (n= 265) or coronary bypass grafting (n= 294). The complexity of coronary artery disease was assessed by Sx score. Sx score was classified as tertiles, as follows: low Sx score (≤ 22), intermediate Sx score (23-32) and high Sx score (≥ 33).

Results: Throughout the study, the intermediate-term incidence of any revascularization was significantly higher in the percutaneous coronary intervention group compared with the coronary bypass grafting group for both overall group and Sx tertiles. The intermediate-term incidence of death from any cause was comparable between the treatment groups in patients with low and intermediate Sx tertiles. However, in patients with high Sx tertile, the intermediate-term incidence of death from any cause was significantly higher in percutaneous coronary intervention group compared with coronary bypass grafting group. In the overall population, adjusted [hazard ratio, 95% CI: 0.88 (0.38-2.05), $p= 0.780$] risks for death from any cause were consistently comparable between percutaneous coronary intervention and coronary bypass grafting, whereas adjusted [hazard ratio, 95% CI: 0.12 (0.05-0.30), $p < 0.001$] risks for any revascularization were consistently significantly higher in the percutaneous coronary intervention group compared with coronary bypass grafting group.

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Conclusion: Coronary lesion complexity assessed by SYNTAX score was closely associated with the higher incidence of any revascularization and in high SYNTAX score, with higher incidence of death from any cause in patients received bare metal stents than coronary artery bypass grafting.

Key words: Coronary artery bypass; stents; percutaneous coronary intervention.

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ÖZET

Giriş: Biz bu çalışmamızda, koroner baypas greftleme cerrahisi ile çıplak metal stent uygulanmış hastalarda SYNTAX (Sx) skoru ile değerlendirilen koroner lezyon kompleksitelerinin klinik sonuçları üzerine etkisini incelemeyi amaçladık.

Hastalar ve Yöntem: Çalışma grubumuz çıplak metal stent uygulanmış (n= 265) ve koroner baypas cerrahisine giden (n= 294) 459 hastadan oluşmaktadır. Koroner arter hastalığı kompleksitesi Sx skoru ile değerlendirilmiştir. Sx skoru, hafif Sx skoru (≤ 22), orta Sx skoru (23-32) ve yüksek Sx skoru (≥ 33) olmak üzere üç gruba ayrılmıştır.

Bulgular: Çalışma süresince orta dönem takipte herhangi bir nedenle revaskülarizasyon sıklığı hem tüm grupta hem de Sx alt gruplarında perkütan koroner girişim uygulanan hastalarda koroner baypas cerrahisine giden hastalara göre daha fazladır. Orta dönem takipte herhangi bir nedenden ölüm sıklığı düşük ve orta Sx gruplarında tedavi grupları arasında benzer bulunmuştur. Ancak yüksek Sx skoru grubunda orta dönem takipte herhangi bir nedenden ölüm sıklığı perkütan koroner girişim uygulanan hastalarda koroner baypas cerrahisine giden hastalara göre daha fazladır. Tüm popülasyonda herhangi bir nedenden dolayı ölüm için düzeltilmiş risk perkütan koroner girişim ve koroner baypas cerrahisi arasında benzerken [hazard ratio, %95 GA: 0.88 (0.38-2.05), p= 0.780], herhangi bir nedenle revaskülarizasyon için düzeltilmiş risk koroner baypas cerrahisi grubuna göre perkütan koroner girişim grubunda belirgin olarak daha fazlaydı [hazard ratio, %95 GA: 0.12 (0.05-0.30), p< 0.001].

Sonuç: Sx skoru ile değerlendirilen koroner lezyon kompleksitesi herhangi bir nedenle revaskülarizasyon sıklığı ile daha yakın ilişkilidir. Yüksek Sx skoru grubunda herhangi bir nedenden ölüm çıplak metal stent uygulanan hastalarda koroner baypas cerrahisine giden hastalara göre daha fazlaydı.

Anahtar Kelimeler: Koroner arter baypas; stentler; perkütan koroner girişim.

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INTRODUCTION

Contemporary treatment guidelines recommend coronary artery bypass grafting (CABG) as the treatment of choice for patients with a complex coronary artery disease (CAD), such as multi vessel disease or left main coronary disease^(1,2). However, recent improvements in revascularization technology, especially in areas involving drug eluting stents (DES) and operation techniques, increase the role of revascularization in the management of complex CAD⁽³⁻⁵⁾. A better understanding of coronary lesion anatomy and the development of percutaneous and surgical techniques, accordingly, lead to the improvement of long-term morbidity and mortality of complex CAD^(1,2).

