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ORIGINAL ARTICLE

Frequency and prognostic impact of intravascular imaging-guided urgent percutaneous coronary intervention in patients with acute myocardial infarction: results from J-MINUET

Hiroyuki Okura[1] · Yoshihiko Saito[1] · Tsunenari Soeda[1] · Koichi Nakao[2] · Yukio Ozaki[3] · Kazuo Kimura[4] · Junya Ako[5] · Teruo Noguchi[6] · Satoshi Yasuda[6] · Satoru Suwa[7] · Kazuteru Fujimoto[8] · Yasuharu Nakama[9] · Takashi Morita[10] · Wataru Shimizu[11] · Atsushi Hirohata[12] · Yasuhiro Morita[13] · Teruo Inoue[14] · Atsunori Okamura[15] · Masaaki Uematsu[16] · Kazuhito Hirata[17] · Kengo Tanabe[18] · Yoshisato Shibata[19] · Mafumi Owa[20] · Kenichi Tsujita[21] · Kunihiro Nishimura[6] · Yoshihiro Miyamoto[6] · Masaharu Ishihara[22] on behalf of The J-MINUET investigators

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Abstract
Previous studies have demonstrated that use of intravascular ultrasound (IVUS) during percutaneous coronary intervention (PCI) was associated with lower incidence of death, myocardial infarction, and target vessel revascularization. Recently, optical coherence tomography (OCT) has emerged as an alternative intravascular imaging device with better resolution. The aim of this study was to investigate frequency and prognostic impact of IVUS or OCT-guided PCI during urgent revascularization for acute myocardial infarction diagnosed by the universal definition. A total of 2788 patients who underwent urgent PCI were selected from a multicenter, Japanese registry of acute myocardial infarction diagnosed by universal definition (J-MINUET). Frequency, clinical characteristics and prognostic impact of the IVUS-, or OCT- guided PCI were investigated. Clinical endpoint was in-hospital death. Angiography-, IVUS-, and OCT-guided urgent PCI were performed in 689 (24.7%), 1947 (69.8%), and 152 (5.5%) patients. In-hospital death in each group was 10.4%, 5.1%, and 3.3%, respectively ($P<0.01$). By univariate and multivariate logistic regression analysis, IVUS-guided PCI (vs. angiography-guided PCI, OR 0.49, 95% CI 0.30–0.81, $P=0.006$) was a significant independent predictor of in-hospital death. Intravascular imaging guided-PCI was frequently adopted during urgent PCI for acute myocardial infarction diagnosed by universal definition and was associated with better in-hospital survival.

Keywords Intravascular imaging · IVUS · OCT · Acute myocardial infarction · PCI

Introduction

Intravascular ultrasound (IVUS) has been increasingly used as a guide for percutaneous coronary intervention during elective as well as emergent clinical senario. Recent randomized studies [1, 2], large scale registries [3,4] as well as meta-analysis [5–9] have consistently demonstrated advantages of IVUS-guidance over angiography-guide alone with respect to the lower incident of death, myocardial infarction and target vessel revascularization.

More recently, a new intravascular imaging device, optical coherence tomography (OCT) has been introduced with better resolution and shorter acquisition time [10–14]. Several preliminary studies suggested possible role of OCT as a guide for PCI [15–17]. One of the advantages of OCT over IVUS is its higher resolution that allows for better visualization of the plaque morphology and the detection of thrombus, plaque rupture and thin-cap fibroatheroma in the setting of the acute coronary syndrome (ACS) [12, 13, 18–20]. On the other hand, one of the advantages of the IVUS over OCT is its better signal penetration allowing for visualization of the entire vessel wall. In addition, both OCT and IVUS may have advantage over angiography-guidance to detect high risk plaque for no reflow/slow flow during PCI [21–24].

The Japanese registry of acute myocardial infarction diagnosed by universal definition (J-MINUET) is a prospective,

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✉ Hiroyuki Okura
hokura@fides.dti.ne.jp

Extended author information available on the last page of the article

multicenter registry of acute myocardial infarction (AMI) diagnosed by the new universal definition to investigate clinical presentation, treatment and outcomes of Japanese patients with AMI in the contemporary cardiac troponin era [25]. The aim of this substudy of the J-MINUET was to clarify frequency and clinical impact of intravascular imaging (IVUS or OCT) guidance during primary PCI for AMI.

