Comparing Clinical Outcomes in Patients With Diabetes Undergoing Coronary Artery Bypass Graft and Percutaneous Coronary Intervention

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Research Article

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Abstract

Background

Coronary artery bypass graft (CABG) is generally regarded as the treatment option for coronary artery disease (CAD) in patients with diabetes. In recent years, with the advent of drug-eluting stents (DES), percutaneous coronary intervention (PCI) was introduced as a suitable alternative for CABG. The aim of this study was to compare the incidence of major adverse cardiac and cerebrovascular event (MACCE) during mid-term period in patients with diabetes treated with 2 revascularization strategies.

Methods

We achieved this historical cohort study on 750 consecutives patients with diabetes in a single cardiovascular center from July 2009 to March 2012. We included patients with diabetes with positive history of consumption antidiabetics agent or FBS>125 during hospitalization who were revascularized by 2 strategies. We excluded those patients whose follow-up was not possible.

Results

Finally, out of 697 eligible patients, 355 patients underwent a CABG and 342 underwent a PCI: 53 patients were lost to follow-up (27 in CABG and 26 in PCI groups). The mean follow-up time was 900.68 ± 462.03 days in the CABG and 782.60 ± 399.05 in PCI groups. There were 17 (9.13%) cardiac deaths in the CABG group and 8 (4.45%) in the PCI group; this difference was not significant ($P = .11$). There was 14 (7.58%) cerebrovascular accident in the CABG group and 4 (2.31%) in the PCI group; this difference was significant ($P = .04$). Moreover, the frequency of the target vessel revascularization in the CABG and PCI groups was 6 (3.32%) and 31 (17.11%) ($P < .001$), respectively. Myocardial infarction in the CABG group was 5 (2.77%) and 14 (7.86%) in the PCI group ($P = .009$). Finally, the frequency of MACCE in the CABG and PCI groups was 41(20.70%) and 47(24.16%) respectively; this difference was not statistically significant ($P = .195$).

Conclusion

This study showed that PCI with drug-eluting stent could be a suitable alternative for CABG in revascularization of patients with diabetes.

Introduction

Individuals with diabetes experience a higher rate of mortality and morbidity from coronary artery disease (CAD) than with patients without diabetes [1, 2]. Increasing number of patients with diabetes will reach to 360 million by 2030 while 3/4 of them will be in developing and non-developed countries [3, 4]. Diabetes worsen outcomes of patients following both medical and invasive treatment strategy compared with non-patients with diabetes [5, 6]. Association of metabolic disorders with DM led to accelerated atherosclerotic progression and complexity of coronary lesion [7, 8]. Concurrent with the epidemiological

transition, the increasing number of diabetes as a major risk factor for CAD and decision-making for treatment strategy have raised much concern in clinicians in recent decades. Revascularization with 2 methods of coronary artery bypass graft (CABG) and percutaneous coronary intervention (PCI), as treatment options for this high risk subgroup of patients, has attracted much attention recently, as one-fourth of 1.5 million revascularizations being performed annually involve patients with diabetes [9, 10]. Hence, in recent years, many studies have been conducted to compare the clinical outcomes of these 2 methods. A marked reduction in the difference between clinical outcomes of the 2 methods is seen following introduction of drug-eluting stents (DES) and new oral antiplatelet drugs [11–13]. Concurrent with introducing DES and reduction in-stent restenosis and repeat revascularization, compared with bare-metal stenting, the best revascularization strategy for patients with diabetes with multivessel CAD remains to be under despot [14]. We achieved this historical cohort study to compare the clinical outcome of CABG and PCI in patients with diabetes with multivessel CAD.

Methods

This study was a historical cohort in a single cardiovascular center to evaluate the incidence of major adverse cardiac and cerebrovascular events (MACCE) in patients with diabetes and multi-vessel coronary disease.