In the last decade, many randomized controlled trials, comparing CABG versus percutaneous coronary intervention (PCI) using bare metal stents (BMS) or DES for long-term prognosis of CAD, were conducted. Long-term outcome studies comparing CABG versus PCI using both BMS and DES revealed that there were no significant differences regarding death or composite death, stroke and myocardial infarction, higher incidence of any revascularization in PCI (both DES and BMS) versus CABG were observed clearly⁽⁶⁻¹¹⁾. After

SYNTAX (Sx-Synergy between Taxus and Cardiac Surgery) trial, in many comparative studies, almost all of them DES versus CABG studies, long-term outcome, based on coronary lesions anatomy by Sx score, were studied⁽¹²⁻¹⁶⁾.

However, there is no study related to how coronary anatomy assessed by Sx score affects the clinical outcomes in patients who have undergone CABG or who have received BMS. Therefore, in this study, we aimed to investigate the relation of coronary anatomy assessed by Sx score with intermediate-term adverse outcomes in patients who underwent PCI using BMS or CABG.

PATIENTS and METHODS

Study Population

From March 2009 to August 2010, 559 consecutive patients undergoing PCI using BMS (n= 265) or CABG (n= 294) in our hospital were enrolled in our study, retrospectively. Patients who had prior history of CABG and PCI, those who underwent concomitant valvular surgery, who had ST-segment elevation myocardial infarction, those who underwent to emergent CABG due to PCI complication or who were treated with cardiogenic shock were excluded

from the study. Besides, the patients in whom clinical outcome could not be reached were excluded. The study was approved by our local ethic committee.

Procedural Characteristics

The physician determined the treatment choice as a PCI or CABG, after taking into account the patients' clinical and angiographic characteristics. The PCIs were performed, according to standard techniques, by experienced interventionalists. Surgical revascularization was performed using standard bypass techniques.

Definitions and Follow-Up

The clinical endpoints of our study were death from any cause or any revascularization. Revascularization was defined as any revascularization procedure performed on coronary arteries. Clinical follow-up was conducted by phone or by clinical office visit led by independent researcher who was unaware of the data of the study.

SYNTAX (Sx) Score

The Sx score is an angiographic tool used in grading the complexity of CAD. Each coronary lesion with a diameter stenosis $\geq 50\%$, in vessels ≥ 1.5 mm, must be scored. The online latest updated version (2.03) was used in the calculation of the Sx scores (www.syntaxscore.com). The Sx score was classified as tertiles: low Sx score (≤ 22), intermediate Sx score (23-32) and high Sx score (≥ 33). All angiographic variables of the Sx score were computed by two experienced cardiologists (MK, AK) who were blinded to procedural data and clinical outcome. In the case of disagreement, the final decision was made by consensus.

Statistical Analysis

Baseline clinical and angiographic characteristics were represented as mean \pm standard deviation or median for continuous variables, and counts or percentage for categorical variables. Continuous variables were compared using student-t test or Mann-Whitney U test, and categorical variables were compared using chi-square or Fisher exact test, accordingly. The Kolmogorov-Smirnov test was used to evaluate the distribution of continuous variables. The Kaplan-Meier analysis was used for cumulative incidence rates of intermediate-term outcomes, and the log-rank test was used to compare PCI and CABG groups. The outcome parameters were adjusted by means of Cox proportional hazard regression models for observed differences, with respect to variables statistically significant ($p < 0.10$) in univariate analysis. Two-sided p value < 0.05 was considered a significance level. The Statistical Package for Social Sciences (SPSS Inc., Chicago, Illinois) version 15.0 was used for statistical analysis.

RESULTS

Demographic, Clinical and Procedural Characteristics

Throughout the study, 559 patients were treated by PCI using BMS ($n = 265$, 61.0 ± 13.1 years and 67.9% male) or CABG ($n = 294$, 62.2 ± 11.0 years and 81.6% male). PCI group had significantly lower Sx score when compared to CABG group (19.2 ± 9.4 vs. 32.4 ± 13.9 , $p < 0.001$). Baseline characteristics shown in Table 1 were summarized according to Sx score tertiles.

