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Five-year clinical outcome of titanium-nitride-oxide-coated bioactive stents versus paclitaxel-eluting stents in patients with acute myocardial infarction: Long-term follow-up from the TITAX AMI trial

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ABSTRACT

Background: The TITAX-AMI randomized controlled trial demonstrated a better clinical outcome with titanium-nitride-oxide-coated bioactive stents (BAS) as compared with paclitaxel-eluting stents (PES) at 2-year follow-up, in patients with acute myocardial infarction (MI) undergoing early percutaneous coronary intervention (PCI). We sought to present the 5-year clinical outcome of the TITAX-AMI trial.
Methods: A total of 425 patients with acute MI were randomly assigned to receive either BAS (214), or PES (211). The primary endpoint was major adverse cardiac events (MACE): a composite of cardiac death, recurrent MI or ischemia-driven target lesion revascularization (TLR). Clinical follow-up was performed to 5 years.
Results: The 5-year cumulative incidence of MACE was significantly lower in patients assigned to BAS as compared with those assigned to PES (16.4% versus 25.1%, respectively, $p = 0.03$). Similarly, the 5-year rates of cardiac death and recurrent MI were significantly lower in patients assigned to BAS (1.9% versus 5.7%, and 8.4% versus 18.0%, $p = 0.04$ and $p = 0.004$, respectively). Yet, the rates of ischemia-driven TLR were similar between the two study groups (11.2% versus 10.9%, respectively, $p = 0.92$). The rate of definite stent thrombosis (ST) was again significantly lower in patients assigned to BAS (0.9% versus 7.1%, respectively, $p = 0.001$).
Conclusions: In the current prospective randomized TITAX-AMI trial, among patients presenting with acute MI who underwent early PCI, BAS achieved a better clinical outcome as compared with PES at 5-year follow-up, as reflected by lower cumulative rates of overall MACE, cardiac death, recurrent MI, and definite ST; yet, with statistically similar rates of ischemia-driven TLR.

1. Introduction

The introduction of coronary stents in the 1990s provided a safer approach for percutaneous coronary interventions (PCI) and endorsed a far better short- and long-term outcome as compared with standalone balloon angioplasty [1,2]. At the beginning of the third millennium, the arrival of drug-eluting stents (DES) on the scene gave a new dimension to coronary interventions, resulting in a marked reduction of restenosis rates by one-half to two-thirds at 5 year follow-up, favorably accounting for a 10–15% need for target lesion revascularization (TLR) following DES at long-term [3,4]. In fact, most randomized trials comparing DES with bare-metal stents (BMS) in the setting of primary PCI for ST-segment elevation myocardial infarction (MI) demonstrated reduced TLR following DES implantation, with no increase in the incidence of stent thrombosis (ST) [5–9]. However, most of these studies have been limited by either inadequate statistical power or the lack of long-term follow-up. Yet, after years of 'real-life' practice, worrisome data have raised concerns about a small, but definite, increase of late and very late ST with the use of DES, a potentially life-threatening complication that possibly culminates in death or MI [10].

The next level was achieved with the design of bioactive stents (BAS). The safety of titanium-nitride-oxide-coated stents has been established in several reports from real-life unselected populations [11,12]. The

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prospective randomized controlled TITAX-AMI (Titanium-Nitride-Oxide-Coated Stents versus Paclitaxel-Eluting Stents in Acute Myocardial Infarction) trial randomized patients with acute MI to receive either titanium-nitride-oxide-coated BAS or a paclitaxel-eluting stents (PES) [13]. At 2 year follow-up, BAS achieved a better outcome as compared with PES, with a significant reduction of the primary endpoint of major adverse cardiac events (MACE), and significantly lower rates of cardiac death, recurrent MI, and ST [13]. We set out to present the 5-year clinical outcome of BAS as compared with PES in patients presenting with acute MI in the TITAX-AMI trial.

