

Percutaneous Coronary Intervention in the Unprotected Left Main Coronary Artery in Patients with High Risk at Surgery

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SUMMARY

Coronary artery by-pass graft surgery (CABGS) is the treatment of choice for lesions of the left main coronary artery. Nevertheless, there are a great number of patients with high risk at surgery due to concomitant diseases and/or clinical instability.

Objectives

To assess the outcomes of percutaneous coronary intervention (PCI) in the unprotected left main coronary artery (LMCA) in high-risk patients for CABGS (EUROSCORE = 6).

Material and methods

Fifty nine patients who had undergone PCI in the unprotected LMCA were assessed; 8 patients in cardiogenic shock secondary to acute myocardial infarction (AMI) and 12 patients not considered to have high risk at surgery were excluded. This study was performed among the remaining 32 high-risk patients treated with conventional stents. In-hospital mortality predicted by logistic EUROSCORE was compared to observed mortality, and the incidence of major adverse events and late follow-up outcomes were assessed.

Results

Median age was 76.5 years, 43% were 80 years old or older, 22% were women, 28% were diabetic, 56% had moderate to severe left ventricular dysfunction, 31% had chronic renal failure, 50% extracardiac arteriopathy, 53% had refractory angina, 22% recent AMI, 28% underwent emergency procedures, and median EUROSCORE was 10.5 points. Distal compromise of LMCA was present in 41% of patients. Angiographic success was achieved in 94% of the procedures. IIB/IIIa inhibitors were used in 47% of cases, cutting balloon in 28%, Rotablator® in 3% and counterpulsation balloon in 31%. A stent was implanted in all patients and other obstructions were treated in 50% of patients. In-hospital mortality rate was 3.1% (95% confidence interval, 0.2%-14.5%, $p = 0.003$), compared to a predicted mortality rate of 23.8%. Neurological deficits, transmural AMI or necessity for performing dialysis were not observed. The procedure failed in one patient who subsequently underwent elective CABGS surgery. Median follow-up was 15.5 months; during this period 6 deaths (2 due to cardiovascular causes) and 4 reinterventions were reported. Cumulative incidence of reintervention was 15.6% (95% CI, 6.0%-31.3%).

Conclusions

PCI in the unprotected LMCA in patients with high risk at surgery should be considered an alternative to CABGS surgery.

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Key words > Left main coronary artery - Percutaneous coronary intervention - Stent - High risk

Abbreviations >

PCI	Percutaneous coronary intervention	DES	Drug-eluting stent
CABGS	Coronary artery by-pass graft surgery	LMCA	Left main coronary artery
AMI	Acute myocardial infarction		

BACKGROUND

Coronary artery by-pass graft surgery (CABGS) is the treatment of choice for lesions of the left main coronary artery. (1)

Nevertheless, there are a great number of patients with high risk at surgery due to concomitant diseases and/or clinical instability, (2) and the amount of patients rejected from surgery or considered poor candidates for the procedure is increasing (30-40% accord-

ing to some series). (3) Mortality rates associated with a conservative treatment are high (4) and percutaneous transluminal coronary angioplasty (PTCA) with stent implant may serve as a valid therapeutic choice.

American guidelines have recently updated the recommendations for the use percutaneous coronary interventions (PCI). (5) According to these guidelines, PCI is a class **II** level of evidence **A** recommendation for the treatment of significant obstructions of the LMCA in patients non-eligible for CABGS, and reflects the favorable outcomes published by several authors. (6-8)

The objective of the present study is to report the effectiveness and safety of PCI in the unprotected LMCA in patients with high risk at surgery.

MATERIAL AND METHODS

Design

Retrospective study of a cohort of patients treated at four medical centers (three in the city of Buenos Aires and one in the Great Buenos Aires) by the same interventional cardiology team.

Definitions

- LMCA significant obstruction: stenosis = 50% compared to reference diameter.
- Unprotected LMCA obstruction: absence of at least one patent by-pass graft to the anterior descendant or circumflex coronary artery.
- An **ostial** obstruction was any lesion within 5 mm of the origin of the artery, a **distal** obstruction was any obstruction treated with balloon angioplasty or stent implant to the origin of the left anterior descendant or circumflex artery, and a **body** obstruction was any lesion localized in other parts of the artery. **Diffuse** obstructions compromised the LMCA in all its extension.
- **Simple** stenting included stent implant of the LMCA only or stenting of the distal LMCA extending into the origin of the circumflex artery (independently of performing a final kissing balloon).
- Angiographic success: defined as residual stenosis < 20% in-stent in the presence of TIMI III flow.
- Clinical success: defined as a PTCA with angiographic success and without hemodynamic impairment or major complications (death, stroke or AMI during hospitalization).

