Complete infarct-related artery revascularization in acute myocardial infarction patients. CORAMI Registry

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Abstract

Introduction: There are still limited data on the occurrence of multiple stenotic lesions within the infarct-related artery (IRA) in acute myocardial infarction (MI), and there is no consensus on the optimal treatment of this patient subgroup, which varies between centers and operators.

Aim: To analyse the clinical efficacy of percutaneous coronary intervention (PCI) strategy of culprit lesion only in patients with myocardial infarction.

Material and methods: Patients with acute MI with the presence of at least two significant lesions in the IRA – (1) the target culprit lesion which required immediate stenting (> 50–100% stenosis) and (2) a second distal critical lesion (70–90%) – were included in the registry. Both lesions in the IRA were considered to be independent lesions requiring two separate stent platforms to be covered (no overlap). The decision on the treatment strategy of either complete (CR) or culprit-lesion-only (CLO) revascularization was at the discretion of the operator.

Results: There were altogether 95 patients enrolled in the registry, 63 (66%) in the group with CR of the IRA and 32 (34%) with CLO revascularization, which did not differ in terms of baseline demographics. In-hospital and long-term outcomes were similar between the groups. Stent thrombosis at 1 year occurred in 1.6% in CR and in 6.2% in CLO groups respectively (statistically not significant). There were no patients from the CLO group who had a planned percutaneous coronary intervention (PCI) of the 2nd lesion in the IRA during 1-year observation.

Conclusions: At 1 year the clinical outcome was similar between those with complete and CLO PCI. Complete coverage of significant lesions did not increase the risk of stent thrombosis or need for repeated revascularization in long-term observation.

Key words: myocardial infarction, revascularization, stent, registry.

Introduction

Concomitant significant stenosis in coronary arteries other than the infarct-related artery (IRA) occurs in 40% to 60% of patients undergoing primary percutaneous coronary intervention (PPCI) for ST-elevation myocardial infarction (STEMI) both in historic and recent data [1–7]. Moreover, the presence of multivessel coronary artery disease in the STEMI setting is usually associated with adverse long-term outcome [1, 3, 5–8]. According to the current European Society of Cardiology (ESC) revascularization guidelines, PCI of only culprit vessel should be performed in STEMI, with an exception of cardiogenic shock (IIa), whereas immediate PCI of all lesions during PPCI may only be considered in selected patients (IIb) [9]. Similarly, the mode of revascularization in non-ST elevation myocardial infarction (NSTEMI) should be decided taking into account comorbidities, clinical data and extent of the atherosclerotic disease. There are multiple data from meta-analyses, randomized trials and registries which either support complete revascularization in acute myocardial infarction [10–14] or support a more conservative guideline-recommended approach [15–18].

However, there are still limited data on the occurrence of multiple stenotic lesions within the IRA in a STEMI and NSTEMI setting. At the same time there is no consensus on the optimal treatment of this patient subgroup. The

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strategies vary between centers but also PCI operators. Scarce data suggest that "spot" only coverage of stenotic lesions with minimization of stent length might be superior to the "full metal jacket" strategy at least in a group of stable angina patients [19, 20]. It was also confirmed that the length and number of implanted drug eluting stents (DES) is associated with increased risk of stent thrombosis [21, 22].

Aim

The aim of the CORAMI registry was to assess the contemporary treatment strategies in acute myocardial infarction patients with multiple stenotic lesions in the IRA with either complete (CR) or culprit-lesion-only (CLO) revascularization and its influence on long-term outcome.

Material and methods

The CORAMI Registry was first planned as a randomized clinical trial (NCT01218815). The study was launched in Polish and Slovenian sites, but due to difficulties with enrollment the study was terminated. The investigators decided that it would be worth continuing the research, so the CORAMI Registry was started instead.

The CORAMI Registry was a prospective, international (Poland, Slovenia), multicenter (6 sites in Poland, 1 in Slovenia) observational study which was performed in experienced invasive cardiology centers with 24/7 PCI duty with patient enrollment between October 2011 and June 2012.

Patients with STEMI or NSTEMI over 18 years old with the presence of at least two significant lesions in the IRA – (1) the target culprit lesion which required immediate stenting (> 50–100% stenosis) and (2) a second distal critical lesion (70–90%) – were included in the registry. Both lesions in the IRA were considered to be independent lesions requiring two separate stent platforms to be covered (no overlap). The decision on the treatment strategy of either CR or CLO revascularization was at the discretion of the PCI operator. Further pharmacological treatment was according to local standards and best clinical practice. Patient follow-up phone calls and/or ambulatory visits were performed at 12 months after the enrollment.

