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Clinical impact of routine angiographic follow-up after percutaneous coronary interventions on unprotected left main

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Abstract

Background: *Patients undergoing percutaneous coronary intervention (PCI) with drug-eluting stent (DES) on unprotected left main (ULM) represent a complex subset. The role of routine coronary angiography at follow up in this subset remains debated.*

Methods: *At the documented center, all patients undergoing successful PCI on ULM lesions performing angiographic follow-up is suggested, but adherence to such a recommendation is inhomogeneous. Consecutive patients undergoing DES PCI on ULM were enrolled and experienced no adverse events during the first 6 months. Patients were then allocated to two groups: those undergoing routine control angiography (CA) and those undergoing clinical follow-up (CF). Primary endpoint was major adverse cardiac events (MACE) defined as cardiac death, myocardial infarction and urgent repeat target vessel revascularization.*

Results: *A total of 190 patients underwent successful DES implantation on ULM and the study population was without early events. CA was performed at 6 months after the index procedure in 91 (48%) patients. After 35 ± 21 months, MACE rates were significantly more common in the CF group as compared with the CA group (16.2% vs. 4.3%, p = 0.009). At multivariable analysis, CA was associated with reduced MACE risk (HR 0.13, 95% CI 0.1–0.7, p = 0.028). Of note, this was mainly driven by higher cardiac death rate in those undergoing CF than in those undergoing CA (p = 0.01).*

Conclusions: *CA after complex PCI, such as ULM PCI, is associated with reduced MACE. Such an observation calls for appropriately designed randomized trials.* (Cardiol J 2018; 25, 5: 582–588)

Key words: coronary angiography, percutaneous coronary interventions, unprotected left main

Introduction

Percutaneous coronary intervention (PCI) for complex lesions, such as unprotected left main (ULM) disease has improved over time. After successful PCI, controlled randomized studies comparing follow-up strategies are lacking. Routine control angiography is commonly used in studies assessing restenosis rate [1, 2]. Such an approach has been recognized to be associated with a detectable, albeit small, risk of morbidity and mortality [3–5]. Moreover, arguments in favor of repeat revascularization in the presence of asymptomatic restenosis are scarce [6] and the clinical impact of routine control angiography on long-term survival has been challenged [7–9]. On this basis, guideline-writing authorities recommend a control angiography after PCI in restricted clinical situations such as patients complaining of angina symptoms or presenting signs of ischemia [10]. Nevertheless, since patients with angiographically-proven reste-
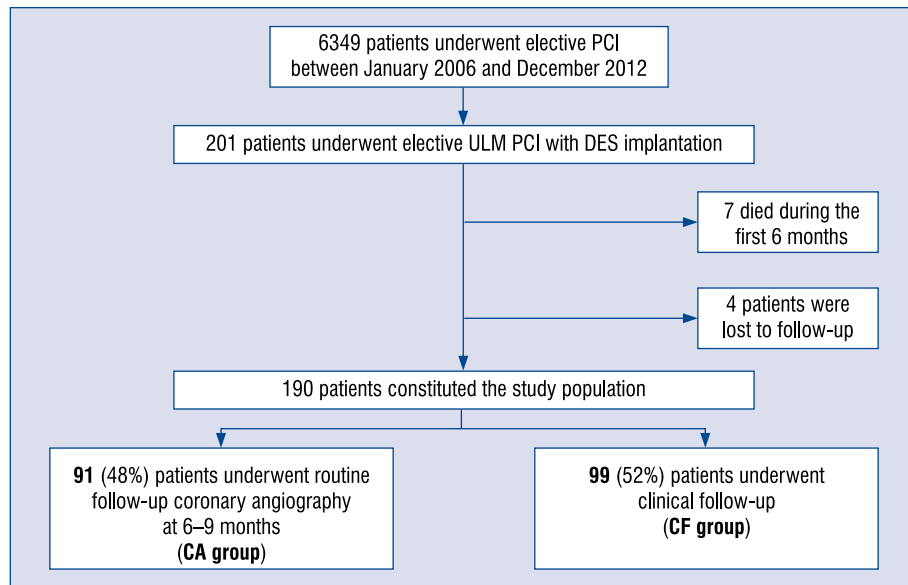
Figure 1. Study flow-chart; CA — coronary angiography; CF — clinical follow-up; DES — drug-eluting stent; PCI — percutaneous coronary intervention; ULM — unprotected left main.

nosis have worse prognosis at long-term follow-up [11–13], when dealing with patients at higher risk, planned coronary angiography may be considered.