Patient Selection

We recruited all the patients from a main cardiovascular data base of Ekbatan hospital, Hamadan, Iran. The proposal of this study was according to the ethical standards of 1964 Helsinki Declaration and approved by the ethics committee of Ekbatan Hospital. We included in this study every patient with diabetes and multi-vessel coronary disease, undergoing elective revascularization by CABG or PCI from July 2009 (when for the first time PCI was available in our center by interventional cardiologists) to March 2012. We excluded patients with poor prognosis, such as those with malignancy, cardiogenic shock, acute myocardial infarction during 24 hours before revascularization, concomitant valve surgery, and previous CABG or PCI; and those with anatomical problems, such as atrial septal defect, ventricular septal defect, and mitral valve sever regurgitation. Thus, we had 572 patients with diabetes (patients with at least 1 FBS>126 mg/ dlit or positive history of diabetes at the time of index admission. All patients signed informed consent to undergo CABG and PCI. Because the study was retrospective, we were unable to obtain informed consent from those patients in whom MACCE occurred, we also obtained informed consent waiver from the same ethics committee.

PCI and CABG

Decision-making about the revascularization strategy was done after consult with surgical services, with attention to the patient's preference. Patients with complex diseases, such as LAD involvement, multivessel disease, sever left ventricular dysfunction, and diabetes, were referred for CABG. Also, PCI with DES stents (drug eluting stent) in patients with diabetes was preferred over bare metal stents (BMS). PCI was often achieved with femoral approach of the Seldinger technique. All patients in the PCI group

received 300 mg clopidogrel and 325 mg aspirin during 24 hours before the intervention. In-group cardiac enzymes and electrocardiograms were checked during the first 24 hours after the intervention routinely.

In the CABG group, off pump CABG was preferred to on pump CABG and left internal mammary artery (LIMA). All patients were monitored for at least 72 hours after surgery at the intensive care unit and antiplatelet agents, such as aspirin and clopidogrel, were not administered 48 hours before surgery. After surgery, heparin was prescribed routinely for all patients.

Patients in the 2 arms of revascularization therapy (CABG or PCI) were advised to take 2 antiplatelet agents (aspirin and clopidogrel) postoperatively. The least time for consumption of antiplatelet drugs in patients with a DES stent was 12 months, for those with the BMS stent 6 months, for the CABG group 2 to 3 months.

During the first year after the index procedure, all patients were visited by clinicians at intervals of 1 to 3 months and the new occurrence of myocardial in fraction was assessed using electrocardiogram and history; and for the subsequent years, this visiting interval was adjusted by clinicians taking into account the patient's condition.

Clinical Outcomes and Follow-up

The outcome in this study was MACCE, including non-fetal myocardial infarction (MI), cardiac death, cerebrovascular accident (CVA), and target vessel revascularization (TVR). We assessed the occurrence of MACCE based on the information provided by telephone contact and hospital readmission and clinical records. If the follow-up was impossible, it was considered as loss to follow-up. Diagnose of cardiac death was based on the main cause of death registered on the death certification and other clinical events determined by the attendance. Cerebrovascular events were defined as strokes and transient ischemic attacks. Post procedural medical treatment was assessed via telephone interviews. By the end of the study time those who did not experience any outcome were considered as censored.

Statistical Analysis

The values are presented in mean ± standard deviation, which were compared using an independent *t* test and frequency, which are tested using the χ^2 test for continuous and categorical variables, respectively. The cumulative clinical event rate during follow-Up at 1 and 3 years in CABG and PCI groups were compared using the log-rank test. After performing a propensity score matching for reducing any selection bias, a Cox proportional hazards regression model was applied to find the significant predictors of MACCE. After determining the best model according to the presence or absence of the predictors based on the Akaike Information Criterion using the stepwise method, the proportionality of hazards was checked using Schoenfeld residuals.