2. Methods

2.1. Study design

The design of the original trial has been previously reported [13,14]. Briefly, the TITAX-AMI trial was a prospective single-blinded multicentre randomized controlled trial conducted in six Finnish centers. From December 2005 to November 2006, 425 patients with acute MI undergoing early PCI were randomized in a 1:1 fashion to receive either Titan-2® BAS (Hexacath, Paris, France) or TAXUS Liberte® PES (Boston Scientific, Natick, Massachusetts, USA). The 5-year analysis was prespecified by the study protocol (follow-up data were planned to be collected yearly for 5 years).

2.2. Procedures and pharmacological intervention

Predilatation of the culprit lesion, PCI technique, selection of access site, antithrombotic agent and use of glycoprotein IIb/IIIa inhibitors were all left to the operator's discretion. In patients not maintained on aspirin, the study protocol recommended premedication with aspirin at a loading dose of 100–500 mg orally, or 250–500 mg intravenously. Clopidogrel was administered at a loading dose of 300–600 mg orally immediately after the index procedure, if the patient was not already maintained on clopidogrel. At discharge, aspirin was prescribed at a dose of 100 mg daily orally, indefinitely, and clopidogrel at a dose of 75 mg daily orally, for at least 6 months.

2.3. Study endpoints and definitions

Diagnostic criteria for non-ST-elevation MI (NSTEMI) and ST-segment elevation MI (STEMI) were previously described in detail [13,14]. The primary endpoint was the first occurrence of MACE, defined as a composite of cardiac death, recurrent MI (safety endpoints), or TLR (efficacy endpoint). The definitions of these endpoints were also previously described [13,14]. Only ischemia-driven TLR events were reported. Secondary endpoints included all-cause death, a composite of cardiac death or recurrent MI, and ST. For the adjudication of 5-year outcome, we adopted the 'definite' category of ST as defined by the Academic Research Consortium (ARC) [15].

2.4. Ethical issues

The study was initiated by the investigators and conducted according to the ethical guidelines of the 1964 Declaration of Helsinki, as revised in 2002. An informed written consent was obtained from every patient after full explanation of the study protocol. The study protocol was approved by the Ethics Committees of the co-ordinating center, Satakunta Central Hospital, and the participating hospitals. The study has been registered as an international Randomized Controlled Trial in www.clinicaltrials.gov, number NCT00495664.

2.5. Statistical analysis

Continuous variables are presented as mean ± SD, whereas categorical variables are described with absolute and relative (percentage) frequencies. Comparisons between the two groups were performed using the unpaired two-tailed *t*-test for continuous variables, and the Pearson chi-square test or Fisher's exact test for categorical variables. Time-to-event curves were constructed using the Kaplan–Meier method and data were compared using the log-rank test. In order to identify the independent predictors of MACE at 5-year follow-up, at first, univariate logistic regression was performed for each of the baseline, angiographic and procedural characteristics. At the second stage, the variables significantly associated (2-sided $p<0.05$) with dependent variables in univariate analyses were included in multivariable analysis. All tests were two-sided and statistical significance was set at 5%. All data were analyzed using SPSS version 11 [16] and SAS system for Windows version 9.1 (SAS Institute Inc., Cary, NC, USA).

3. Results

3.1. Baseline clinical, angiographic and procedural characteristics

During the study period, 840 patients were evaluated regarding eligibility for enrolment in the trial. Ultimately, a total of 425 patients (51%) fulfilled the inclusion criteria and were randomized in a 1:1 fashion to the two treatment arms (214 to the BAS group and 211 to the PES group). Baseline clinical characteristics of the two study groups were well matched, except for a higher prevalence of previous PCI in the BAS group (Table 1). Baseline angiographic and procedural data are presented in Table 2. Procedural success was achieved in 99.5% of patients in the BAS group and 98.1% in the PES group.