Intermediate-Term Outcome

The incidence of death from any cause and any revascularization throughout the follow-up (median 360 days) for overall group was 7.7% and 10.7%, for PCI group 7.2% and 17.7%, and for CABG group 8.2% and 4.4%, respectively.

The number of total events and the cumulative events' rates are presented in Table 2, for PCI and CABG groups, according to Sx score tertiles. During follow up, intermediate-term incidence of any revascularization were significantly higher in PCI group than in CABG group, for both the overall study group and the Sx tertiles (low, intermediate and high). However, intermediate-term incidence of death from any cause was not significantly different in patients with low and intermediate Sx tertiles who were treated with either PCI or CABG. In patients with high Sx tertile, intermediate-term rates of any death from any cause were significantly higher in PCI group when compared to CABG group (Table 2, Figure 1,2).

The incidence of death from any cause was significantly increased in patients with high Sx scores compared with those with low or intermediate Sx scores, and the incidence of any revascularization was gradually increased from low to high Sx scores. However, in the CABG group, there was similar incidence of death from any cause and any revascularization in terms of Sx score.

In the PCI group, intermediate-term death incidence was significantly increased according to the increasing Sx score from low to high tertiles (2.9% vs. 7.8% vs. 34%, $p < 0.001$). However, intermediate-term death incidence was not changed in the CABG cohort with increasing Sx score (6.7% vs. 8.3% vs. 9%, $p = 0.531$).

In the overall population, the unadjusted and adjusted risks for death from any cause were consistently comparable between PCI and CABG, whereas the unadjusted and adjusted risks for any revascularization were consistently significantly higher in the PCI group compared with the CABG group (Table 3).

Table 1. Baseline clinical and angiographic characteristics of patients group

Variables	Low SYNTAX score (n= 265)			Intermediate SYNTAX score (n= 112)			High SYNTAX score (n= 182)		
	PCI (n= 175)	CABG (n= 90)	p	PCI (n= 64)	CABG (n= 48)	p	PCI (n= 26)	CABG (n= 156)	p
Age (years)	60.6 ± 13.5	61.3 ± 10.5	0.94	59.5 ± 12.8	61.8 ± 10.2	0.33	66.7 ± 9.9	62.8 ± 11.5	0.10
Male (%)	67.4	84.4	0.003	76.6	81.3	0.55	50	80.1	0.001
BMI (kg/m ²)	29 ± 7.3	26.6 ± 3.1	0.05	29.8 ± 6.4	28.1 ± 3.7	0.19	26.8 ± 3.3	27.6 ± 3.7	0.33
DM (%)	17.7	22.2	0.37	26.6	29.2	0.76	26.9	25.6	0.89
HTN (%)	51.4	34.4	0.009	56.3	39.6	0.08	50	52.6	0.80
Smoking (%)	42.3	36.7	0.37	57.8	22.9	< 0.001	31.8	33.3	0.79
LV-EF (%)	54.8 ± 8.8	52.4 ± 10.3	0.15	48.6 ± 9.6	46.6 ± 8.8	0.23	48 ± 10	44.7 ± 9.0	0.08
ACS (%)	22.9	14.4	0.10	7.8	10.4	0.01	57.7	17.3	< 0.001
CRD (%)	19.4	8.9	0.02	15.6	25	0.42	15.4	20.5	0.54
Medications (%)									
Acetilsalisilic acid	18.3	13.3	0.30	15.6	18.8	0.66	23.1	17.9	0.53
ACE-I									
CCB	24.6	18.9	0.29	26.6	27.1	0.95	26.9	29.5	0.79
Beta-blocker	9.7	6.7	0.40	10.9	6.3	0.39	11.5	10.3	0.84
Statin	6.3	5.6	0.81	7.8	12.5	0.40	11.5	7.1	0.42
No. of lesions	4.3 ± 1.9	4.3 ± 2.0	0.73	5.8 ± 1.6	5.9 ± 1.6	0.79	6.4 ± 1.5	7.5 ± 1.6	0.003
Dominance-R (%)	82.3	78.9	0.50	84.4	71	0.08	73.1	93	0.001
CTO (%)	18.3	13.3	0.38	26.6	31.3	0.58	50	49.7	0.97
Bifurcation (%)	25.1	28.9	0.55	57.8	58.3	0.95	76.9	86.5	0.20
Osteal (%)	4	12.2	0.01	12.5	16.7	0.53	19.2	20	0.92
Diffuse/small (%)	12.6	5.6	0.08	14.1	27.1	0.08	42.3	38.7	0.72
Calcified (%)	6.3	8.9	0.43	12.5	14.6	0.74	38.5	25	0.30
Thrombus (%)	32.6	26.7	0.32	23.4	35.4	0.16	61.5	25.2	< 0.001
Long lesion (%)	27.4	34.4	0.23	42.2	35.4	0.46	53.8	69	0.12
LMCA (%)	0	0	-	0	6.3	0.04	15.4	25.6	< 0.001
LAD (%)	43	100	< 0.001	67	100	< 0.001	80.8	100	< 0.001
RCA (%)	32	51	0.02	39	41	0.78	73.1	42	0.29
LCx (%)	38	53	0.002	31	33	0.81	69.2	44	0.10