Population study

Patients included were high-risk patients for CABGS (EUROSCORE = 6) who had undergone PCI in the unprotected LMCA.

Patients with LMCA lesions eligible for CABGS who had undergone elective PTCA on their own decision or based on medical advice were excluded.

Angioplasty was considered as any attempt to clear an obstruction with a coronary guide wire irrespective of the result.

Operative risk was calculated with EuroSCORE (9), and logistic EuroSCORE (10) was used to estimate operative mortality, in all patients (see Appendix).

Percutaneous coronary intervention procedure

Femoral artery was the access of choice. All patients received oral aspirin (100 mg/day) and sodium heparin (100U/kg;

patients treated with glycoprotein IIb-IIIa inhibitors received 75 U/kg) before the intervention.

At least one stent implant was attempted in all cases. A kissing balloon was performed in stenting of the distal LMCA to optimize the final outcome. The indication of glycoprotein IIb/IIIa inhibitors and counterpulsation balloon depended on the operator's criterion.

All patients received clopidogrel (loading dose: 300 mg and 75mg/day for at least 4 weeks).

Control angiography was performed according to the will of the treating physician.

Follow-up

Outcomes assessed during follow-up were death and new LMCA revascularization (by PTCA or CABGS).

Statistical analysis

Continuous variables are expressed as medians (percentile 25/75%) and categorical variables as percentages.

The final end point (in-hospital mortality) was assessed comparing operative mortality estimated by logistic EuroSCORE with the observed mortality, considering a binomial distribution. Percentages were informed with their corresponding 95% confidence interval (95% CI).

Differences between groups were compared by Mann-Whitney test (for continuous variables) or Fisher's exact test (for categorical variables).

During follow-up, the presence of combined events (cardiovascular death or new revascularization) was assessed by the Kaplan-Meier curves; in turn, variables associated with the presence of combined events were determined and entered in a logistic regression model. A p value < 0.05 was considered statistically significant. Statistical analysis was performed with the software Stats Direct (version 2.3.1) and Epi Info (version 6.04d) (<http://www.cdc.gov/epiinfo>).

RESULTS

Between January 2002 and December 2006 we consecutively performed a PCI in 59 patients with severe compromise of the LMCA (Figure 1); 32 of these patients who presented high risk at surgery were treated with conventional stents, except for 7 patients who received drug eluting stents (DES).

Population basal characteristics are shown in Table 1.

Percutaneous coronary intervention procedure

Table 2 summarizes the angiographic characteristics and the type of treatment used during the procedures.

Clinical success was achieved in 30 patients (93.8%). One patient died during the procedure after a ventricular arrhythmia with hemodynamic decompensation. A patient with a failed PTCA attempt to the distal LMCA underwent CABGS one week after the intervention with favorable outcomes.

At least one stent implant was attempted in all cases. Simple stenting was performed in all patients with ostial lesions (n = 11), in 2 patients with body lesions (n = 3) and in 12 patients with distal or diffuse obstructions (n = 18) of the LMCA.

Concomitant stenting of other obstructions unrelated to the LMCA was performed in 16 patients (50%).