Methods

Study design and protocol

The study design, protocol and overall results of the J-MINUET have been reported previously [25]. In brief, a total of 3283 consecutive patients with AMI diagnosed by cTn-based criteria [26] were enrolled from 28 institutions between July 2013 and May 2014. Overall, in-hospital mortality of ST-elevation myocardial infarction (STEMI, $n=2262$), non-ST elevation myocardial infarction with CK elevation (NSTEMI+CK, $n=563$) and NSTEMI without CK elevation (NSTEMI−CK, $n=458$) were 7.1%, 7.8% and 1.7%, respectively. A total of 2788 patients (84.9%) who underwent urgent PCI with detailed procedural information were selected from 3283 patients enrolled in the J-MINUET. Frequency and prognostic impact of angiography (Angio), IVUS, or OCT- guided PCI were investigated. Urgent coronary angiography was performed via femoral, radial or brachial approach according to the each operator's discretion. After diagnostic coronary angiography, the culprit lesion was treated under angiography-, IVUS-, or OCT-guided PCI. Use of IVUS or OCT were left to the each operator's decision.

Clinical outcome

Clinical event was collected at the time of discharge. Clinical endpoint was in-hospital death. The secondary endpoint was major adverse cardiac events (MACE), defined as a composite of all death, cardiac failure, ventricular tachycardia (VT) and/or ventricular fibrillation (VF) and bleeding during hospitalization. Cardiac failure was defined as congestive heart failure and/or cardiogenic shock that required treatment. The study was conducted in accordance with the Declaration of Helsinki. The protocol was approved by the ethics committees of each participating institution.

Statistical analysis

All continuous data are expressed as medians (25–75th percentile) and the differences among three groups for the continuous data were tested by ANOVA. Non-continuous and categorical variables are expressed as percentages and compared using the χ^2 test. We applied ANOVA to the Angio-guided, IVUS-guided and OCT-guided PCI groups, then post hoc pairwise comparisons between each group were conducted with Bonferroni corrections. Univariate and multivariate logistic regression models are used to calculate odds ratios (ORs) for all cardiac events and 95% confidence intervals (CIs). Multivariable analyzes are performed using covariates that were statistically significant prognostic risk factors and established prognostic risk factors for cardiac events among all covariates. Missing values were imputed using the multivariate normal model, using the chained equations approach. Multiple imputation is used to replace each missing value with 2 or more acceptable values, representing a distribution of possible covariates. Multiple imputation method is a more sophisticated imputation method than the case-wise deletion method, which analyzing cases with complete information, or the single imputation method. All statistical tests were 2-sided and $P<0.05$ was regarded as significant. P values < 0.0125 were used for post hoc pairwise comparisons conducted with Bonferroni corrections. Statistical analysis was performed with SAS, version 9.3 (SAS Institute).

Results

Baseline clinical characteristics

A total of 2788 (84.9%) from 3283 patients underwent urgent PCI and thus enrolled in this subanalysis. Angiography-, IVUS-, and OCT-guided PCI were performed in 689 (24.7%), 1947 (69.8%) and 152 (5.5%), respectively. Baseline clinical characteristics in each group are shown in Table 1. There were significant between group differences in age, prevalence of hypertension, dyslipidemia, previous history of myocardial infarction, PCI, CABG, atrial fibrillation, type of AMI and Killip classification on admission. Lesion and procedural characteristics are shown in Table 2. There were significant between group differences in frequency of radial approach, initial TIMI 2/3 flow, use of stent, use of DES, use of thrombectomy, use of distal protection device, stent size, stent length and final TIMI 3 flow. Table 3 summarizes medication on admission. There were nosignificant between group differences in baseline medication on admission.

