Original Article

Undesired Outcomes of the Catania Stent Compared to the Xience Stent in Patients Undergoing Angioplasty: A Double-Blind Randomized Controlled Trial

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Abstract

Background: The present study tries to compare the unintended outcomes of the Catania stent versus Xience stent in patients undergoing angioplasty**. Materials and Methods:** In a three month, follow-up, double-blinded, randomized controlled trial, 83 patients undergoing angioplasty, who met the inclusion criteria were entered into the study. After randomization 43 patients were treated with the Xience stent and 40 patients with the Catania stent. Stent-related outcomes such as Cardiac and Non-Cardiovascular Death, Myocardial Infarction (MI), Target Lesion Revascularization (TLR), Stent Thrombosis (ST), Coronary Artery Bypass Grafting (CABG), Peripheral vasculopathy, and Cerebral Vascular Accident (CVA) were compared between the groups. **Results:** There was no statistically significant difference in the incidence rate of complications and clinical outcomes between the two treatment groups ($P > 0.05$). The incidence of MI, TLR, CABG operation, peripheral vasculopathy, or CVA was not observed in any patient and there was no statistically difference in mortality (4.7% vs. 2.5%; $P = 0.527$) and stent thrombosis (2.3% vs. 2.5%; $P = 0.735$). **Conclusion:** All in all, the present study could not find the significant differences between the Catania stent and Xience stent in terms of clinical outcomes during the follow-up period.

Keywords: *Angioplasty, Catania stent, clinical outcome, stent thrombosis, Xience stent*

Introduction

The outreach of stents has made remarkable progress in the remedy of obstructive coronary artery disease since the introduction of balloon angioplasty.[1] Two broad categories of stents are available: Bare metal stents (BMS) and drug-eluting stents (DES).[2] The unexpected gelation of vessels owing to subacute stent thrombosis (SAT) and late in-stent restenosis (ISR) are two significant complications that are faced with the extensive use of BMS.[3,4] However, DES is more effective than BMS in reducing restenosis and the need to target vessel revascularization (TVR).[2,5-7] Introduction of DES was a major achievement in interventional cardiology. Several studies using DES have shown a substantial reduction in angiographic restenosis and target vessel revascularization in comparison to bare metal stents.[7-10] DES has now become the mainstream therapy for coronary artery stenosis due to the very low rate expected for in-stent restenosis. Xience V (an everolimus-eluting stent) is one of the second-generation DES that has been newly approved in the US; in 2007. This stent is designed from a cobalt-chromium alloy and is thinner and more flexible than the first-generation ones.[2,11] The Xience V stent has a superior anti-restenotic efficiency as well as long-term safety. Moreover, the Xience stent is based on the multi-link platform and delivery system.[2,11] In an investigation, patients treated with the Xience stent were compared with patients treated in the past with BMS, sirolimus-eluting stents (SES), and paclitaxel-eluting stents (PES). In this assessment, the efficacy of the Xience was found to be superior to BMS, had clinical outcomes similar to SES, was also as safe as PES, and was maybe more effective than PES.[12] In a recent investigation, the safety and efficacy of the Everolimus-eluting Xience V stent (EES) was compared with the Zotarolimus-eluting resolute stent (ZES-R). Both stents showed comparable safety and efficacy at a one-year follow-up. Also excellent safety and efficacy of both types of second-generation drug-eluting

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stents was suggested.[13] Comparison of the everolimus eluting XIENCE V stent with the paclitaxel eluting TAXUS LIBERTE stent indicated that the EES had a substantial clinical benefit over the PES with regard to the measures of both safety and efficacy that were maintained at the two-year of follow-up.[14] The assessments prepared by the SPIRIT program in several studies indicated that Xience V reduced late loss compared to the Bare and Taxus stents.[15-18] Although DES was shown to reduce the restenosis rates, there were some concerns about the safety, due to reports of increased risk of late and very late stent thrombosis.[5,19]