3.2. Clinical outcome of the TITAX AMI at 5-year follow-up

At 5-year follow-up, complete datasets on all clinical events were available in 211 (98.6%) and 204 (96.7%) patients in the BAS and PES groups, respectively. Clinical outcome data are presented in Table 3. The 5-year cumulative incidence of MACE was significantly lower in patients assigned to BAS as compared with those assigned to PES (16.4% vs. 25.1%, respectively, $p=0.03$) (Fig. 1). Similarly, the 5-year rates of cardiac death and recurrent MI were significantly lower in patients assigned to BAS (1.9% vs. 5.7%, and 8.4% vs. 18%, $p=0.04$ and $p=0.004$, respectively) (Fig. 2A and B). Yet, the rates of ischemia-driven TLR were similar between the two study groups (11.2% vs. 10.9%, respectively, $p=0.92$) (Fig. 2C).

Among the secondary endpoints, the rate of all-cause death occurred at similar frequencies in the BAS and PES groups (8.9% vs. 10.4%, respectively, $p=0.63$). However, the composite of cardiac death or recurrent MI was significantly lower in patients assigned to BAS (8.4% vs. 19.9%, respectively, $p=0.001$). The rate of ARC-definite ST was significantly lower in patients assigned to BAS (0.9% vs. 7.1%, respectively, $p=0.001$) (Fig. 2D). In 8 patients, clopidogrel was prematurely discontinued before the event of ST, and all of these patients were in the PES group. Four out of 15 ST events (26.7%) were fatal.

Table 1
Baseline clinical characteristics of the study groups.

Variable	BAS group N = 214	PES group N = 211	*p* value
Age (years)	64 ± 11	64 ± 11	0.72
Male gender	162 (76)	157 (74)	0.82
Risk factors			
Family history of CAD	103 (48)	95 (45)	0.56
Diabetes	48 (22)	33 (16)	0.08
Hypertension	122 (57)	106 (50)	0.17
Hypercholesterolemia	141 (66)	151 (72)	0.21
Smoking	113 (53)	97 (46)	0.18
Medical history			
Prior myocardial infarction	33 (15)	20 (9)	0.08
Prior PCI	22 (10)	10 (5)	0.04
Prior CABG	16 (7)	13 (6)	0.70
Medications			
Thrombolysis	26 (12)	40 (19)	0.06
GP IIb/IIIa inhibitors	116 (54)	96 (45)	0.08
Indication for PCI			
NSTEMI	131 (61)	114 (54)	0.14
STEMI	83 (39)	97 (46)	0.14

Continuous variables are presented as mean ± SD, while categorical variables are presented as frequency (percentage).
CAD indicates coronary artery disease; PCI, percutaneous coronary intervention; CABG, coronary artery bypass grafting; GP, glycoprotein; NSTEMI, non-ST-elevation myocardial infarction; STEMI, ST-elevation myocardial infarction; BAS, bioactive stent; PES, paclitaxel-eluting stent.

Table 2
Angiographic and procedural characteristics of the study groups.