The primary end-point of this analysis were: overall mortality at 1 year, confirmed stent thrombosis at 12 months according to the Academic Research Consortium (ARC) definition, repeated myocardial infarction at 12 months, urgent target vessel revascularization (TVR) at 12 months and planned TVR (PCI or CABG) at 12 months. Secondary clinical endpoints included: immediate in-hospital angiographic complications (at least one or more of the following: distal embolisation, no-reflow, slow-flow, acute coronary artery occlusion, artery perforation, tamponade, dissection type B and above), urgent in-hospital TVR (PCI and/or CABG), complete radiation dose in mGy.

The CORAMI Registry complied with the Declaration of Helsinki and was approved by the Bioethics Committee at the Jagiellonian University in Krakow, Poland (KBET/140/L/2010 of October 7th, 2010).

Statistical analysis

Data were analyzed according to the established statistical standards. Categorical variables were presented with counts and as percentages and continuous variables as means (± standard deviation). Differences between groups were tested using Fisher's exact test or Pearson's χ^2 test for categorical variables and the Mann-Whitney *U* test for continuous variables. Values of p less than 0.05 were considered statistically significant. Two-sided tests were applied. All calculations were done with JMP 9.0.0 software by an experienced statistician.

Results

There were altogether 95 patients enrolled in the registry, 63 (66%) in the group with complete revascularization of the IRA and 32 (34%) with CLO revascularization. Baseline demographics and procedural aspects are presented in Table I. The balance of STEMI diagnosis was similar between the groups (CR vs. CLO 73% vs. 84%, p = 0.305). In-hospital and long-term outcome as well as adherence to dual antiplatelet therapy are presented in Table II. There were no patients from the CLO group who had a planned PCI of the 2nd lesion in the IRA during 1-year observation.

Discussion

The CORAMI Registry is one of the first studies scheduled to evaluate the impact of complete infarct artery revascularization in patients who are treated with coronary angioplasty with stenting during the acute phase of STEMI and NSTEMI. The incidence of two independent stenotic lesions in the IRA is a rare situation (3% in our population, data not shown) but certainly requires scientific evaluation as there are no clear guidelines on how to intervene, especially in a myocardial infarction setting [9]. Therefore, these decisions are often based on coronary anatomy, patient clinical status and empirical experience of a single PCI operator including thrombolysis in myocardial infarction (TIMI) flow after initial lesion stenting, presence of hemodynamic compromise, location of the distal lesion as well as artery diameter. In the CORAMI study patients with two lesions identified in the IRA were analyzed. The first lesion was treated as the culprit one, which was always stented, and the other was treated with a stent based on the discretion of the PCI operator but had to be less than 90% in diameter stenosis (we did not want to include patients with obvious flow limiting critical lesions > 90%, which should be stented during the index procedure). Our early assumption that most such patients will receive multiple stents to cover all le-

Table I. Baseline characteristics, angiography and PCI

Variable	CR	CLO	Value of *p*
No. of patients	66% (63)	34% (32)	–
Age	66.3 ±11.3	69.7 ±11.9	0.182
Gender (male)	75% (47)	75% (25)	0.966
BMI [kg/m^2]	27.5 ±3.4	27.1 ±3.1	0.518
Previous myocardial infarction	11% (7)	9% (3)	0.794
Arterial hypertension	63.5% (40)	62.5% (20)	0.912
Hyperlipidemia	40% (25)	31% (10)	0.546
Diabetes mellitus	16% (10)	12.5% (4)	0.767
Chronic kidney disease	3% (2)	3% (1)	0.989
Previous stroke	1.6% (1)	0% (0)	0.473
Previous PCI	6% (4)	3% (1)	0.613
Previous CABG	1.6% (1)	0% (0)	0.473
Smoking	59% (37)	37.5% (12)	0.262
Clinical status on admission:			
HR	77.3 ±19.5	75.8 ±13.6	0.971
SBP	141 ±26	131 ±21	0.075
DBP	81 ±17	76 ±11	0.042
Number of critically stenosed arteries:			
1-vessel disease (IRA only)	35% (22)	31% (10)	0.820
Multivessel disease	65% (41)	69% (22)	
Infarct-related artery (IRA):			
LAD	25% (16)	41% (13)	0.269
Cx	8% (5)	9% (3)	
RCA	67% (42)	50% (16)	
TIMI before PCI:			
0	41% (26)	56% (18)	0.407
1	14% (9)	16% (5)	
2	21% (13)	9% (3)	
3	24% (15)	19% (6)	
Number of stents in IRA:			
≥ 2 stents in IRA	100% (63)	0% (0)	< 0.001
1 stent in IRA	0% (0)	100% (32)	
No stents in IRA	0% (0)	0% (0)	
Type of stent:			
DES	44% (28)	34% (11)	0.385
PCI procedure time [min]	33.0 ±21.7	26.6 ±18.1	0.092
Radiation [mGy]	1406 ±921	1171 ±1250	0.055
LVEF (%)	53.2 ±10.9	51.5 ±12.3	0.566
1st stent diameter [mm]	3.2 ±0.4	3.2 ±0.4	0.824
1st stent length [mm]	20.5 ±7.3	21.1 ±7.4	0.737
2nd stent diameter [mm]	3.2 ±0.5	–	–
2nd stent length [mm]	20.2 ±7.9	–	–
TIMI 3 flow after PCI	95% (60)	91% (29)	0.401
Thrombectomy	25% (16)	37.5% (12)	0.242