SYNTAX: Synergy between PCI with Taxus and cardiac surgery, PCI: Percutaneous coronary intervention, CABG: Coronary artery bypass grafting, BMI: Body mass index, DM: Diabetes mellitus, HTN: Hypertension, LV-EF: Left ventricular ejection fraction, ACS: Acute coronary syndrome, CRD: Chronic renal disease, ACE-I: Angiotensin converting enzyme inhibitors, CCB: Calcium channel blockers, R: Right, CTO: Chronic total occlusion, LMCA: Left main coronary artery, LAD: Left anterior descending, RCA: Right coronary artery, LCx: Left circumflex artery.

DISCUSSION

Our study results indicate that the complexity of CAD assessed by Sx score might have a greater effect on the adjusted intermediate-term incidence of any revascularization in patients who received BMS compared to those who underwent CABG. However, according to Sx score, adjusted intermediate-term incidence of death from any

cause was comparable between treatment groups. Detailed analysis according to Sx tertiles revealed that, while intermediate-term death was similar in patients with low and intermediate Sx score tertiles who were treated with either PCI or CABG, any revascularization had borderline statistical significance for the PCI group. Patients with high Sx score tertiles had significantly increased incidences of both intermediate-term death and any revascularization

Table 2. Intermediate-term clinical outcomes in patients underwent to PCI compared with CABG according to SYNTAX score

Outcome	No of total events		Cumulative event rate (%)		HR (95% CI)	p
	PCI	CABG	PCI	CABG		
Overall group	265	294				
Death from any cause	19	24	7.2	8.2	0.89 (0.49-1.63)	0.723
Any revascularization	47	13	17.7	4.4	4.39 (2.37-8.11)	< 0.001
Low SYNTAX score	175	90				
Death from any cause	5	6	2.9	6.7	0.42 (0.13-1.40)	0.160
Any revascularization	18	3	10.3	3.3	3.21 (0.94-10.9)	0.061
Intermediate SYNTAX score	64	48				
Death from any cause	5	4	7.8	8.3	1.00 (0.27-3.74)	0.994
Any revascularization	14	4	21.9	8.3	3.03 (0.99-9.23)	0.050
High SYNTAX score	26	156				
Death from any cause	9	14	34	9	5.18 (2.22-12.0)	< 0.001
Any revascularization	15	6	57	3.8	31.3 (11.8-82.8)	< 0.001

SYNTAX: Synergy between PCI with Taxus and cardiac surgery, PCI: Percutaneous coronary intervention, CABG: Coronary artery bypass grafting, HR: Hazard ratio.