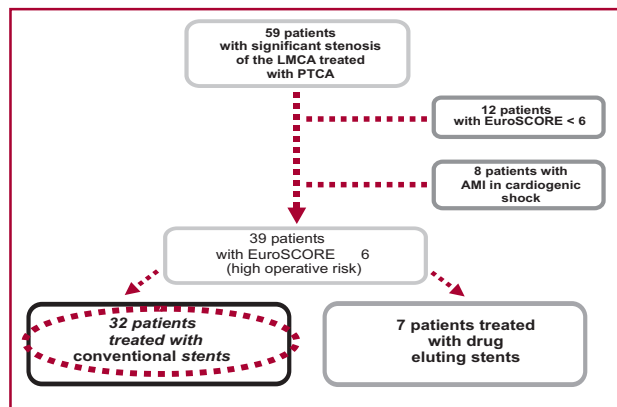


Fig. 1. Patients selection

Table 1. Population basal characteristics

	n	
Age (years)	76.5	(72.8-81.8)
≥ 80 years	13	40.6%
Female	7	21.9%
Hipertensión	18	56.3%
Dyslipemia	18	56.3%
Diabetes	9	28.1%
Smoking habits	17	53.1%
Ventricular dysfunction	18	56.3%
Chronic renal failure	10	31.3%
COLD	9	28.1%
Extracardiac arteriopathy	16	50.0%
Cerebrovascular disease	1	3.1%
Previous CABGS	2	6.3%
Previous AMI	10	31.3%
Refractory unstable angina	17	53.1%
Recent AMI	7	21.9%
Emergency	9	28.1%
Mechanical respiratory assistance	2	6.3%
EUROSCORE	10.5	(8-12)
≥ 13 points	7	21.9%

In-hospital outcomes

Logistic EuroSCORE predicted operative mortality was 23.8%, and observed mortality was 3.1% (1 patient) (95% CI, 0.2%-14.5%, p = 0.003).

No transmural myocardial infarctions, neurological deficits, urgent reinterventions or dialysis were reported after the procedure.

Follow-up

Median follow-up was 15.5 (8-32.3) months.

During that period, 6 patients died; sudden death did not occur. Four patients died of non cardiac causes

(one of digestive bleeding, two of sepsis and one of cancer at 2, 10, 12 and 18 months, respectively). Two deaths were due to cardiovascular conditions: one AMI 8 months after the procedure and one death occurred during a programmed CABGS two months after the procedure.

Cumulative rate of reintervention was 15.6% (95% CI 6.0%-31.3%). Severe and symptomatic restenosis occurred in 4 patients at 2, 6, 8 and 15 months after the procedure; a DES was implanted in three patients and one patient underwent CABGS (Figure 2).

Figure 3 shows a Kaplan-Meier curve with survival free from cardiovascular death or from need of new reintervention, with a mean event-free time of 46.7 months.

Predictors of late events

Lesions of the circumflex artery (p = 0.01) and simple stenting of the LMCA (p = 0.005) were associated with cardiovascular death or need of new revascularization during follow-up.

The logistic regression analysis reported that both variables maintained their predictive value (p = 0.04 and 0 = 0.02, respectively).

DISCUSSION

By-pass graft surgery and left main coronary artery disease

The results of the CASS (11) and Veterans (12) studies, performed more than two decades ago, demonstrated that, compared with medical treatment, CABGS was the gold standard treatment in patients with significant obstruction of the LMCA. This group of patients had poor clinical outcomes when the condition was associated with moderate to severe left ventricular dysfunction, obstruction of the right coronary artery ≥ 70% and/or lesion of the LMCA ≥ 60%. (11)

Patients with LMCA disease use to be elder, and the prevalence of extracardiac arteriopathy, left ventricular dysfunction, three-vessel disease and acute coronary syndromes is higher compared to patients without obstruction of the LMCA. (2)

Jönsson et al reported that patients with severe LCMA obstructions presented a significant increase in early and late mortality rates (3 and 1.5%, respectively) compared to patients without obstructions or with less severe obstructions. (13)

In turn, in-hospital and 3-year mortality at the Cleveland Clinic was 2.3% and 15.6%, respectively, in patients with LMCA disease treated with CABGS. Age, renal failure and functional class = 3 were independent predictors of early mortality. Late mortality rates in low-risk patients and high-risk patients were 4.5% ± 2.5% y 39.8% ± 8.5%, respectively, and were associated with age, renal failure and chronic obstructive lung disease (COLD). (14)

Tabla 2. Angiographic and procedure characteristics

	n	
Site of obstruction		
Ostial	11	34.4%
Body	3	9.4%
Distal	13	40.6%
Diffuse	5	15.6%
Isolated LMCA	6	18.8%
+ 1 vessel	13	40.6%
+ 2 vessels	8	25.0%
+ 3 vessels	5	15.6%
Severe coompromise		
Anterior descendant coronary artery	18	56.3%
Circumflex coronary artery	14	43.8%
Right coronary artery	13	40.6%
Counterpulsation balloon	10	31.3%
Iib-Illa inhibitors	15	56.3%
Cutting balloon	9	28.1%
Rotablator®	1	3.1%
Intravascular ultrasound	2	6.3%
Obstruction %	72.5 (60-86.3)	
Reference diameter (mm)	3.5 (3-3.6)	
Maximum balloon diameter (mm)	3.5 (3-4)	
Stent length (mm)	14.0 (12-18)	
Simple	25	78.1%
Complex		
T stent	4	12.5%
V stent	1	3.1%
Kissing stent	1	3.1%