In-hospital death in angio-, IVUS- and OCT-guided PCI groups were 72 of 689 (10.4%), 100 of 1947 (5.1%) and 5 of 152 (3.3%), respectively ($P<0.0001$). Predictors of in-hospital death were age, Killip class, smoking, door-to-balloon time < 90 min., use of stent, final TIMI 3, use of IABP, use of PCPS, insulin, heart rate, max CK and IVUS-guided PCI. By multivariate logistic

Table 1 Clinical characteristics and presentation

	Angio-guided ($n=689$)	IVUS-guided ($n=1947$)	OCT-guided ($n=152$)	P
Age (years)	70 (61–78)	69 (60–78)	69 (63–76)	0.078
Male gender	517 (75%)	1505 (77%)	117 (75%)	0.481
Concomitant diseases				
Hypertension	63%	67%	57%	0.008
Diabetes	28%	29%	30%	0.713
Dyslipidemia	45%	55%	46%	< 0.0001
Chronic kidney disease	a44%	42%	36%	0.153
Current smoking	35%	36%	32%	0.379
Previous history				
Previous MI	14%	10%	11%	0.042
Previous PCI	18%	14%	18%	0.009
Previous CABG	5%	2%	0.7%	0.0008
Atrial fibrillation	7%	5%	0.7%	0.002
Stroke	12%	10.5%	8%	0.367
Peripheral artery disease	5%	4%	2%	0.383
STEMI/NSTEMI+CK/NSTEMI-CK	534/101/54	1449/286/212	118/22/12	0.185
Type of MI (1/2)	521/19	1837/43	127/1	0.044
Killip classification				0.003
Class 1	70%	78%	87%	
Class 2	12%	8%	5%	
Class 3	5%	5%	2%	
Class 4	11%	10%	6%	
VT/VF on arrival	4%	6%	3%	0.981
Systolic blood pressure (mmHg)	137 ± 33	139 ± 33	135 ± 29	0.275
Heart rate (beats/min)	79 ± 21	78 ± 21	64 ± 16	0.075
Max CK (IU/dL)	2654 ± 3181	2611 ± 2995	2669 ± 3006	0.933

MI myocardial infarction, *PCI* percutaneous coronary intervention, *CABG* coronary artery bypass grafting, *STEMI* ST elevation myocardial infarction, *NSTEMI+CK* non-ST elevation myocardial infarction with CK elevation, *NSTEMI−CK* non-ST elevation myocardial infarction without CK elevation, *VT* ventricular tachycardia, *VF* ventricular fibrillation

regression analysis with multiple imputation including these indices plus OCT-guided PCI, age (OR 1.07, 95% CI 1.05–1.09, $P<0.001$), Killip class (OR 2.32, 95% CI 1.95–2.75, $P<0.001$), current smoking (OR 0.65, 95% CI 0.49–0.84, $P=0.003$), heart rate (OR 1.01, 95% CI 1.00–1.02, $P=0.041$), doo-to-balloon time < 90 min. (OR 0.60, 95% CI 0.40–0.91, $P=0.019$), final TIMI 3 (OR 0.51, 95% CI 0.30–0.88, $P=0.019$), use of stent (OR 0.51, 95% CI 0.27–0.96, $P=0.038$), use of IABP (OR 1.75, 95% CI 1.13–2.70, $P=0.012$), use of PCPS (OR 8.93, 95% CI 4.68–17.04, $P<0.001$), insulin (OR 2.44, 95% CI 1.17–5.10, $P=0.017$), max. CK (OR 1.00, 95% CI 1.00–1.00, $P<0.001$) and IVUS-guided PCI (vs. angiography-guided PCI, OR 0.49, 95% CI 0.30–0.81, $P=0.006$) were statistically significant independent predictors of in-hospital death (Table 4).

MACE in angio-, IVUS- and OCT-guided PCI groups were 133 of 689 (19.3%), 354 of 1947 (18.2%) and 18 of 152 (12.5%), respectively ($P=0.096$). VT/VF were similarly documented in the three groups (3.9% vs. 4.2% vs. 2.0%, $P=0.379$).