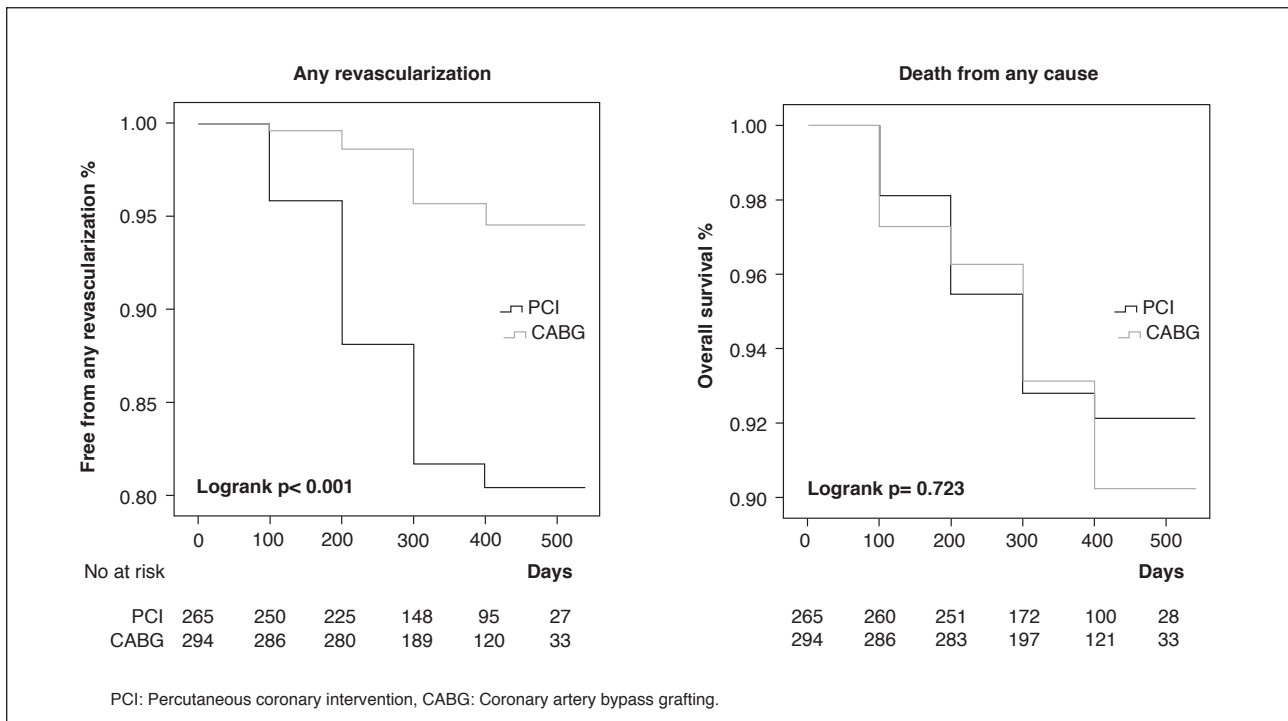


Figure 1. Kaplan-Meier survival curves for intermediate-term outcomes in overall patients (Left panel shows any revascularization; right panel shows death from any cause).

after BMS placement compared to CABG treatment. However, the results for high Sx group are not able to be generalized due to the fact that the number of patients who underwent PCI in this group was low.

Before the DES era, many studies comparing BMS with CABG in the management of multivessel disease were

conducted⁽⁶⁻⁹⁾. In almost all of these randomized controlled studies, CABG was found to be superior to PCI in the management of multivessel disease in terms of long-term repeat revascularization; however, there were no significant differences in treatment modalities for composite endpoints, including long-term death, myocardial infarction and cerebrovascular events. In two large meta-analyses,