Results

After evaluating 3614 clinical records of those who underwent revascularization in this center, 572 patients with diabetes who met our study criteria were included in this study. We had 53 (9.28%) losses to follow-up (27 in CABG arm and 26 in PCI arm). Finally, the study was conducted with 519 patients with diabetes (334 in CABG arm and 185 in PCI arm). The mean follow-up time was 891.45 ± 458.34 days in the CABG and 790.96 ± 415.21 in the PCI groups. A total of 488 patients were observed, 469 for 1 year and 160 for 3 years. Baseline clinical characteristics of the patients are shown in Table 1. In brief, the frequency of ejection fraction (EF) < 0.40 was not significantly different between PCI and CABG groups. Also, the mean EF was significantly higher in the PCI group than in the CABG group. The proportion of peripheral vascular disease, Lad involvement, number of treated vessels, left ventricular (LV) dysfunction, insulin treated, consumption of clopidogrel, number of diseased vessels, and the amount of stent/graft per patient were significantly higher in the CABG group compared with the PCI group (Table 1).

Table 1
Baseline Clinical Characteristics of Patients.

Variable	CABG	PCI	*P* Value
	(n = 355)	(n = 342)	
Age (mean ± SD)	61.68 ± 8.9	61.42 ± 10.6	0.720
EF	0.474 ± 0.07	0.490 ± 0.09	0.002
EF (< 0.40), n(%)	38(11.38)	22(12.43)	0.722
male, n (%)	186(55.7)	98(52.9)	0.552
Hypertension, n (%)	200(59.8)	116(62.7)	0.527
Hyperlipidemia, n (%)	143(42.81)	85(45.95)	0.491
Smoking, n (%)	71(21.26)	24(24.32)	0.424
Peripheral vascular disease (%)	49(14.67)	10(5.41)	0.001
MI history, n (%)	82(24.55)	42(22.70)	0.635
Stroke history, n (%)	9(2.69)	3(1.62)	0.423
Lad involvement, n (%)	334(100)	161(87.3)	< 0.001
Treated vessel territory, n (%)	258(77.25)	67(36.22)	< 0.001
RCA	319(95.51)	116(62.70)	< 0.001
LAD	238(71.26)	49(26.49)	< 0.001
LCX			
LV function, n (%)	160(42.90)	51(27.57)	< 0.001
Mild	27(8.08)	12(6.49)	
Moderate	9(2.69)	9(4.86)	
Severe	138(41.32)	113(61.08)	
Normal			
Treated/untreated diabetes	308(92.22)	160(86.49)	0.039
Treatment of diabetes	52(14.6)	39(11.4)	0.397
Insulin	191(53.8)	180(52.6)	
Oral drug	83(23.4)	86(25.1)	
Dietary	29(8.2)	37(10.8)	
Nothing			

Variable	CABG	PCI	*P* Value
	(n = 355)	(n = 342)	
aspirin(%)	349(98.3)	340(99.4)	0.171
clopidogrel(%)	301(84.8)	328(95.9)	< 0.001
No. of disease vessels, n (%)	21(5.9)	157(45.9)	< 0.001
One vessel disease	77(21.7)	141(41.2)	
Two vessel disease	257(72.39)	44(12.87)	
Three vessel disease			
Number of stent/graft per patient, n (%)	33(9.30)	261(76.32	
1	105(29.58)	73(21.35)	
2	171(48.17)	8(2.34)	
3	44(12.39)	0(0%)	
4	2(.56)	0(0%)	
5			

The procedural characteristics of the patients are presented in Table 2. Table 2 shows that 94.6% of patients with CABG had the on-pomp type, 78.1 of patients with CABG had LIMA type of graft on LAD, 84.7 had DES type of stent, and 64.9 had EES type of drug eluting stent.

Table 2
Procedural Characteristics of Patients

Variable	N (%)
Type of CABG, n (%)	316(94.6)
On Pomp	18(5.4)
Off Pomp	
Type of graft on LAD, n (%)	261(78.1)
LIMA on LAD	73(21.9)
SVG on LAD	
Type of drug eluting stent, n (%)	96(64.9)
EES	25(16.9)
PES	6(4.1)
ZES	21(14.2)
BES	
Type of stent DES/BMS*	145(84.7)
DES stent	26(15.3)
BMS stent	
• indicates that patients who implemented both DES & BMs were excluded.	