In the present study, it was sought to assess the clinical impact of routine control angiography in patients undergoing successful PCI on complex lesions such as ULM diseases.

Methods

Study design

A retrospective observational study was conducted which included consecutive patients who underwent successful PCI with drug-eluting stent (DES) implantation for ULM lesions at the documented center between January 2006 and December 2012. During the study period, in accordance with internal protocol at the present institution, patients undergoing successful PCI on ULM lesions were recommended to undergo routine control angiography at 6–9 months. However, adherence to our recommendation was inhomogeneous due to referring physician and patient preference. As a consequence, some patients only received coronary angiography (CA) at follow up while the others underwent non-invasive clinical follow-up (CF).

Clinical and procedural characteristics were prospectively collected for each patient and entered into a dedicated catheterization laboratory database (Estensa, Esaote, Genoa, Italy).

The left main coronary artery was defined as unprotected in the absence of previous coronary artery bypass grafting (CABG) and if CABG had been performed but grafts to the left coronary system were occluded. PCI was defined successful if a stent was implanted, visual final diameter stenosis was ≤ 20% and a thrombolysis in myocardial infarction (TIMI) 3 flow in the treated segment. Pre and post-dilatation, kissing balloon dilatation, ventricular assistance and adjunctive intravascular imaging were used at the operator's discretion.

The study flow-chart is reported in Figure 1. Briefly, patients who had undergone successful PCI with DES implantation on ULM were first retrospectively identified. Then, patients with adverse events occurring during the first 6 months were excluded. The selected study population was allocated into two groups: patients who received CA and those who underwent CF.

For all patients enrolled, clinical records were carefully evaluated and clinical follow-up was obtained by outpatient visit (in patients who decided to be followed-up at this Institution) or by telephone interview (for the remaining patients).

Study end-points

Primary composite endpoint was major adverse cardiac events (MACE), defined as cardiac death, myocardial infarction (MI) and urgent repeat target vessel revascularization (TVR) occurring after 6 months during follow-up.

Cardiac death was defined as any death without clear non-cardiac cause. MI during the follow-up was diagnosed according to clinical symptoms,

Table 1. Baseline characteristics of the study groups.

	All (n = 190)	CA group (n = 91)	CF group (n = 99)	P (1 vs. 2)
Age [years]	69 ± 10	66 ± 10	71 ± 10	0.5
Male	155 (81%)	75 (82.4%)	80 (79.2%)	0.3
Risk factors:				
Diabetes	55 (28.9%)	27 (29.7%)	28 (27.7%)	0.4
Hypertension	154 (81%)	71 (78.0%)	83 (82.2%)	0.3
Dislipidemia	117 (61.5%)	58 (63.7%)	59 (58.4%)	0.3
Current smokers	36 (18.9%)	17 (18.7%)	19 (18.8%)	0.6
Renal failure:	23 (12.1%)	8 (8.8%)	15 (14.9%)	0.2
History of MI	43 (22.6%)	15 (16.5%)	28 (27.7%)	0.05
Prior PCI	54 (28%)	26 (28.6%)	28 (27.7%)	0.5
Prior CABG	22 (11.5%)	9 (8.8%)	13 (12.9%)	0.3
Mild LVEF disfunction (EF 49–30)	27 (14.2%)	11 (12.1%)	16 (15.8%)	0.3
Severe LVEF disfunction (EF < 30)	17 (8.9%)	8 (8.8%)	9 (8.9%)	0.6
Admission diagnosis:				
Stable angina	136 (71.7%)	68 (74.7%)	68 (68.7%)	0.15
NSTEMI	18 (9.4%)	7 (7.7%)	11 (10.9%)	0.3
Unstable angina	36 (18.9%)	16 (17.6%)	20 (20.4%)	0.5

CA — coronary angiography; CF — clinical follow-up; CABG — coronary artery bypass grafting; LVEF — left ventricular ejection fraction; MI — myocardial infarction; NSTEMI — non-ST-segment elevation myocardial infarction; PCI — percutaneous coronary intervention

electrocardiographic changes and elevation of cardiac biomarkers as explained in the third universal definition [14].