Catania (CeloNova BioSciences) is another stent that has recently been used.[5] The Catania stent is flexible, made of a cobalt-chromium alloy, is balloon-expandable, and its surface is treated with Polyzene-F. Its application in a first-in-man assessment has shown a great safety profile and high efficacy in the treatment of *de novo* coronary lesions (5). Another study has evaluated the 12-month safety and efficacy of the Catania stent and confirmed the positive results of the former study.[20] It seems that comparative studies assessing the value of the Catania stent over the currently used drug-eluting stents like Xience, are needed. The present survey in a double-blind, randomized controlled trial, which tries to compare the unintended outcomes of the Catania and Xience stents in patients undergoing angioplasty.

Materials and Methods

This double-blind, randomized controlled trial was conducted on 83 patients undergoing angioplasty in the Chamran Hospital, Isfahan, Iran, between June 2012 and March 2013. Determination of the sample size was done using the Krejcie and Morgan's table.

The non-probability consecutive sampling method was used. After enrollment, all the patients were randomly divided into one of the two groups (group 1: Patients received the Xience stent and group 2: Patients received the Catania stent) by the Random Allocation Software.[21]

The inclusion criteria were, age between 30 and 75 years, stable or unstable angina, and/or documentation of myocardial ischemia, attributable to native coronary artery stenosis. Written informed consent was obtained from all the participants, as approved by the Ethics Committee of the Isfahan University of Medical Sciences.

The exclusion criteria were chronic renal failure (serum creatinine >2.5 mg/dl), ongoing acute myocardial infarction or myocardial infarction within the last 48 hours, left ventricular ejection fraction <30%, cardiogenic shock, and documented or suspected systemic and/or infectious disease. In such cases the patients were not acceptable candidates for emergent coronary artery bypass graft, planned two-stent implantation (except bail-out), other types of stent implantation, diffuse/severe coronary calcifications, extreme vessel tortuosity, unprotected left main stenosis, and saphenous vein graft and arterial bypass (internal mammary artery).

The endpoint of the study was to define the rate of all deaths (Cardiac Death and Non-Cardiovascular Death), Myocardial Infarction (MI), Target Lesion Revascularization (TLR), Stent Thrombosis (Definite, Probable, Possible), Coronary Artery Bypass Grafting (CABG), Peripheral Vasculopathy and Cerebral Vascular Accident (CVA), during follow-up.

To assess the incidence rate of Stent Thrombosis, depending upon 'event certainty' and 'time frame', the Academic Research Consortium (ARC) classification was used.[22]

Data are presented as Mean ± 1 SD or Median (twenty-fifth and seventy-fifth percentile) for continuous variables and Number (Percent) for categorical ones. As the number of patients in each group was smaller than 50, the Shapiro–Wilk test was used for normality testing. Statistical differences among the studied groups were assessed by the Independent-Samples T-test, Mann-Whitney, Chi-square, and Fisher's Exact test.

On account of the statistically significant differences between the two groups, in terms of variables such as 'hypertension' and 'history of myocardial infarction' and also due to the control of the effect of potential confounders on the relationship between the occurrence of the main outcome and type of stent (group), we used the multivariate regression models.

All analyses were done using the Statistical Package for Social Sciences Version 20 (SPSS Inc., Chicago, IL, USA) and *p*-values less than 0.05 were considered significant.

Results

Figure 1 shows the flow chart of the study. This figure shows the number of patients who entered the study, were assigned to the study groups, and analyzed. On the basis of the eligibility criteria, a total of 89 patients were randomly divided, six of whom did not enter the analyses (because of not consenting to participate in the trial).

Eighty-three patients (43 men and 40 women) entered the study. Their ages ranged from 37 to 75 years, with a mean age of 60.7 ± 9.4 years and a median age of 60 years. Other demographic and clinical features of the study population categorized by the group are shown in detail in Table 1. As shown by the analysis of the statistics, the age and sex structure of the studied groups is well-distributed. There were no statistically significant differences between the two groups with respect to the mean of weight, height, body mass index (BMI), and frequencies of smoking, diabetes mellitus, history of coronary artery disease (CAD), hyperlipidemia, and vessel place ($P > 0.05$).