The cumulative clinical event rate during the follow-up at 1 and 3 years and the comparison between the 2 groups are depicted in Table 3. During the follow-up time, the rate of cardiac death and CVA were not significantly different in the CABG and PCI groups. The rate of TVR was significantly lower in the CABG group in 1 and 3 years of follow-up. Also, the rate of non-fetal MI was higher in PCI significantly in the 3-year follow-up. The overall rate of MACCE was not different significantly in the CABG and PCI groups (Table 3).

Table 3
Cumulative Clinical Event Rate During Follow-up at 1 Year and 3 Years

Event	CABG % (n)	PCI %(n)	*P* Value
Cardiac death	2.79 (9)	2.24 (4)	0.473
0–1 year	5.61 (13)	3.43 (4)	0.184
0–3 years			
CVA	1.47 (5)	0 (0)	0.068
0–1 year	4.85 (13)	2.58 (3)	0.137
0–3 years			
TVR	1.56 (5)	6.06 (11)	0.027
0–1 year	2.63 (6)	16.80 (21)	< 0.001
0–3 years			
MACCE	6.40 (21)	8.15 (15)	0.673
0–1 year	14.04 (34)	21.78 (28)	0.269
0–3 years			
MACCE ex TVR	4.91 (16)	4.43 (8)	0.623
0–1 year	10.95 (28)	12.29 (15)	0.667
0–3 years			
Non-Fetal MI	0.62 (2)	2.80 (5)	0.095
0–1 year	1.32 (3)	7.56 (9)	0.006
0–3 years			

The clinical outcome of the follow-up after stenting during the study period and comparing DES versus BMS and DES versus CABG are shown in Table 4. The results showed that the rate of clinical outcome for cardiac death and MACCE without TVR were higher in the CABG group compared with DES, while the rate of TVR was significantly higher in DES compared with CABG. Moreover, the MACCE, cardiac death, CVA, TVR, non-fetal MI, and MACCE without TVR rates were significantly higher in BMS compared with DES (Table 4).

Table 4
Clinical Outcome of Follow-up After Stenting During Study Period

	DES(n = 145), n (%)	BMS (n = 26), n (%)	P value*	CABG (n = 334), n (%)	P value**
Cardiac death	0(0)	2(14.28)	< 0.001	15(8.59)	0.014
CVA	1(1.36)	2(14.28)	0.041	14(7.58)	0.063
TVR	12(15.28)	7(42.42)	0.013	6(3.52)	< 0.001
MACCE	14(17.61)	9(51.42)	0.001	39(20.91)	0.757
MACCE ex TVR	4(5.36)	6(37.50)	< 0.001	32(19.5)	0.020
Non-Fetal MI	3(4.05)	3(20.68)	0.029	5(4.12)	0.439
*** The comparison between DES versus BMS.**					
****The comparison between CABG versus DES.**					

Table 5 shows the results of the cox proportional hazards regression for MACCE. Using the stepwise method, hyperlipidemia, age (> 60), treatment modality (PCI versus CABG), LAD involvement, left ventricular dysfunction, clinical presentation, and complete revascularization were selected as the best predictors. The Schoenfeld residual test resulted in the proportionality of hazards for the predictors. Propensity score matching was applied on the covariates using the treatment modality as the response for the logistic regression. After forcing the matching into the cox regression model, the results showed that patients with hyperlipidemia were 2.04 more likely to get MACCE compared with patients without hyperlipidemia, this was 3.07 for patients in PCI arm compared with CABG (Fig. 1), and 4.54 for patients with severe left ventricular dysfunction compared with healthy people (Table 5).