Management of patients with high risk at surgery

Assessment of risk in cardiac surgery is based on scores such as Parsonnet score (15) and EuroSCORE, among the most recognized. (9) Compared to other scores, EuroSCORE has achieved the best performance to predict events in our country, (16, 17) with predicted mortality rates of 0.6%-1.1% in low-risk patients (0-2 points), 2.6%-3.5% in intermediate-risk patients (3-5 points), and 10.3%-12,2% in high-risk patients (6 points or greater). (9)

It should be noticed that EuroSCORE predicts not only operative mortality, but also late events in patients treated with CABG surgery (18) and PTCA (19) due to the presence of multiple concomitant conditions. This is clearly reflected in our population, with a mortality rate of 66% for non cardiovascular causes.

Percutaneous coronary intervention in the left main coronary artery

PTCA outcomes have resulted quite promising since the advent of conventional stenting; nevertheless,

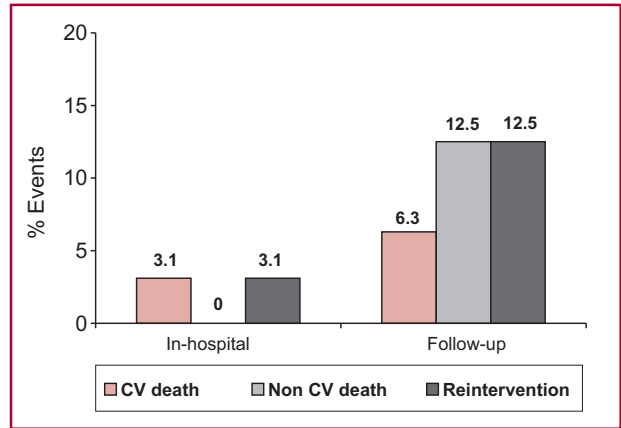


Fig. 2. Events during hospitalization, follow-up and cumulative events.

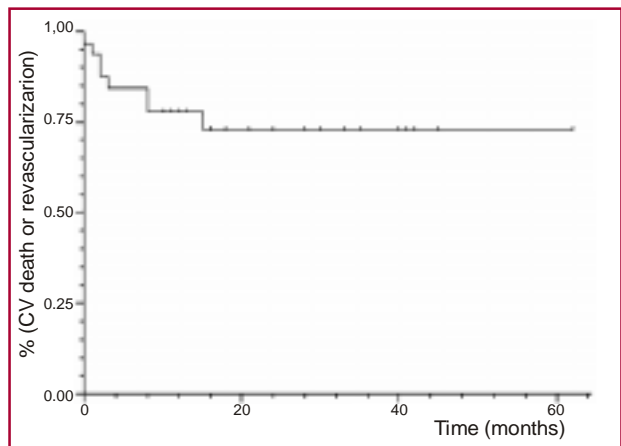


Fig. 3. Kaplan-Meier curves showing outcomes free from cardiovascular death or revascularization

restenosis (22-31%) remains as the main limitation of the procedure. (20) Patients free of events during the first year, experienced favorable outcomes at 5 years. (21)

In general, angiographic success was greater than 95%. Nevertheless, in-hospital mortality and late mortality were significantly different among patients with low risk at surgery and patients with high risk at surgery, 1.2% to 9% and 11% to 22%, respectively. (3, 7, 22-24)

The French registry of unprotected left main coronary artery treatment (3) has clearly reflected these differences, reporting 30-day mortality rates of 1.2% and 12.5% (p = 0.006) and one-year mortality rates of 16.5% and 28.1% (p = NS) in low-risk patients and high-risk patients treated with PTCA or CABGS. Therefore, the different registries and experiences comparing PTCA and CABGS should be analyzed considering populations at similar risks.

In concordance with other series which published the results of stent implant for the treatment of LMCA disease, our study showed that concomitant coronary artery disease and the need to treat lesions of the distal bifurcation were associated with the presence of events during follow-up; (20-22) other predictors are: patients' operative risk, (25) ventricular function (8, 23) and in-stent final diameter. (22)

The advent of DESs constituted an important progress in preventing restenosis. (26)

Sheiban (27) and Valgimigli (28) found that the use of DESs in patients with LMCA disease was associated with a significant reduction in the need of reintervention compared to conventional stents; nevertheless, no differences in late mortality were observed. In turn, TSEARCH and RESEARCH registries reported a 6% rate for need of reintervention associated to DES implant. (29)

Recently, a randomized trial which included systematic use of intravascular ultrasound and cutting balloon (30) informed restenosis rates of 6% and 22% with paclitaxel eluting stents and conventional stents, respectively ($p = 0.021$).