There was no statistically significant difference in the incidence of complications and clinical outcomes between the two treatment groups ($P > 0.05$). The incidence of MI,

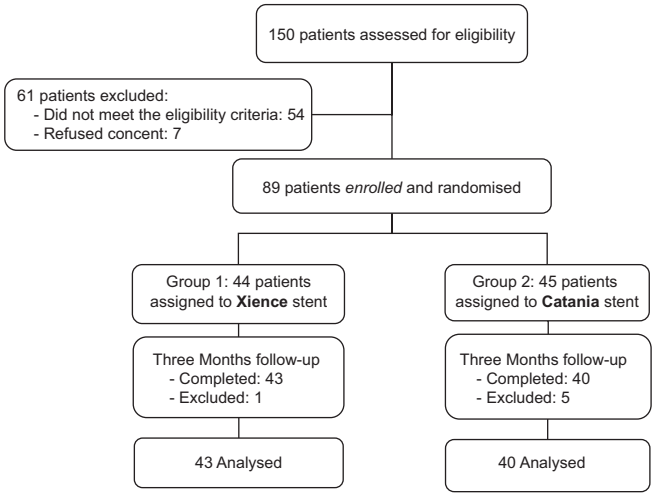

Figure 1: Trail profile

TLR, CABG operation, peripheral vasculopathy, and CVA were not observed in any of the patients. Furthermore, there was no statistically significant difference in mortality (4.7% vs. 2.5%; $P = 0.527$) and stent thrombosis (2.3% vs. 2.5%; $P = 0.735$) [Table 2].

After performing a univariate analysis, the clinical outcomes and some other independent variables such as, hypertension (HTN) and history of MI (based on the univariate analysis, at significance levels of 0.05) were included in the multiple logistic regression analysis. All variables were entered simultaneously ('Enter' method).

Even after adjusting for the potential confounders, there were no statistically significant differences between the Xience and Catania stents in terms of any outcome variables during the follow-up period.

Discussion

The present study as a double-blind, randomized controlled trial, compares the unintended outcomes of the Catania stent versus the Xience stent in patients undergoing angioplasty during three months of follow-up.

As our results indicate, there are no statistically significant differences between the Catania Polyzene-F coated stent and Xience stent with regard to all the unintended clinical outcomes during the follow-up period.

The first-in-man study of the Catania stent from May 2007 through August 2007, as a nonrandomized, single-arm study, on 55 patients with coronary artery diseases, showed superb safety and high-level efficacy in the treatment of *de novo* coronary artery lesions. In this survey it was suggested that the Catania stent could be an alternative to both BMS and DES, which could lessen the late loss, restenosis, and target lesion revascularization, with no long-term dual antiplatelet therapy.[5] Also, in a six-month clinical outcome assessment, in the comparison between patients treated with Xience stent and patients who were treated in the past with BMS, paclitaxel-eluting stents, and sirolimus-eluting stents, in 2007, Xience was better than

Table 1: The comparison of demographic, laboratory, and clinical patterns of 83 patients under angioplasty by the studied groups

Characteristics	Group		*P*-value
	Xience stent ($n = 43$)	Catania stent ($n = 40$)	
Age (year)	60.58±9.061	60.80±9.923	0.917
Gender (Male/ Female)	23/20	20/20	0.751
Weight (kg)	68 (60.0-81.0)	72 (67-80)	0.119
Height (cm)	167 (158-176)	167 (160-175)	0.366
BMI (kg/m^2)	24.97 (23.0-27.9)	25.59 (23.0-27.5)	0.630
Tobacco and smoking usage	11 (25.6)	9 (23.1)	0.792
DM	17 (39.5)	11 (27.5)	0.247
HTN	24 (55.8)	11 (27.5)	0.009
Family history of CAD	20 (48.8)	14 (35)	0.209
History of MI	14 (32.6)	4 (10.3)	0.015
HLP	8 (18.6)	5 (12.5)	0.445
Stent placement			0.468
Proximity/Mid	21/22	22/15	
Vessel place			0.516
LAD/RCA/LCX/OM	26/10/5/2	27/4/4/2	