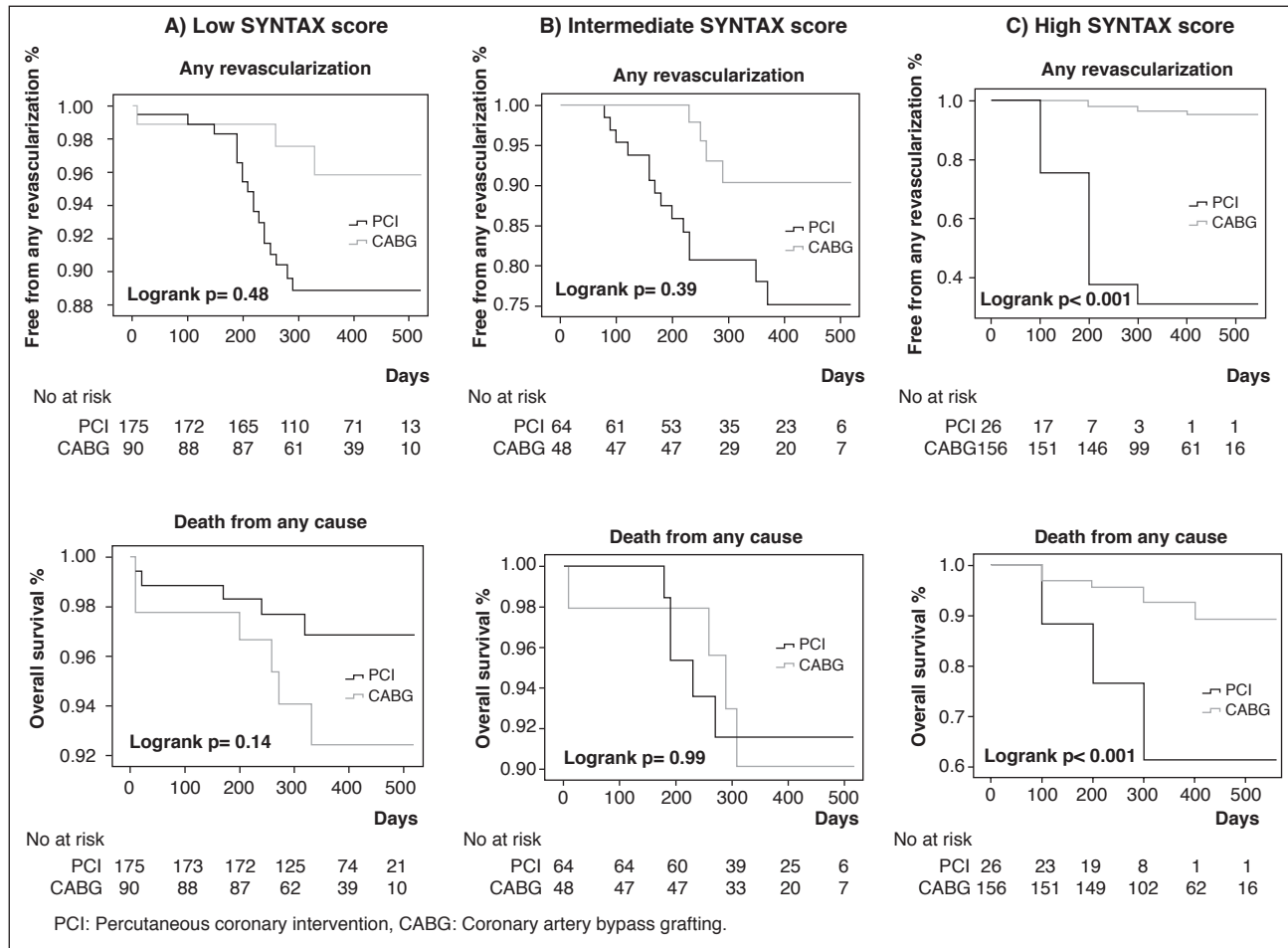


Figure 2. Kaplan-Meier survival curves for intermediate-term outcomes according to SYNTAX score category. A) Top shows any revascularization; bottom shows death from any cause in patients with low SYNTAX score, B) Top shows any revascularization, bottom shows death from any cause in patients with intermediate SYNTAX score, C) Top shows any revascularization, bottom shows death from any cause in patients with high SYNTAX score.

Table 3. Cox proportional hazard analysis of clinical events in overall population

Outcome	Unadjusted		Adjusted for SYNTAX score		Adjusted for SYNTAX score and all covariates*	
	HR (95% CI)	p	HR (95% CI)	p	HR (95% CI)	p
Death from any cause	0.89 (0.49-1.63)	0.723	0.88 (0.38-2.05)	0.780	0.95 (0.42-2.16)	0.910
Any revascularization	4.39 (2.37-8.11)	< 0.001	0.12 (0.05-0.30)	< 0.001	0.11 (0.04-0.28)	< 0.001

SYNTAX: Synergy between PCI with Taxus and cardiac surgery, HR: Hazard ratio.
 * Adjusted for age, gender, diabetes mellitus, hypertension, smoking, body mass index, left ventricular ejection fraction, previous medication history (ASA, clopidogrel, beta-blocker, angiotensine converting enzyme inhibitor use), lesion characteristics (chronic total occlusion, bifurcation lesion, long lesion, calcified lesion, aorto-osteal lesion, lesion with thrombus, tortuous vessel, diffuse and small vessel disease), chronic obstructive pulmonary disease, chronic renal disease, acute coronary syndrome and SYNTAX score.

enrolling over 10.000 patients, the results of these clinical trials were confirmed^(17,18). As it is well-known, due to the reduction of the incidences of restenosis through the use of DES, the differences between PCI and CABG are potenti-

ally reduced or eliminated. From this perspective, our study could be considered to have only a limited role in clinical practice; however, the use of BMS in under-developed and developing countries continues to be still very high.