Discussion

The principal findings of this study were: (1) intravascular imaging-guided PCI was frequently (75%) adopted during urgent coronary revascularization for acute myocardial infarction diagnosed by universal definition, and (2) intravascular imaging-guidance (in particular IVUS-guidance) during PCI was associated with lower in-hospital death. These results are quite in concordance with previous studies comparing between IVUS-guidance and angiography-guidance during elective PCI [3, 5–7]. There are several possible advantages of IVUS/OCT over angiography alone. First, IVUS/OCT allow for accurate coronary lumen as well as vessel measurements and thus provide useful information about device (balloon or stent) sizing [27, 28]. As a result

Table 2 Procedural characteristics

	Angio-guided (n = 689)	IVUS-guided (n = 1947)	OCT-guided (n = 152)	P
Onset-to-door time (min)	141 (70–342)	150 (68–365)	152 (61–385)	0.222
Door-to-balloon time (min)	78 (55–123)	73 (52–120)	82 (54–120)	0.289
Door-to-balloon time < 90 min	63%	63%	61%	0.839
Coronary angiographya				
Radial approach	32%	31%	21%	0.01
Initial TIMI 2/3 flow	29%	39%	38%	< 0.0001
Infarct related artery (LAD)	39%	45%	44%	0.080
Multivessel diseases	39%	46%	30%	< 0.0001
PCI				
Stent use	66%	99%	93%	< 0.0001
DES use	49%	66%	72%	< 0.0001
Thrombectomy	45%	64%	68%	< 0.0001
Distal protection use	1.5%	9.2%	4.2%	< 0.0001
Stent size (mm)	3.0 (2.5–3.5)	3.0 (2.75–3.5)	3.0 (2.75–3.5)	0.045
Stent length (mm)	20 (18–30)	23 (18–28)	22 (18–26)	0.006
Max. inflation pressure (atm)	18 (14–20)	18 (14–20)	18 (14–20)	0.788
Final TIMI 3 flow	88%	93%	93%	< 0.0001
IABP	16%	18%	16%	0.579
PCPS	4%	3%	3%	0.458

LAD left anterior descending artery, *DES* drug-eluting stent, *PCI* percutaneous coronary intervention, *TIMI* thrombolysis in myocardial infarction, *IABP* intra-aortic balloon pumping, *PCPS* percutaneous cardio-pulmonary support

Table 3 Medications on admission

	Angio-guided (n = 689) (%)	IVUS-guided (n = 1947) (%)	OCT-guided (n = 152) (%)	P
Antiplatelets	26	23	26	0.271
Dual antiplatelets	6	7	4	0.407
Oral anticoagulants	5	4	3	0.344
Calcium channel blockers	32	34	24	0.506
Beta blockers	13	13	7	0.065
Nitrates	6	6	7	0.661
Nicorandil	5	4	1	0.155
ACEI	8	6	7	0.303
ARB	25	25	22	0.772
Aldosterone receptor blockers	2	1	1	0.214
Loop diuretics	9	8	9	0.530
Statin	20	23	22	0.277
Insulin	4	4	4	0.895
H_2 blockers	7	6	9	0.360
Proton pump inhibitors	17	14	14	0.391

ACEI angiotensin converting enzyme inhibitors, *ARB* angiotensin receptor blockers

of the accurate measurements, IVUS/OCT offer better final minimal lumen or minimal stent area, both of which are consistently reported as predictors of long-term outcome [29–31]. In addition, IVUS/OCT may be useful to identify unfavorable findings after stenting such as incomplete expansion, incomplete stent apposition and edge dissection [32]. These unfavorable findings may be detected only by IVUS/OCT and thus the use of IVUS/OCT may facilitate the additional interventional procedures to achieve optimal stenting. Final minimal stent area may be achieved with use of the post-dilatation using a bigger balloon with or without higher pressure may result in the bigger final MSA. ISA may

Table 4 Multivariable predictors of in-hospital death

	OR	95% CI	*P* value
Age	1.07	1.05–1.09	< 0.0001
Killip class	2.32	1.95–2.75	< 0.0001
Smoking	0.65	0.49–0.84	0.003
Heart rate	1.01	1.00–1.02	0.041
DTBT < 90 min	0.60	0.40–0.91	0.019
Final TIMI 3	0.51	0.30–0.88	0.019
Stent	0.51	0.27–0.96	0.038
IABP	1.75	1.13–2.70	0.012
PCPS	8.93	4.68–17.04	< 0.001
Insulin	2.44	1.17–5.10	0.017
Max. CK	1.00	1.00–1.00	< 0.001
IVUS-guided PCI	0.49	0.30–0.81	0.006
OCT-guided PCI	0.44	0.14–1.38	0.16