Table 5
Results of Cox Regression to Predict Time to MACCE

Variable	Hazard ratio	CI 95%(HR)	Significance
Age(> 60)	1.67	0.90–3.09	NS
Hyperlipidemia(yes)	2.04	1.15–3.59	S
Group(PCI)	3.07	1.56–9.09	S
LAD involvement	4.35	0.58 – 12.27	NS
Normal LV dysfunction	Ref	-	NS
Mild LV dysfunction	1.52	0.78–2.94	NS
Moderate LV dysfunction	1.89	0.73–4.89	S
Severe LV dysfunction	4.54	1.65–12.48	
Type setting	1.66	0.90–3.12	NS
Complete (yes)	2.18	0.96–4.91	NS
NS: Not Significant, S: Significant			

Discussion

This study showed that there was no statistically significant difference in the unadjusted incidence of MACCE between PCI and CABG groups. In contrast, the adjusted analysis using the cox PH model depicted a hazard ratio of 3.07 for the PCI group relative to CABG for the incidence of MACCE. According to this study, the incidence rate of CVA was similar in 2 arms of CABG and PCI. In most of the previous studies, the lower rate of MACCE in CABG versus PCI groups have been demonstrated [15–18].

In a 5-years follow-up trial by Contini et al in 2012, the incidence of MACCE was higher in the PCI group than the CABG group [19]. Also, Tartaniti et al showed that in patients with diabetes and multi-vessel coronary disease, survival rate was similar in the PCI and CABG groups [20]. In an evaluation of a difference between CABG and PCI in patients with diabetes and mult-vessel coronary disease, Hee L et al depicted that the rate of MACCE occurrence in PCI is statistically higher than in CABG (29% vs 14%; $P = .016$)[21]. Deamen et al in their study “Arterial Revascularization Therapies (ARTS), part I and II” demonstrated a higher occurrence of MACCE in PCI (47.3%) than in CABG (17.7%), while the results for CVA was vice versa (5.4% vs 6.3%)[22]. In a systematic review of comparing CABG vs PCI programmed by Saswata et al in 2013, patients with diabetes generally had better outcomes with CABG than with PCI (18.7% vs 26.6%; $P = .005$) as well as cardiac events [23]. In a meta-analysis evaluating the incidence rate of MACCE in patients with diabetes and multi-vessel coronary disease by Fan zhang et al, a 12% reduction was detected in the CABG group [24]. After adjusting for the effect of group, being as CABG or PCI in the Cox PH model, we found that the hazard of MACCE occurrence in patients with PCI is 3.07

more likely than CABG arm, which is significant. The results of the Cox PH model showed that patients with hyperlipidemia were 2.04 more likely to experience MACCE compared with patients without hyperlipidemia. The results also showed that patients with severe LV dysfunction experienced MACCE 4.54 times more than those with normal LV function.

Our study demonstrated that the incidence rates of cardiac death during 1 year and 3 years follow- up were not statistically different between CABG and PCI groups. In a study to find the optimal coronary revascularization policy in patients with diabetes, Kamalesh et al showed that there was no difference in the survival rate of cardiac death between the 2 arms [25]. To compare medical therapy, PCI, and CABG as 3 therapeutic strategies for stable coronary disease in 2013, Lima et al found cardiac mortality rates of 18.8% and 12.5% for PCI and CABG, respectively [26]. In an editorial, review, which was a randomized clinical trial comparing CABG versus PCI, conducted by Emmanuel Moss et al, MACCE was significantly higher with PCI compared with CABG, as well as cardiac death in patients with diabetes and multi-vessel coronary disease in 2013[27].

In our study, the incidence rates of TVR were statistically different in the 2 arms at 1- and 3-year follow-up and was lower in the CABG group. Bhatt ad topol in a study “The Arterial Revascularization Therapy Study (ARTS) and the Stent or Surgery (SoS)” demonstrated that the rate of TVR was significantly lower in CABG [28]. A similar result was found by Contini et al [19]. The incidence rate of non-fetal MI was significantly different between the 2 groups in the 3-year follow-up, while the survival rate was similar in these 2 groups during the 1-year follow-up. A similar result was found in another study [25]. Non-fetal myocardial infarction incidence rates were not significantly different in patients with PCI or CABG in the study of Leia et al [21].