Variable	BAS group N = 214	PES group N = 211	*p* value
Lesion characteristics			
Left anterior descending artery	98 (46)	91 (43)	0.63
Bifurcation lesion	53 (25)	50 (24)	0.82
Reference vessel diameter (mm)	3.16 ± 0.45	3.11 ± 0.50	0.35
Lesion length (mm)	13.6 ± 5.6	13.2 ± 6.4	0.47
Initial TIMI flow grade			
0	46 (21)	45 (21)	1.0
1	10 (5)	14 (7)	0.41
2	61 (29)	38 (18)	0.01
3	97 (45)	114 (54)	0.08
Procedural characteristics			
Direct stenting	26 (12)	32 (15)	0.48
Post-dilatation	89 (42)	73 (35)	0.16
Nominal stent size (mm)	3.16 ± 0.42	3.11 ± 0.45	0.19
Stent length (mm)	17.4 ± 4.5	17.7 ± 5.3	0.48
Total stent length (mm)	18.5 ± 6.4	19.2 ± 7.2	0.26
Number of stents per culprit lesion	1.1 ± 0.3	1.1 ± 0.4	0.24
Multivessel PCI	30 (14)	19 (9)	0.13
Final TIMI flow grade 3	211 (98.6)	204 (96.7)	0.22
Acute procedural success	213 (99.5)	207 (98.1)	0.20
Maximum creatine kinase MB (μg/l)[a]	63.8 ± 100.8	70.9 ± 117.0	0.53
Maximum troponin I (μg/l)[b]	34.7 ± 76.6	26.5 ± 59.2	0.31
Maximum troponin T (μg/l)[c]	5.1 ± 22.4	2.6 ± 3.8	0.39
Ejection fraction (%)	51.6 ± 7.3	55.7 ± 7.7	<0.001
Medication at discharge			
Beta-blockers	202 (94.4)	200 (94.8)	0.86
Lipid-lowering agents	193 (90.2)	190 (90.0)	0.96
ACE inhibitor/ARB	144 (67.3)	156 (73.9)	0.13

Continuous variables are presented as mean ± SD, while categorical variables are presented as frequency (percentage).
TIMI indicates Thrombolysis In Myocardial Infarction; PCI, percutaneous coronary intervention; BAS, bioactive stent; PES, paclitaxel-eluting stent; ACE, angiotensin-converting enzyme; ARB, angiotensin receptor blockers.
[a] Available in 145 patients in the BAS group and in 141 patients in the PES group.
[b] Available in 140 patients in the BAS group and in 145 patients in the PES group.
[c] Available in 72 patients in the BAS group and in 61 patients in the PES group.

3.3. Dual antiplatelet therapy

Clopidogrel was prescribed at discharge for a mean period of 7.6 months in the BAS group versus 10.0 months in the PES group ($p<0.001$). A total of 67 patients (31%) in the BAS group and 138 patients (65%) in the PES group were receiving dual antiplatelet therapy with aspirin and clopidogrel at the end of 12-month follow-up ($p<0.001$). Clopidogrel treatment was not extended beyond 12 months in either of the two study groups.

3.4. Independent predictors of MACE at 5-year follow-up

By multivariable logistic regression analysis, the independent predictors of MACE at 5-year follow-up were smaller stent diameter ($p=0.007$, HR 2.05, 95% CI 1.22–3.46), previous coronary bypass surgery ($p=0.007$, HR 3.22, 95% CI 1.37–7.53), and assignment to the PES group ($p=0.003$, HR 2.06, 95% CI 1.24–3.43).

4. Discussion

4.1. Main findings

The current long-term follow-up report of the TITAX-AMI trial demonstrated that in patients undergoing early PCI for acute MI, the implantation of BAS, as compared with PES, was associated with significantly lower cumulative rates of overall MACE, cardiac death, recurrent MI, and ARC-definite ST at 5-year follow-up. However, the rates of ischemia-driven TLR were statistically similar. To the best of the authors' knowledge, the TITAX-AMI trial is the first trial reported to date presenting a head-to-head randomized comparison of BAS versus PES in the setting of acute MI.

Table 3
Clinical outcome in the 2 individual study groups at 5 year follow-up.

Variable	BAS group N = 214	PES group N = 211	HR	95% CI	*p* value
MACE	35 (16.4)	53 (25.1)	1.72	1.06–2.77	0.03
Cardiac death	4 (1.9)	12 (5.7)	3.17	1.00–9.98	0.04
Recurrent MI	18 (8.4)	38 (18.0)	2.39	1.32–4.35	0.004
Ischemia-driven TLR	24 (11.2)	23 (10.9)	0.97	0.53–1.78	0.92
All-cause death	19 (8.9)	22 (10.4)	1.20	0.63–2.28	0.63
Cardiac death or recurrent MI	18 (8.4)	42 (19.9)	2.71	1.50–4.89	0.001
Definite ST	2 (0.9)	15 (7.1)	8.12	1.83–35.93	0.001

Variables are presented as frequency (percentage).
MACE indicates major adverse cardiac events; MI, myocardial infarction; TLR, target lesion revascularization; ST, stent thrombosis; BAS, bioactive stent; PES, paclitaxel-eluting stent; HR, hazard ratio; CI, confidence interval.