CK creatine kinase, *DTBT* door-to-balloon time, *IABP* intra-aortic balloon pumping, *PCPS* percutaneous cardio-pulmonary support, *IVUS* intravascular ultrasound, *OCT* optical coherence tomography, *PCI* percutaneous coronary intervention

be treated using a bigger balloon. IVUS/OCT may be useful to detect high risk lesions for slow flow/no reflow during PCI [21], 24. Gray scale IVUS as well as IVUS derived tissue characterization have been reported predict slow flow/no reflow after stenting [21, 22]. Indeed, final TIMI 3 flow could be achieved more frequently after IVUS-or OCT-guided PCI. Therefore, it is possible that use of intravascular imaging helped identify those lesions with high likelihood of slow flow/no reflow during PCI. Because quantitative as well as qualitative angiographic, IVUS and OCT data are not available in our registry, these advantages of intracoronary imaging could not be confirmed.

In this study, there were differences in the interventional procedures that might explain different outcome. First, stent was less frequently used in the angio-guided PCI group. Although exact reason for the lower frequency of stent use in angio-guided group is uncertain, this may in part be explained by the higher incidence of restenotic lesions in the angio-guided group as compared with IVUS-or OCT-guided group (10% vs. 3% vs. 6%). Although stent has been shown to have better long-term event-free survival than balloon angioplasty alone in ACS patients, stent use was not associated with lower in-hospital mortality in the bare-metal stent era [33, 34]. On the other hand, in our present study, stent use was an independent predictor of in-hospital death. Therefore, it is possible that less frequent use of stent in the angio-guided group did affect our results. Second, aspiration thrombectomy and distal protection were less frequently performed in angio-guided PCI group. Although routine use of distal protection as well as thrombectomy have not been proven to improve acute as well as long-term results in patients with acute myocardial infarction [35, 36], selective use of distal protection device or thrombectomy based on the IVUS or OCT finding might be helpful. An ongoing prospective, randomized trial to test the efficacy of the distal protection using a distal protection device (Filtrap) in patients at high risk (attenuated plaque ≥ 5 mm) for distal embolization during PCI in patients with ACS (VAMPIRE3 study, NCT01460966) will provide the role of selective distal protection based on IVUS finding. Third, stent size was significantly bigger in the IVUS-guided PCI group. The difference in the stent size might have contributed to the better outcome.

Recently, a subanalysis of the Coronary REvascularization Demonstrating Outcome Study in Kyoto (CREDO-Kyoto) acute myocardial infarction (AMI) registry showed that IVUS-guided PCI was not associated with a lower risk for target vessel revascularization or stent thrombosis [39]. In this study, drug-eluting stent was less frequently (20%) used as compared with J-MINUET. Door-to-balloon time was significantly longer in IVUS-guided group than in angio-guided group. Distal protection was similarly performed in both groups (9.2% in IVUS-guided PCI group and 8.0% in angio-guided PCI group, *P* = NS). These differences in the PCI procedure might have been resulted from the differences in the study period (CREDO-Kyoto: 2005–2007, J-MINUET:2013–2014). Importantly, IVUS-or OCT-derived findings to predict slow flow/ no reflow have been reported after 2007 [21, 22, 26] and therefore, at the time of this study, impact of IVUS-guidance on PCI procedure might have been less than current clinical practice.