Comparing the incidence rate of MACCE in DES and BMS, cardiac death, CVA, TVR, MACCE ex TVR, and non-fetal MI, our results demonstrated an overall significant reduction in the occurrence rate of MACCE in DES versus BMS groups. In the ERACI III registry planned by Ong et al in 2007 in Argentina, the 3-year MACCE was significantly lower in DES compared with BMS [29] and similar results are found in the study of Contini et al[19]. The results from Kapur et al in 2009 showed no significant differences between DES and BMS in CVA and non-fetal myocardial infarction incidence rates [17]. In a meta-analysis of 14 trials comparing CABG and DES in patients with diabetes and multi-vessel coronary artery disease, De Luca et al in 2014 showed that CABG reduces the incidence rate of TVR compared with DES, while a lower rate of MACCE was found for CABG than DES [30]. A similar result was driven by Wander and Chhabra in 2010, as the clinical benefits of DES versus BMS at 12 months showed that the incidence rate of TVR was significantly reduced; also, in a study by Xiaolong et al it was found that CABG can significantly reduce the rates of myocardial infarction than DES in patients with diabetes and multi-vessel coronary disease [31].

The present study showed no difference in the occurrence of MACCE compared with CABG and DES and CVA and non-feta MI, while a statistical difference was depicted in the occurrence of cardiac death comparing CABG and DES (0% vs 8.59%; $P = 0.014$) as well as for TVR (15.28% vs 3.52%; $P < .001$).

Comparing the differences between DES and bilateral internal thoracic artery grafts in patients with diabetes in 2012, Moshkovitz et al demonstrated that MACCE survival rate in patients with diabetes who were revascularized by CABG was better than PCI with DES [32]. In 2 other studies performed by Aamir Javaid et al in 2007 and Yan QIAO et al in 2009, it was found that clinical outcome and MACCE rate in patients with diabetes multi-vessel coronary disease were higher in PCI with DES than the CABG strategy [33, 34]. The occurrence of cardiac death was higher in CABG compared with DES. While there was no significant difference between the 2 arms of CABG and DES in our study, a higher rate of CVA incidence was found in CABG compared with DES in Yan QIAO et al [34]. In our study, the survival rate of TVR in CABG and DES was 3.52 and 42.42, respectively. Similar results were found in Moshkovitzh et al study where the hazard ratio of TVR was 7 in DES likely than CABG [32]. Yan showed that the incidence rates of non-fetal MI in patients with CABG and DES were statistically the same during the study period [34].

Conclusion

Patients with diabetes with CAD who had similar mid-term clinical outcome underwent CABG or PCI. Patients with CABG in this study experienced more CVA, while the frequency of TVR and non-fatal MI was higher in the PCI arm. Finally, this study showed that PCI with drug-eluting stent could be a suitable alternative for CABG in revascularization of patients with diabetes.

Abbreviations

CI
Confidence Interval
CAD
Coronary Artery Disease
CAD
Coronary Artery Disease
CABG
Coronary Artery Bypass graft
PCI
Percutaneous Coronary Intervention
DES
Drug-Eluting Stents
MACCE
Major Adverse Cardiac and Cerebrovascular Events
ICU
Intensive Care Unit
CVA
Cerebrovascular Accident
TVR

Target Vessel Revascularization

Declarations

Ethics approval and Consent to Participate

The study was approved by the ethics committee of Ekbatan Hospital, and all patients signed informed consent to undergo CABG and PCI. Because the study was retrospective, we were unable to obtain informed consent from those patients in whom MACCE occurred, we also obtained informed consent waiver from the same ethics committee.

Consent for Publication

Not applicable.

Availability of Data and Material

Data are available and can be accessed from the corresponding author with reasonable inquiry.

Competing Interests

The authors declare that they have no competing interests.

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None.

Authors' Contributions

M.A., and A.A. conceptualized the idea for this review, formulated the study question, and objectives, assisted with the development of the final methods, contributed to the data analysis/ interpretation, and writing the manuscript. H.R.B., Y.M., B.N., M.A., and A.A. contributed to the writing of the manuscript. All authors read and approved the final manuscript.