Urgent TVR was defined as TVR occurring in the setting of an unplanned hospitalization due to documented or suspected acute myocardial ischemia.

Secondary end-points included the individual components of primary end-point and the composite of cardiac death and MI. Another secondary end-point was any TVR including those performed at the time of planned CA.

Statistical analyses

Continuous variables were expressed as mean ± standard deviation, categorical data as n/N (%). The χ^2 or Fisher exact tests were used for categorical variables. P value < 0.05 was considered significant. Multivariable Cox proportional hazard model adjusted for potential confounding variables were used to assess the independent role of routine control angiography in the risk for MACE. The model included all clinical features reporting a difference between the two groups plus cardiovascular risk factors, age, sex, clinical presentation, number of diseased vessels, number of treated vessels, stent type and stent length. The rates of freedom from major events were constructed according to Kaplan and Meier, and comparisons were made using the log-rank test. The SPSS 18.0 statistical software (SPSS Italia, Inc., Firenze, Italia) was used for analyses.

Results

The study flow-chart is reported in Figure 1. Out of 6349 patients who underwent elective PCI at the present institution during the study period, 201 patients underwent elective ULM PCI and were eligible for the study. Eleven patients were then excluded: 7 died during the first 6 months and 4 patients were lost to follow-up. Thus, a total of 190 patients constituted the study population. Out of these, 91 (48%) patients had elective follow-up coronary angiography and constituted the CA group while the remaining 99 (52%) constituted the CF group.

Baseline clinical characteristics of the study groups are summarized in Table 1 showing the absence of significant differences in cardiovascular risk factors and cardiac clinical presentation. Similarly, angiographic and procedural characteristics (Table 2) were similar between the right coronary artery and CF group except for a significantly

Table 2. Procedural characteristics of the study groups.

	All (n = 190)	CA group (n = 91)	CF group (n = 99)	P (1 vs. 2)
Radial approach	145 (76.3%)	69 (75.8%)	76 (76.7%)	0.5
Contrast dose [mL]	338.4 ± 126	341.7 ± 125	335 ± 127	0.7
No of disease vessels:				
1 vessel	69 (36.3%)	33 (36.2%)	36 (36.3%)	0.5
2 vessels	60 (31.6%)	28 (30.7%)	32 (32.3%)	0.5
3 vessels	53 (27.9%)	24 (26.3%)	29 (29.2%)	0.4
No. of treated vessel:				
1 vessel	111 (58.4%)	49 (53.8%)	62 (62.3%)	0.4
2 vessels	59 (31%)	30 (32.9%)	29 (29.3%)	0.5
3 vessels	4 (2%)	2 (2.2%)	2 (2.0%)	0.4
Complete revascularization	141 (74%)	69 (75%)	72 (73%)	0.3
Assisted PCI (IABP or Impella)	16 (8.4%)	7 (7.6%)	9 (9.1%)	0.3
Intravascular imaging (IVUS or OCT)	49 (26%)	27 (29.7%)	22 (22.2%)	0.13
Stent length [mm]	27.8±13	28.6±13	27.1±14	0.5
Stent diameter [mm]	3.6±0.4	3.6±0.4	3.6±0.5	0.7
Multiple stents	38 (20%)	17 (19%)	21 (21%)	0.5
Bifurcation strategy				
Side branch stenting	19 (10%)	15 (16.5%)	4 (4.0%)	0.003
TAP stenting	14 (7%)	10 (11%)	4 (4.0%)	0.055
Other side branch stenting technique	5 (2.6%)	5 (5.5%)	0 (0%)	0.023
Final kissing balloon	123 (64.7%)	59 (64.8%)	64 (64.4%)	0.5

CA — coronary angiography; CF — clinical follow-up; IABP — intra-aortic balloon pump; IVUS — intravascular ultrasound; OCT — optical coherence tomography; PCI — percutaneous coronary intervention; TAP — T-stenting and small protusion

Table 3. Clinical events during follow-up in the study group.