BMI: Body mass index; DM: Diabetes mellitus; HTN: Hypertension; CAD: Coronary artery disease; MI: Myocardial infarction; HLP: Hyperlipidemia; Data are Mean ± SD, Median [IQR], N and N (%); *P*-values derived from T-test, Mann-Whitney, Chi-square, and fisher's exact tests; *Statistically significant

Table 2: The comparison of clinical outcomes between the studied groups during three months follow-up after intervention

Outcomes	Group		*P*
	Xience stent ($n = 43$)	Catania stent ($n = 40$)	
Mortality	2 (4.7)	1 (2.5)	0.527
Cardiac death	1	1	
Non-cardiac death	1*	0	
Stent thrombosis (ST)	1 (2.3)	1 (2.5)	0.735
Myocardial Infarction (MI)	0	0	-
Target Lesion Revascularization (TLR)	0	0	-
Coronary Artery Bypass Grafting (CABG)	0	0	-
Peripheral vasculopathy	0	0	-
Cerebral vascular accident (CVA)	0	0	-

Data are presented as number and number (Percent); *P*-values derived from fisher's exact test; *Cause of death: GI bleeding

BMS for target vessel revascularization and major adverse cardiac events (MACE), with clinical outcomes equal to SES.[12] Our results are in-keeping with their findings.

In a recently published study the safety and efficacy of the Xience everolimus-eluting stent (EES) were compared with the Endeavor Resolute zotarolimus-eluting stent (ZES-R) in a huge real-world registry (3056 patients treated with Xience and 1998 patients treated with zotarolimus-eluting stent). It was suggested that these two drug-eluting stents had excellent safety and efficacy.[13]

Although drug-eluting stents were found to lessen restenosis and the need for revascularization, several studies showed that they did not reduce the total mortality and were also associated with increased rates of stent thrombosis.[5,19,23,24] Nordmann *et al.,* in a meta-analysis study compared the effect of DES versus BMS among studies, between 1980 up to 2006. They suggested that with regard to treatment of coronary artery disease, drug-eluting stents did not reduce the total mortality in comparison to bare metal stents. They also expressed that long-term follow-up and evaluation of cause-specific deaths in patients receiving DES was compulsory to specify the long-term safety of these stents.[19]

The seconder study for evaluating the Catania Polyzene-F coated stent's safety and efficacy at a 12-month clinical follow-up, confirmed the first-in-man study of the Catania stent. In this survey, 300 patients were evaluated between May 2007 and March 2008, in a prospective, non-randomized, single-arm study.[20] The most important limitation of their study was the lack of randomized comparison with a different stent, and we have considered this limitation in our survey. According to the aforesaid studies and taking into account our findings, the Catania stent, as a biodegradable and polymer-free DES, could be effective for preventing unintended and late and very late outcomes.

The major limitation of our study was the lack of a follow-up period, which should be considered in future studies. Follow-up was only reported through three months, which was too short for describing the conclusions concerning stent thrombosis and matters related to safety. Also more randomized controlled trial studies should be carried out with different DESs and BMSs to evaluate the exact position of the Catania stents.

According to the increased concerns about the safety of DESs, due to the reports of the rising risk of late and very late stent thrombosis, the Catania stent, because of its safety profile, could be suggested as an alternative stent for patients who did not qualify for a long-term drug regimen. All in all, we could not find any significant difference between the Catania Polyzene-F coated stent and Xience stent.

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Conflicts of interest

There are no conflicts of interest.

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