4.2. Efficacy endpoint

In the TITAX-AMI trial, the hazard ratio for ischemia-driven TLR (efficacy endpoint) associated with BAS as compared with PES at 1-year follow-up was 1.3 ($p=0.5$). This hazard ratio decreased to 0.97 ($p=0.92$) in the current 5-year report. Clearly, there was a slightly higher rate of repeat interventions in the PES arm of the trial during the period from 1-year to 5-year follow-up. This can be considered as a 'catch-up phenomenon'. On the other hand, the fact

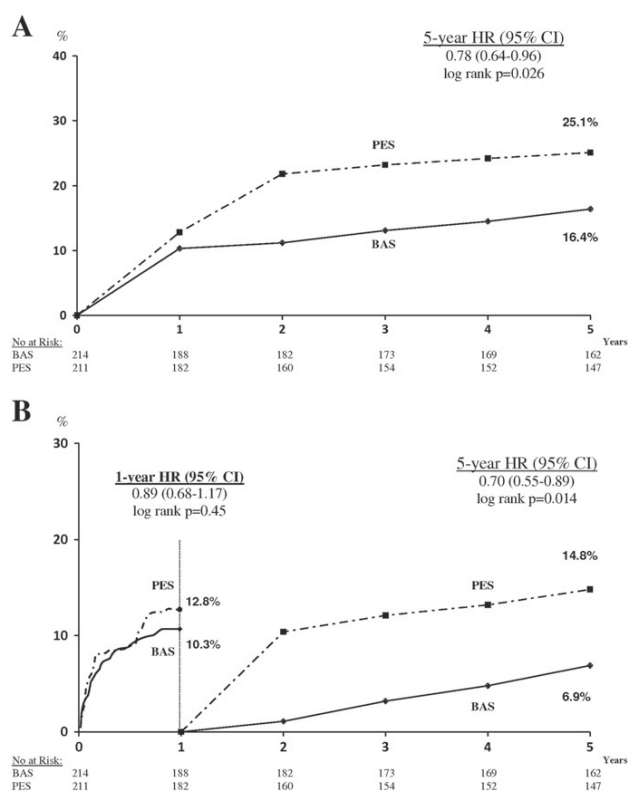

Fig. 1. Kaplan–Meier time-to-event curves of the primary endpoint over a 5 year follow-up. Kaplan–Meier curves show the cumulative incidence of major adverse cardiac events (the primary endpoint), a composite of cardiac death, non-fatal myocardial infarction, or ischemia-driven target lesion revascularization (panel A); a landmark analysis with the incidence up to 1 year and from 1 to 5 years of follow-up (panel B). BAS = bioactive stents, PES = paclitaxel-eluting stents.