Limitations

There are possible limitations to be mentioned. First, although this is a prospective multicenter nationwide registry, comparison between angio-, IVUS- and OCT-guidance was a post hoc analysis. Therefore, results of this study may be hypothesis generating. Prospective, randomized study should be conducted to confirm our results. Second, detailed cause of death is available in only a part of the study population, and therefore, all-cause death rather than cardiac death has been used as a hard endpoint in the main paper of the J-MINUET study [25]. Furthermore, a previous meta-analysis of the IVUS-guided PCI vs. angio-guided PCI included all-cause death as an endpoint and demonstrated better survival in the IVUS-guided PCI group [5]. Therefore, it may be reasonable to use all-cause death ratherthan cardiac death as an endpoint to show the possible advantage of the intracoronary imaging-guidance. Third, long-term prognostic impact of the IVUS or OCT is still uncertain. A previous study suggested that IVUS may predict long-term prognosis in ACS patients [39]. Extended follow-up of this study population is necessary to clarify long-term impact of the intravascular imaging guidance on clinical outcome.

In conclusion, intravascular imaging (IVUS or OCT)-guided urgent PCI was frequently adopted in patients with acute myocardial infarction diagnosed by universal definition. Use of IVUS may be associated with better in-hospital survival. Impact of OCT-guided PCI on in-hospital survival needs further investigation with larger sample size.

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Compliance with ethical standards

Conflict of interest The authors report no relationships that could be construed as a conflict of interest.

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Affiliations

Hiroyuki Okura[1] · Yoshihiko Saito[1] · Tsunenari Soeda[1] · Koichi Nakao[2] · Yukio Ozaki[3] · Kazuo Kimura[4] · Junya Ako[5] · Teruo Noguchi[6] · Satoshi Yasuda[6] · Satoru Suwa[7] · Kazuteru Fujimoto[8] · Yasuharu Nakama[9] · Takashi Morita[10] · Wataru Shimizu[11] · Atsushi Hirohata[12] · Yasuhiro Morita[13] · Teruo Inoue[14] · Atsunori Okamura[15] · Masaaki Uematsu[16] · Kazuhito Hirata[17] · Kengo Tanabe[18] · Yoshisato Shibata[19] · Mafumi Owa[20] · Kenichi Tsujita[21] · Kunihiro Nishimura[6] · Yoshihiro Miyamoto[6] · Masaharu Ishihara[22] on behalf of The J-MINUET investigators

[1] Department of Cardiovascular Medicine, Nara Medical University, 840 Shijyo-cho, Kashihara, Nara, Japan

[2] Cardiovascular Center, Saiseikai Kumamoto Hospital, Kumamoto, Japan

[3] Department of Cardiology, Fujita Health University, Toyoake, Japan

[4] Cardiovascular Center, Yokohama City University Medical Center, Yokohama, Japan

[5] Department of Cardiovascular Medicine, Kitasato University, Sagamihara, Japan

[6] Department of Cardiovascular Medicine, National Cerebral and Cardiovascular Center, Suita, Japan

[7] Department of Cardiology, Juntendo University Shizuoka Hospital, Shizuoka, Japan

[8] Department of Cardiology, National Hospital Organization Kumamoto Medical Center, Kumamoto, Japan

[9] Department of Cardiology, Hiroshima City Hospital, Hiroshima, Japan

[10] Division of Cardiology, Osaka General Medical Center, Osaka, Japan

[11] Department of Cardiovascular Medicine, Nippon Medical School, Tokyo, Japan

[12] Department of Cardiology, The Sakakibara Heart Institute of Okayama, Okayama, Japan

[13] Department of Cardiology, Ogaki Municipal Hospital, Ogaki, Japan

[14] Department of Cardiovascular Medicine, Dokkyo Medical University, Tochigi, Japan

[15] Department of Cardiology, Sakurabashi Watanabe Hospital, Osaka, Japan

[16] Cardiovascular Center, Kansai Rosai Hospital, Amagasaki, Japan

[17] Department of Cardiology, Okinawa Prefectural Chubu Hospital, Uruma, Japan

[18] Division of Cardiology, Mitsui Memorial Hospital, Tokyo, Japan

[19] Department of Cardiology, Miyazaki Medical Association Hospital, Miyazaki, Japan

[20] Department of Cardiovascular Medicine, Suwa Red Cross Hospital, Suwa, Japan

[21] Department of Cardiovascular Medicine, Kumamoto University Graduate School of Medical Sciences, Kumamoto, Japan

[22] Division of Coronary Artery Disease, Hyogo College of Medicine, Nishinomiya, Japan