	All (n = 190)	CA group (n = 91)	CF group (n = 99)	P (1 vs. 2)
Primary endpoint				
MACE (CD + MI + urgent TVR)	20 (10.5%)	4 (4.3%)	16 (16.2%)	0.009
Secondary endpoints				
Any TVR	19 (10%)	14 (15.4%)	5 (5%)	0.014
CD	7 (3.7%)	0 (0%)	7 (7%)	0.01
MI	7 (3.7%)	2 (2.2%)	5 (5%)	0.3
Urgent TVR	6 (3.1%)	2 (2.2%)	4 (4%)	0.3
CD + MI	14 (7.4%)	2 (2.2%)	12 (12.1%)	0.009

CA — coronary angiography; CF — clinical follow-up; CD — cardiac death; MACE — major adverse cardiac events; MI — myocardial infarction; TVR — target vessel revascularization

higher side-branch stenting (p = 0.003) in the CA group. After a mean of 35 ± 21 months, a total of 20 (10.5%) patients experienced MACE (Table 3). MACE rates were significantly more frequent in the CF group than CA group (16.2% vs. 4.3%, p = 0.009), mainly due to a significantly higher cardiac death rate (p = 0.01). The rates of urgent TVR and MI were similar in the two groups. Any TVR rate was significantly higher in the CA group than in the CF group (15.4% vs. 5% of CF, p = 0.014).
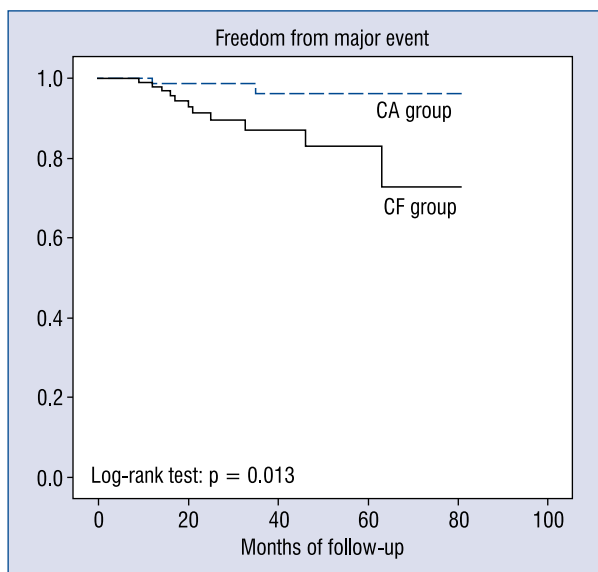
Figure 2. Kaplan-Meier major adverse cardiac events-free survival curves in patients with unprotected left main percutaneous coronary intervention undergoing coronary angiography (CA) or clinical follow-up (CF).

The Kaplan-Meier MACE-free survivals reported in Figure 2 shows a statistically better outcome for the CA group than CF group (p = 0.013).

At univariate analysis, significant predictors of MACE were age (p = 0.003), severe ventricular dysfunction (p = 0.015), follow-up modality (CF or CA) (p < 0.0001). At multivariable analysis, the follow-up modality (CF vs. CA) was the only independent predictor of MACE, CA being associated with a reduced risk (HR 0.13, 95% CI 0.1–0.7, p = 0.028).

Discussion

Previous randomized and non-randomized trials consistently reported that routine coronary angiography at follow-up increased repeat coronary revascularization without reduction in MACE, although the rate of MI was lower in the routine coronary angiography group of the sub-studies of Balloon Angioplasty and Anticoagulation Study and the TAXUS-IV trial [7–9, 16–18]. Recently the Randomized Evaluation of Routine Follow up Coronary Angiography after Percutaneous Coronary Interventional Trial (REACT) has confirmed that routine CA after PCI was not associated to clinical benefits and early coronary revascularization rates were increased within routine CA strategy [19]. However, the trial was underpowered to detect modest benefits of a routine CA after PCI and in the subgroup analyses the routine CA strategy is associated to a trend with a lower incidence of MACE in patients undergoing ULM PCI. Therefore, the impact of routine CA strategy in high risk patients, such as patients had undergone ULM PCI, in real world practice has not been fully evaluated.