Chieffo et al (31) found a similar incidence of major events at 1-year follow up in patients with LMCA lesions treated with CABGS or DESs (adjusted OR, 0.568; 95% CI, 0.229-1.344; $p = \text{NS}$). Mortality rates at 1 year were 6.4% and 2.8%, respectively.

Lee et al (32) reported the outcomes of 173 consecutive patients with significant obstruction of the LMCA. Fifty patients with high risk at surgery, rejected from CABGS or with a limited life expectancy, were considered eligible for PTCA with DES implant, while the remaining patients were treated with surgery.

One month mortality was 2% and 5%, and 1-year survival was 95.5% and 84.8% for DES and CABGS, respectively. Parsonnet's score, diabetes and treatment with CABGS were independent predictors for major events. Major events included stroke (8%, 10 patients), bleeding with subsequent reintervention (7%, 9 patients); severe pneumonia (6%, 7 patients) and definite pacemaker implant (4%, 5 patients). Complications were extremely rare in patients treated with DESs.

Study limitations

Our report has some limitations which should be mentioned.

Firstly, the retrospective nature of this study is an important limitation, as it does not allow a strict clinical or anatomical selection or exclusion of patients which would have been necessary to indicate PTCA in this group of patients.

Secondly, the sample size is small, limiting the assessment of the number of events during hospitalization and follow-up. However, we have treated a high-risk population and we have found low event rates than expected, leading to assume a real benefit.

Thirdly, our results were compared to logistic EuroSCORE predicted operative mortality as we did

not use a comparative group of patients treated with CABGS. Although this methodology might be discussed, it confronts our results with the best operative outcomes expected.

Fourthly, we are currently implanting DESs in these patients except in cases of contraindications to long-term treatment with thienopyridines (for example, recent digestive bleeding, need for major surgery within the 6 months following the procedure); this situation is relatively frequent and has limited the indication of these devices. This report does not inform DESs outcomes as the sample size is too small to reach to definite conclusions.

Fifthly, the use of counterpulsation balloon was lower than expected; angiography was not routinely performed during follow-up. We should not forget that our population included a high proportion of elder patients, with extracardiac arteriopathy, chronic renal failure and emergency procedures. In this type of patients with poor arterial accesses, it is generally difficult to repeat angiographic procedures, and this fact is an important conditioning at the moment to choose the treatment strategy.

Sixthly, we must highlight that this experience was carried out in several medical centers by a team of experimented operators. The inclusion of a greater number of centers and operators (for example, in a multicenter registry) might be helpful to reinforce the impact of these outcomes.

Finally, these results should not be extrapolated to inexperienced operators in complex interventions or in patients with significant obstructions of the LMCA with habitual risk at surgery. At present, several randomized trials are comparing CABGS versus PTCA with DES implant in this subset of patients. (33-35)

CONCLUSIONS

The results of this study suggest that PCI in the unprotected LMCA in patients rejected from surgery or with high risk at surgery should be considered an alternative to CABGS surgery.

Competing interests

None declared.

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RESUMEN

Angioplastia del tronco de la arteria coronaria izquierda no protegido en pacientes con alto riesgo quirúrgico

El tratamiento de elección de la enfermedad del tronco de la coronaria izquierda (TCI) es la cirugía de revascularización miocárdica (CRM). Un número creciente de pacientes pre-

senta comorbilidades y/o inestabilidad clínica que condicionan un alto riesgo quirúrgico.

Objetivos

Evaluar los resultados de la angioplastia (ATC) del TCI no protegido en pacientes con alto riesgo para CRM (EUROSCORE \geq 6).

Material y métodos

De 59 pacientes con ATC de TCI no protegido se excluyeron 8 con infarto agudo de miocardio (IAM) en shock cardiogénico y 12 sin características de alto riesgo; de los restantes pacientes de alto riesgo fueron objeto de este estudio los 32 tratados con *stents* convencionales.

Se comparó la mortalidad hospitalaria predicha por EUROSCORE logístico con la observada, así como la incidencia de complicaciones mayores y su evolución alejada.