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Figures

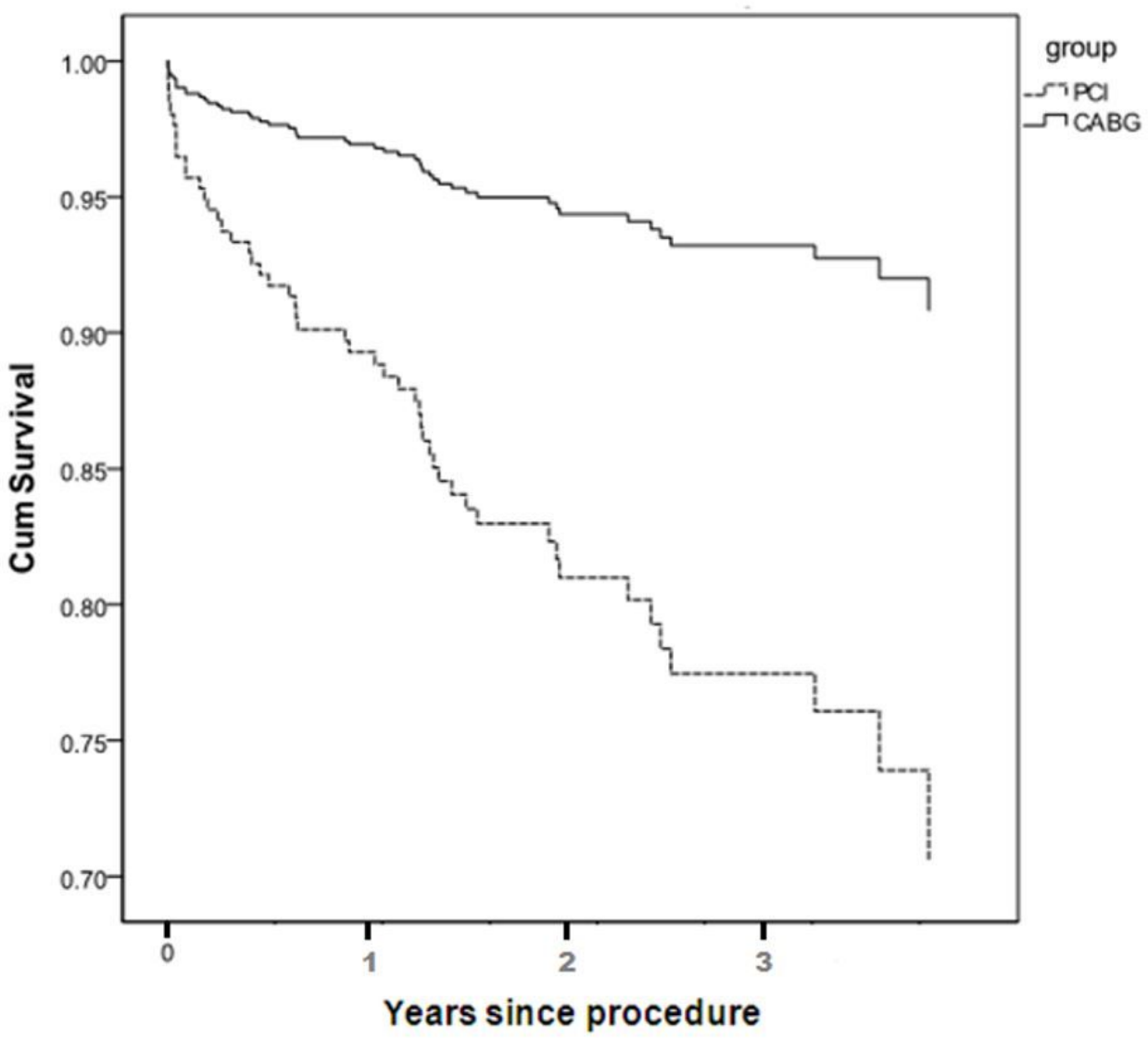

Figure 1

Survival function of MACCE.