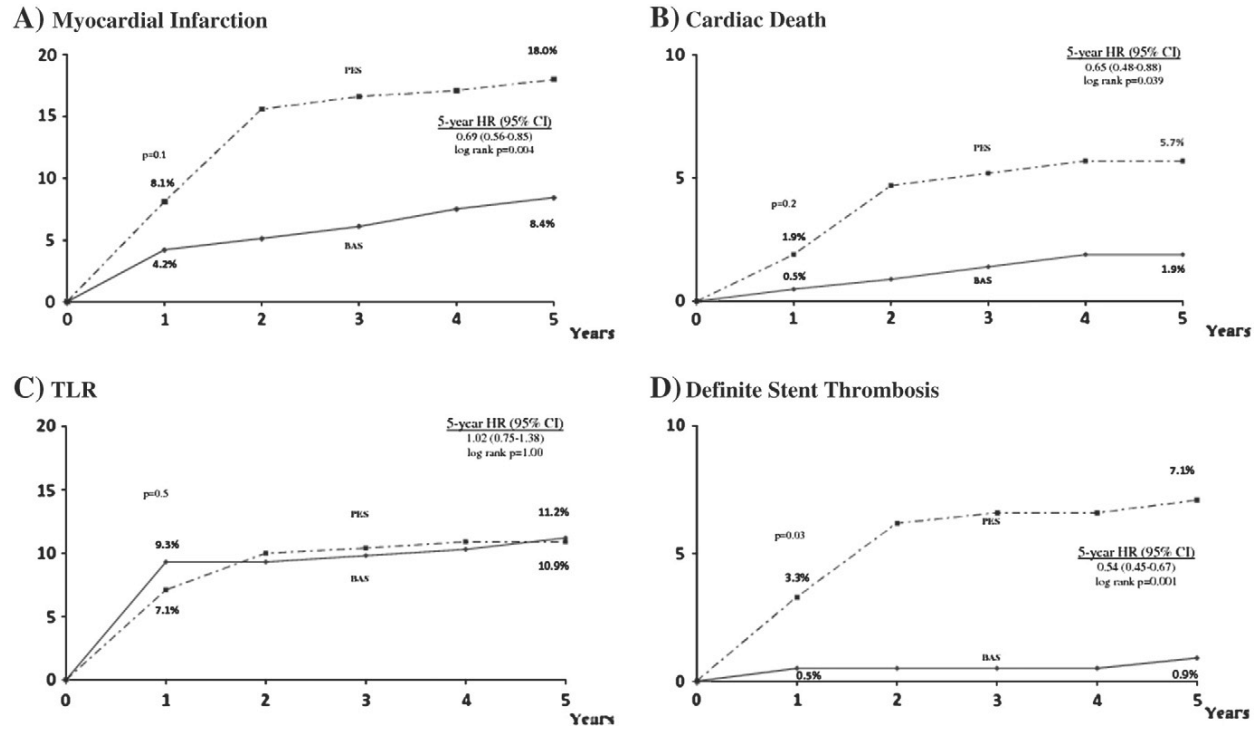

Fig. 2. Kaplan–Meier time-to-event curves of the individual components of the primary endpoint as well as stent thrombosis over a 5 year follow-up. Kaplan–Meier curves show the cumulative incidence of non-fatal myocardial infarction (panel A); cardiac death (panel B); ischemia-driven target lesion revascularization (panel C); and stent thrombosis (panel D). BAS = bioactive stents, PES = paclitaxel-eluting stents, TLR = target lesion revascularization.

that no routine angiographic follow-up was performed may have influenced the relative rates of TLR between the two stent groups. It is well acknowledged that angiographic follow-up increases the absolute differences between stents with respect to TLR beyond that which would otherwise be observed with clinical follow-up alone. Nevertheless, with clinical follow-up, the results would more closely reflect real-life practice, avoiding repeat intervention for clinically 'silent' angiographic lesions, the so-called 'oculo-stenotic reflex'. Interestingly, the incidence of TLR associated with PES in the current trial at 5-year follow-up was substantially higher than that reported from the PASSION trial at a similar point of follow-up (10.9% vs. 7.7%, respectively) [17]. This might possibly be attributed to some divergence between the two studies with respect to the mean stent diameter used in the PES arm (3.11 ± 0.45 vs. 3.21 ± 0.30, respectively) [14,17].

