



Clinical Outcomes of Xience V Everolimus Eluting Coronary Stents in the Treatment of Coronary Artery Disease

Authors

Dr Sheikh Mohamad Tahir¹, Dr Adeel Majeed Belim², Dr Vikram Singh³,
Dr Shubana Ashraf⁴

¹Consultant Cardiologist, Department of Cardiology, Super Speciality Hospital, GMC Srinagar, J&K, India

²Consultant Cardiologist, Fortis Balaji Hospital, Johdpur, India

³Consultant Cardiologist, Indus International hospital, Mohali, Punjab

⁴Consultant Neurologist, Super Speciality Hospital, GMC Srinagar, J&K, India

Abstract

Background: *The objective of the present study will be to determine the clinical outcomes of the patients who underwent coronary artery stenting with Xience V everolimus eluting stents for the treatment of coronary artery disease (de novo coronary artery lesions).*

Methods: *Our study was carried out in department of cardiology, Batra hospital and medical research center. All consecutive patients who had undergone percutaneous coronary intervention with only XIENCE V everolimus eluting coronary stents in our hospital from May 2012 to February 2013 were selected and followed up after 1 year. Patient case file and records were reviewed from the Cath lab and record section of our hospital. Coronary angiography reports were reviewed for lesion characteristics. Mode of presentation, past history, course in hospital and lab reports were recorded as per the documents available. Coronary angiograms were reviewed if needed Clinical follow-up was performed by telephone contact or office visit at 12 months after the index procedure. Patients who visited the follow up clinics at 1 year, clinical status was recorded by clinical history, physical examination, laboratory tests and ECG.*

Results: *In a total of 128 patients, 154 lesions were treated with 165 stents. 3 patients (2.3%) died. 6 patients (4.7%) had an MI during the follow up period. 8 (6.3%) patients had target lesion revascularization during the follow up period. 10 patients (7.8%) had to undergo target vessel revascularization in total during the follow up period. MACE as an end point was seen in 9.4% of the patients. All the patients were on dual antiplatelet at one year. A total of 3 patients (2.3%) died over one year. A total of six patients (4.7%) developed MI.*

Conclusion: *Our study showed that in unrestricted daily practice, implantation of Xience V EES was associated with low rates of adverse outcomes like MI and death, just as has been reported from various randomised controlled trials and some registries.*

Keywords: *Coronary artery disease, Coronary Stent, de novo coronary artery lesion, Xience V everolimus eluting stents.*

Introduction

The treatment of coronary artery disease (CAD) has been dramatically revolutionized since the

introduction of percutaneous coronary intervention (PCI) by Andreas Gruentzig in 1977^(1,2). Balloon angioplasty and subsequently,

coronary stenting has significantly influenced the management of stable and unstable CAD⁽³⁾. Initial results with percutaneous balloon angioplasty only, although encouraging, raised concern regarding per procedural complications, such as plaque rupture and coronary dissection, which are often clinically translated into acute myocardial infarction (MI), especially in the days following the procedure. Emergency coronary artery bypass grafting (CABG) due to acute vessel closure as a result of dissection was not uncommon. In addition, at follow-up, the benefits derived from revascularization were further counterbalanced by the high incidence of restenosis, which could reach 40%⁽⁴⁾. The advent of stents in the early 1990s significantly reduced these side effects and contributed to the widespread use of PCI. Nowadays, in the USA, more than a million patients are treated with PCI every year, often for no acute CAD⁽⁵⁾. The beneficial angiographic and clinical effects of stents were documented by several trials that demonstrated a significant reduction of restenosis and target-vessel revascularization (TVR) in patients allocated to bare-metal stent (BMS) implantation compared with those with percutaneous transluminal coronary angioplasty (PTCA)^[6]. BMSs reduced restenosis rates from 30–40% in the balloon angioplasty era to 20–25% by providing a mechanical scaffold to maintain radial support, minimizing elastic recoil^(6,7). The advantage of coronary stents in reducing the occurrence of restenosis after PCI is essentially due to the ability to eliminate the elastic recoil and negative vessel remodelling that occurs after balloon dilation⁽⁸⁾. However, with the widespread use of BMS, two notable complications emerged: in-stent restenosis and stent thrombosis. Although stent thrombosis was significantly reduced with the use of dual antiplatelet therapy after stent implantation, in-stent restenosis still remains a challenge⁽⁹⁾. In-stent restenosis is a more simple reaction to the coronary intervention, resulting from an excessive proliferative neointimal response. In the pathophysiology of in-stent restenosis, there are