The results of the present study show that routine CA, despite being not recommended by contemporary guidelines, may be appropriate in patients undergoing successful complex PCI. In particular, patients who underwent PCI on ULM. PCI may have a major clinical benefit since an early recognition and treatment of restenosis may help reduce mortality at follow up. Several studies have demonstrated the safety and feasibility of complex PCI such as ULM PCI and many centers currently perform these procedures which are associated with considerable risk of restenosis and adverse clinical outcomes. Yet the most appropriate strategy to follow these patients after successful revascularization remains debated. Indeed, routine control angiography is often recommended between 6 and 12 months after PCI, but evidence in support of this strategy is lacking. Previous studies have reported that routine control angiography after PCI leads to higher rates of repeat interventions, without clear advantages when compared with a conservative management in which repeat angiography is reserved to patients presenting recurrent symptoms or objective sign of myocardial ischemia [7, 8, 15, 16] including patients receiving ULM PCI [20].

In the present study, the clinical impact of routine control angiography was evaluated in patients undergoing complex PCI, such as revascularization for ULM stenosis. The main finding of this study is that even if routine control angiography is associated (as expected) with a higher rate of repeat TVR, it appears to improve late outcome since the composite of cardiac death, nonfatal MI and urgent TVR was significantly reduced. Such findings may suggest that "elective" repeat revascularization procedures may have a beneficial impact on clinical outcomes in high risk patients [21, 22]. In keeping with this notion, in a recent study, the evidence of asymptomatic restenosis was predictive of 4-year mortality [13]. In the same study, which was not focused on complex PCI patients, the received management (conservative or repeat revascularization) did not influence outcome [13].

Of note, the results of the present study are in contrast with that of another study on most appropriate follow up strategy in undergoing ULM PCI. Indeed, Biondi-Zoccai et al. [20] reported no

benefit with CA vs. CF. This study has the same limitations as the present study as they were both retrospective, observational, single center register. Importantly, Biondi-Zoccai et al. [20] reported a much higher rate of angiographically-driven TVR (thus reflecting a different attitude in the management of mild restenosis) and including any TVR (not just urgent TVR) as a component of primary end-point.

Recently a multicenter registry, included consecutive patients with a critical lesion of an ULM treated with second generation DES, has demonstrated that planned angiographic control was associated with more TVR but with lower rates of cardiovascular death [23]. Although the study has a retrospective design, the number of patients enrolled has allowed propensity score balancing to correct the heterogeneity of the study groups. In the present study a similar incidence of TVR was found and a similar benefit on prognosis for patients with planned angiographic control but presently herein, have not completely removed the risk of selection bias tending to favor the performance of routine angiography in healthier patients, despite the multivariate analysis.

Limitations of the study

The major limitation of this study is the retrospective, observational and single center design as the choice of follow-up strategy was left to the referring physician and/or patient. Therefore, differences can be expected in baseline and procedural characteristics of the groups and multivariate analysis may not have completely eliminated the risk of selection bias tending to favor the performance of routine angiography in healthier patients. Furthermore, the relatively small number of patients precludes the possibility of propensity score balancing to correct heterogeneity of the study groups. The strategy of clinical follow-up is related to the referring physician discretion. Therefore, selected strategy of clinical follow-up and, specifically, the use of non-invasive tests are unknown for both study groups. In conclusion, the results of this study call for future evaluations of the clinical impact of systematic angiographic follow-up in patients who have successfully undergone ULM PCI.

Conclusions

The present study evaluated the clinical impact of routine control angiography in patients undergoing to PCI revascularization for ULM stenosis. The main finding is that even if routine control angiography is associated (as expected) with a higher rate of repeat TVR, it appears to improve late outcome since the composite of cardiac death, nonfatal MI and urgent TVR was significantly reduced, suggesting that "elective" repeat revascularization procedures may have a beneficial impact on clinical outcomes in high risk patients. The present findings are hypothesis generating and need to be confirmed by adequately powered, randomized and controlled trials.

Conflict of interest: None declared

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