4.3. Safety endpoints

Evidently, the remarkable increase in the cumulative MACE rate at 5-year follow-up associated with PES implantation was principally driven by a substantial increase in the safety endpoints (cardiac death and recurrent MI, and probably the underlying ARC-definite ST). The rates of overall MACE amounted to an absolute risk increase of 8.7% in the PES group as compared with the BAS group, which would translate into 87 major events avoided at 5-year follow-up per 1000 patients treated with BAS rather than PES. Consequently, the number of patients needed to treat with BAS rather than PES, to prevent one major event would be as low as 12 patients, a figure quite small in terms of real-world practice. It is noteworthy that the incidence of ST associated with PES at 1-year follow-up (3.3%) in the present trial was similar to those reported with DES from the HORIZONS-AMI trial (2.6% with PES) and the TYPHOON trial (3.4% with sirolimus-eluting stent) at a similar time point [5,9,14].

The cumulative incidence of MACE associated with PES in the current trial at 5-year follow-up was substantially higher than that reported from the PASSION trial at a similar point of follow-up (25.1% vs. 18.6%, respectively) [17]. Most likely, this higher event rate was mainly driven by a higher rate of recurrent MI in patients assigned to PES in the present trial as compared with the PASSION trial at the same time point (18% vs. 6.8%, respectively), possibly influenced by a higher rate of ARC-definite ST (7.1% vs. 3.9%, respectively) [17]. Essentially, the rates of ARC-definite ST at 30 days for the PES arm in the two trials were 2.4% and 0.6%, respectively [14,18]. Given the comparable design between the two trials, the disparity in the safety endpoints might be explained on the basis of variations in pharmacological interventions. Glycoprotein IIb/IIIa inhibitors were used in 73.2% of patients in the PES group in the PASSION trial, as compared with only 45% in the corresponding group in the current trial [14,17].

On the other hand, the cumulative incidence of MACE associated with BAS in the current trial at 1-year follow-up was somewhat higher in the current trial than that reported in the EVIDENCE registry of BAS at the same point of follow-up (10.3% vs. 7.2%, respectively) [19]. And although cardiac death rate was numerically lower in the current trial (0.5% vs. 1.2%, respectively), the rates of non-fatal MI, definite ST, and TLR were higher (4.2% vs. 1.5%, 0.9% vs. 0.3%, and 9.3% vs. 5.1%, respectively) [19]. The inclusion of patients presenting with acute MI in the current trial, in contrast to the all-comer population with no exclusion criteria in the EVIDENCE registry, might explain the higher rates of MACE, MI, ST, and TLR in the current trial at 1-year follow-up. Additionally, in a recently published propensity score matched comparison of BAS, PES, and sirolimus-eluting stents, the primary endpoint of MACE (a composite of death, MI, and target vessel revascularization) at 3-year follow-up occurred in 20%, 23%, and 19%, respectively [20]. Hazard ratio for MACE with BAS was 0.95 compared with PES, and 1.0 compared with sirolimus-eluting stents. Moreover, in a randomized

comparison between BAS and the second-generation zotarolimus-eluting stent, the rates of MACE at 1-year follow-up were similar between the two stent arms ($p = 0.5$) [21].