Table II. Primary and secondary clinical endpoints and adherence to DAPT

Variable	CR	CLO	Value of *p*
No. of patients	66% (63)	34% (32)	–
12 months observation:			
Death	6.4% (4)	9.4% (3)	0.593
Stent thrombosis	1.6% (1)	6.2% (2)	0.219
Acute MI	1.6% (1)	3.1% (1)	0.622
Urgent TVR	4.8% (3)	9.4% (3)	0.383
Planned TVR	0% (0)	0% (0)	–
In-hospital events:			
Death	1.6% (1)	6.2% (2)	0.219
Stent thrombosis	1.6% (1)	6.2% (2)	0.219
Angiographic complications*	1.6% (1)	3.1% (1)	0.622
Urgent TVR (PCI or CABG)	1.6% (1)	6.2% (2)	0.219
DAPT at 12 months:			
Clopidogrel	47.6% (30)	34% (11)	0.452
Prasugrel	1.6% (1)	6.2% (2)	
Ticagrelor	4.8% (3)	6.2% (2)	
ASA only	46% (29)	53.6% (17)	

**Defined as at least one or more of the following: distal embolisation, no-reflow, slow-flow, acute coronary artery occlusion, artery perforation, tamponade, dissection type B and above. DAPT – dual antiplatelet therapy, ASA – acetylsalicylic acid, TVR – target vessel revascularization, PCI – percutaneous coronary intervention, CABG – coronary artery bypass graft, MI – myocardial infarction.*

sions turned out to be at least exaggerated. In as many as 34% of STEMI and NSTEMI cases the second distal lesion in the IRA was left without stenting and intended for conservative treatment. During a 12-month follow-up none of the 2nd lesions in the CLO group were scheduled for an elective PCI. Elective PCIs of non-target vessel lesions were performed equally between study groups in follow-up since ca. 2/3 of study patients had multivessel disease diagnosed in baseline angiography.

The benefit of the CLO strategy in STEMI and NSTEMI during in-hospital stay was observed for decreased overall PCI time and lower radiation exposure for the patient, but was only borderline in terms of statistical inference. Even though the mean length of the implanted scaffold in the CR group was ca. 41 mm vs. 21 mm, the immediate PCI outcome in both groups was similar (a rate of TIMI 3 flow). Periprocedural complications as defined by the protocol were rare in both groups. Both during in-hospital and 12-month observation the occurrence of death, stent thrombosis and urgent TVR was more frequently observed in the CLO group, but due to low sample size it was not statistically significant. Thus we need to conclude that in the CORAMI patient sample there was no benefit from complete IRA revascularization at least in terms of occurrence of clinical endpoints in longer observation. Contrary to some reports, there was no excess of stent thrombosis with more stents implanted [21, 22]. It is also interesting to observe that as many as half of patients in the CORAMI registry did not take dual antiplate-

let therapy any longer at 12 months. The CORAMI study raises a number of issues that would ideally be answered in a larger randomized study.

This was a registry study with low sample size, and drawing definite conclusions based on the results of CORAMI should be cautious. There was no independent angiographic core lab evaluation of PCI procedures and procedural complications. The follow-up observation was mainly performed by telephone calls. In addition, the results cannot be applied to patients treated with new stents designs (i.e. mesh covered stents, self-expandable stents) or bioresorbable vascular scaffold implantation during primary PCI for STEMI [23, 24].

Conclusions

Complete infarct-related artery revascularization in acute myocardial infarction was performed in two-thirds of patients in the CORAMI Registry. At 1 year the clinical outcome was similar between those with complete and CLO PCI. Complete coverage of significant lesions did not increase the risk of stent thrombosis or need for repeated revascularization in long-term observation.

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Conflict of interest

The authors declare no conflict of interest.

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