The Sx score is a significant tool in the evaluation of coronary angiographic complexity and the score is based on the visual assessment of coronary lesions by coronary angiograms⁽¹⁹⁾. In many previous studies, the reproducibility of this score and its usage in the prediction of long-term adverse events has been shown. Garg et al. and Tanboga et al. revealed that both inter- and intraobserver variability of the Sx score are acceptable limits in clinical practice^(20,21). Also, it has been shown that the Sx score was useful in prediction of long term adverse events both in multivessel disease and left main coronary lesions^(12,15,22). In multivessel disease, treatment choice (PCI or CABG), comorbid conditions and extent and severity of coronary lesions have an effect on long-term outcomes. The relation of the extent and severity of CAD with adverse outcome has been shown in patients who underwent PCI or CABG, but in these studies, due to the fact that a comprehensive lesion scoring system, such as Sx, was not used, the effect of treatment choice on long-term outcomes is underestimated⁽²²⁻²⁴⁾. The effect of the coronary lesion's anatomy assessed by the Sx score on long-term outcomes in patients who underwent PCI or CABG has been thoroughly studied. As the introduction of the Sx score was made in the DES era, BMS was not used in the studies that existed at that time. The common result of these studies is that coronary lesion complexity assessed by the Sx score has an impact on the intermediate-term prognosis in patients with complex CAD treated either with PCI or CABG. However, in some CABG studies Sx score was not found to be associated with long-term death incidence^(25,26). In the present study, the incidences of intermediate-term death were similar between CABG and PCI using BMS for overall population; however, death from any cause was increased in high Sx score patients treated with PCI. Low and intermediate Sx groups exhibited similar results with treatment groups. However, in this particular study, unlike to the PCI group, the intermediate-term incidence in the CABG cohort was not changed as the Sx score increased. In DES versus CABG studies, the similar incidence of long-term death in overall population was shown in treatment modalities⁽¹³⁻¹⁶⁾. In our study population, increased incidence of death in patients with high Sx score tertile in PCI treated group might be overestimated due to the small number of patients in this group. Similarly, Kappetein et al. reported that patients who had high Sx score tertile and who were treated with PCI for multivessel disease had increased mortality⁽¹⁶⁾. Between the treatment modalities, the incidence of long-term revascularization was higher in PCI group compared to CABG group in overall population, and as the Sx score increased, the incidence of long-term revascularization

increases. Our results are consistent with previous reports; however, in contrast to our study, all of the previous studies were performed with DES⁽¹³⁻¹⁶⁾. In our study population, the higher incidence of the intermediate-term any revascularization in PCI group, compared to CABG group, decreased the intermediate-term efficacy of PCI.

Limitations

First, the choice of treatment was at the discretion of the physician, and the non-randomized character of the study is one of most significant limitation. As expected in retrospectively trial design, both treatment groups were some heterogeneous regarding important factors that influence clinical outcomes. As an example, patients undergoing PCI were significantly more obese and had clearly less LAD disease, a factor that undoubtedly impacts on prognosis. In addition, patients undergoing PCI had more often acute coronary syndromes and thus worse prognosis. As mentioned previously, the high Sx score group was consisting of only 26 patients with PCI but 156 with CABG. This clearly emphasizes the weakness of the study since reliable conclusion might not be drawn from such a low number of patients. Second, the superiority of DES over BMS in the treatment of complex CAD is well known, but in most of the developing countries almost all of the stenting procedures are carried out by BMS due to problems associated with cost and insurance. In our study only 16 patients received DES, therefore these patients were not included to study. Third, the low number of patients with a Sx score ≥ 33 in PCI cohort is an important limitation; however, the limited use of BMS in Sx score ≥ 33 group naturally decreases PCI.

Conclusion

Coronary anatomy assessed by Sx score appears to have no effect on intermediate-term death between treatment choice; however, the incidence of intermediate-term any revascularization was increased in PCI using BMS cohort when compared to CABG cohort, proportional to coronary complexity. Patients with high Sx tertiles had increased incidences of death from any cause in PCI group when compared to CABG in low and intermediate Sx tertiles. As a result, we suggest, to catheter laboratories using BMS, that both PCI and CABG treatment choice can be used with similar degrees of safety in patients with low and intermediate Sx, whereas for high Sx score tertile patients, the use of CABG rather than PCI with BMS might be more appropriate.

CONFLICT of INTEREST

None declared.

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