4.4. Stent thrombosis following primary PCI with DES

In a recent report, the rate of infarct-related artery ST in patients with ST-segment elevation MI treated with DES was 3.2% at 2 year follow-up [22]. Moreover, the same report demonstrated a surprisingly high incidence of ST (8.2%) in patients with a large thrombus burden before stent implantation [22]. A higher rate of late ST was observed in MI patients than in those with stable angina in a post-mortem analysis of patients who died following DES implantation [23]. This analysis suggests that culprit lesion morphology influences local vascular healing response to DES placement. In the case of DES, greater delay in arterial healing as manifested by poor endothelialization and persistent peri-strut fibrin deposition may extend the risk of ST far beyond 30 days following stent implantation. Furthermore, late ST occurs potentially due to mismatch between the stent and the vessel which might be related to stent malapposition, overlapping stent placement, penetration of necrotic core, excessive stent length, bifurcation lesions, hypersensitivity to drug or polymer, or thrombogenic surface [24,25]. A remarkably high rate of ST at 5-year follow-up was reported in the current study (7.1%). In a late-breaking registry comparing long-term safety outcome following first- versus second-generation DES in an all-comer population, the rate of ARC-definite ST following PES at 4-year follow-up was 4.4% [26]. Restriction to patients with AMI, and slightly longer follow-up might underlie the higher rate of ST in the PES arm of the current study. Similarly, in the 3-year follow-up report of the HORIZONS-AMI randomized controlled trial, the rate of ST was above 4.5% in the PES group [27]. Interestingly, in the PASSION trial comparing PES versus bare-metal stents in the setting of acute MI, the 5-year rate of ARC-definite ST was 3.9% [17]. In the later report, very late ST was almost exclusively seen with PES. Finally, despite the significant difference in cardiac mortality, all-cause death was not statistically different between the two stent arms ($p = 0.63$). In fact, non-cardiac deaths were numerically higher in the BAS group (7% versus 4.8%) at 5-year follow-up. This underscores the importance of adopting stent-related safety outcome (cardiac death) rather than patient oriented outcome (non-cardiac death) when adopting safety endpoints for randomized trials comparing stent designs.

4.5. Dual antiplatelet therapy

Premature discontinuation of thienopyridine therapy is recently acknowledged as the most important predisposing factor for late and very late ST following DES implantation [25]. In the present study, 65% of patients in the PES group and 31% in the BAS group were still maintained on clopidogrel therapy at 12-month follow-up. These figures are consistent with those reported from the SPIRIT III trial in which the proportion of patients receiving dual antiplatelet therapy at 24-month follow-up was 59.4% and 63.9%, in the everolimus-eluting stent group and PES group, respectively [28]. The substantial dropout of patients in the PES group off the dual antiplatelet drug coverage before concluding the recommended period of 12 months may bear some relevance to the reported higher rate of definite ST in this group at 12 months ($p = 0.031$) [14]. It is worth mentioning that late definite ST occurred exclusively in the PES arm [14]. Actually, in the current trial, less patients in the PES group received glycoprotein IIb IIIa inhibitor than in the BAS group ($p = 0.08$) [14]. However, this would be expected to influence the 30-day (acute and subacute) incidence of ST. Yet, the rate of ARC-definite ST at 30 days was not statistically different between the two groups ($p = 0.1$) [14]. Nevertheless, the divergence of the curves of MACE, cardiac death, non-fatal MI, and definite ST for the two stent arms occurred chiefly during the period from one-year to two-year follow-up (very late ST). These findings pinpoint the importance of extended duration of dual antiplatelet therapy in patients receiving first-generation DES further beyond the 12-month period recommended by the guidelines.

4.6. Limitations of the study

The sample size was based on a small real-life cohort, and therefore the present trial was underpowered to reveal subtle potential differences in primary and individual endpoints, although we chose the setting of acute MI known to predispose to clinical complications. The design of our study did not include angiographic follow-up or routine non-invasive testing for myocardial ischemia, and therefore we probably underestimated the incidence of silent or angiographic restenosis. On the other hand, by adopting clinical follow-up only, the chance of unnecessary TLR due to the so-called 'oculo-stenotic reflex' or patient's subjective anxiety was avoided. In addition, stenting was performed in patients with relatively large infarct-related arteries with low risk of in-stent restenosis.

5. Conclusions

In the current prospective randomized TITAX-AMI trial, among patients presenting with acute MI who underwent early PCI and were followed clinically without routine coronary angiography, BAS achieved a better clinical outcome as compared with PES at 5-year follow-up. This was reflected by lower cumulative rates of overall MACE, cardiac death, recurrent MI, and ARC-definite ST; yet, with statistically similar rates of ischemia-driven TLR.

Conflict of interest

All authors have no conflict of interest to declare.

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