Resultados

La mediana de edad fue de 76,5 años, el 41% tenía 80 años o más, el 22% eran mujeres, el 28% diabéticos, el 56% tenía disfunción ventricular moderada a grave, el 31% insuficiencia renal crónica, el 50% vasculopatía periférica, el 53% angina refractaria, el 22% IAM reciente, el 28% procedimientos de emergencia y la mediana de EUROSCORE fue de 10,5 puntos.

El 41% de los pacientes presentaban compromiso del TCI distal. El éxito angiográfico fue del 94%. Se utilizaron inhibidores IIb/IIIa en el 47%, *cutting balloon* en el 28%, Rotablator® en el 3% y balón de contrapulsación en el 31%. En todos se implantó un *stent* y en el 50% se trataron otras obstrucciones.

La mortalidad hospitalaria fue del 3,1% (intervalo de confianza del 95% 0,2%-14,5%, $p = 0,003$), en tanto que la predicha era del 23,8%. Ningún paciente presentó déficit neurológico, IAM transmural ni requirió diálisis. Un paciente debió ser sometido a CRM electiva por fracaso del procedimiento.

La mediana de seguimiento fue de 15,5 meses, período en el que se registraron 6 muertes (2 cardiovasculares) y 4 reintervenciones. La incidencia acumulada de reintervención fue del 15,6% (IC 95% 6,0%-31,3%).

Conclusiones

La ATC del TCI no protegido en pacientes con alto riesgo quirúrgico debería considerarse una alternativa a la CRM.

Palabras clave > Tronco de coronaria izquierda - Angioplastia - *Stent* - Alto riesgo

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APPENDIX

EUROSCORE: scores assigned to each item are added to calculate the overall risk.

Age: 1 point per 5 years or part thereof over 60 years.

Female: 1 point.

Chronic pulmonary disease (longterm use of bronchodilators or steroids for lung disease): 1 point.

Extracardiac arteriopathy (any one or more of the following: claudication, carotid occlusion or >50% stenosis, previous or planned intervention on the abdominal aorta, limb arteries or carotids): 2 points.

Neurological dysfunction disease (severely affecting ambulation or day-to-day functioning): 2 points.

Previous cardiac surgery (requiring opening of the pericardium): 3 points.

Renal failure (serum creatinine > 2.3 mg/dl): 2 points.

Active endocarditis (patient still under antibiotic treatment for endocarditis at the time of surgery): 3 points.

Critical preoperative state (any one or more of the following: ventricular tachycardia or fibrillation or aborted sudden death, preoperative cardiac massage, preoperative ventilation before arrival in the anaesthetic room, preoperative inotropic support, intraaortic balloon counterpulsation or preoperative acute renal failure (anuria or oliguria): 3 points.

Unstable angina (rest angina requiring nitrates until arrival in the anaesthetic room): 2 points.

LV dysfunction moderate or poor: 3 points.

Recent myocardial infarction (<90 days): 2 points.

Pulmonary hypertension (systolic PA pressure > 60 mmHg): 2 points.

Emergency (carried out on referral before the beginning of the next working day): 2 points.

Other than isolated CABGS: 2 points.

Surgery on thoracic aorta: 3 points.

Postinfarction septal rupture: 4 points.

Logistic EuroCORE (predicted operative mortality): each item has a coefficient and all should integrate the following formula. **Xi** = 1 if a categorical risk factor is present and 0 if it is absent. For age, **Xi** = 1 if patient age < 60; and (age - 58) if patient age > 60.

$$\frac{e^{(\beta_0 + \sum \beta_1 X_1)}}{1 + e^{(\beta_0 + \sum \beta_1 X_1)}}$$

	β_i coefficient		β_i coefficient
Age	0.0666354	Moderate LV dysfunction	0.4191643
Female	0.3304052	Poor LV dysfunction	1.094443
serum creatinine \geq 2.3 mg/dl	0.6521653	Critical preoperative state	0.9058132
Extracardiac arteriopathy	0.6558917	Pulmonary hypertension	0.7676924
Chronic pulmonary disease	0.4931341	Active endocarditis	1.101265
Neurological dysfunction	0.841626	Postinfarction septal rupture	1.462009
Emergency	0.7127953	Other than isolated CABGS	0.5420364
Previous cardiac surgery	1.002625	Surgery on thoracic aorta	1.159787
Recent myocardial infarction	0.5460218	β_0 constant	- 4.789594
Unstable angina	0.5677075		