four clear but overlapping components: platelet deposition, leukocyte recruitment, smooth muscle cell migration and proliferation and matrix deposition. While the risk of developing in-stent restenosis is linked to a variety of clinical and procedural factors (particularly diabetes, long lesions, small vessels and procedural failure), all BMS, regardless of the thickness of the struts, provoke a considerable proliferative response⁽⁸⁾.

First-generation drug-eluting stents (DESs) were designed to target in-stent restenosis caused by neointimal hyperplasia. To this end, coronary artery stents were coated with a polymer allowing controlled local delivery of a pharmaceutical agent with antineoplastic and anti-inflammatory properties. Subsequently, DESs replaced BMSs in the majority of percutaneous coronary intervention (PCI) procedures. However, as the use of DESs expanded beyond the well-studied indications of the randomized controlled trials, concern arose regarding the safety profile of the first-generation DESs^(10,11). Drug-eluting stents (DES) were based on the concept of local drug release at the site of tissue injury to resist smooth muscle proliferation. The astonishing results of the first studies performed with rapamycin and paclitaxel-eluting stents confirmed the concept that a high local concentration was essential in order to control the excessive proliferative response⁽⁸⁾.

The past 10 years witnessed the extraordinary promise of DES and several stents with different types of drug were tested. Some drugs, such as paclitaxel, can be coated directly on a metal stent, whereas the majority of the drugs need to be attached to a polymer, which acts as a drug reservoir⁽¹²⁾. On the basis of the positive outcomes of the SPIRIT family of randomized trials, EES were approved by US FDA for use in coronary artery disease. However, when DES are implanted in everyday clinical practice, they are often implanted for more complex patients and lesions where the benefit in reducing restenosis and repeat revascularization might be greater. As has been

seen with the first-generation DES, the clinical event rates are often higher in real world registries compared with those seen in the randomized trials. The objective of the present study will be to determine the clinical outcomes of the patients who underwent coronary artery stenting with Xience V everolimus eluting stents for the treatment of coronary artery disease (de novo coronary artery lesions) at our hospital (Batra Hospital and Medical research center Delhi). Thus we sought to evaluate the clinical outcomes of Xience V EES implantation in daily practice.

Material and Methods

Study Area: Our study was carried out in department of cardiology, Batra hospital and medical research center. Ours is a super-speciality hospital with fully functional Cath lab. Our hospital receives all sorts of cardiac patients, directly from the catchment area as well as referred from different areas and performs different types of cardiac interventions, both emergency and elective including primary PCI, elective PCI, EPS, RFA, device closures of septal defects, PPI, CRT and ICD implantations, peripheral vascular interventions etc. Our hospital has a fully functional CTVS department. Our hospital and Cath lab maintains record of all the procedures. Our study which was a retrospective follow up study made use of these records to select patients in a defined period and then followed them up.

Study Population: All consecutive patients who had undergone percutaneous coronary intervention with only XIENCE V everolimus eluting coronary stents in our hospital from May 2012 to February 2013 were selected and followed up after 1 year. This included all patients (males/females, urban/rural etc). The patients who had undergone coronary artery stenting with stents other than XIENCE V everolimus eluting stent, in addition to XIENCE V everolimus stents and those patients who underwent stenting of bare metal or drug eluting instenotic lesion were

excluded .In other words patients in whom intervention was done in only denovo lesions were included in the study.

Sample Size and Sample Technique: All consecutive patients who had undergone percutaneous coronary intervention with only XIENCE V everolimus eluting coronary stents in our hospital from May 2012 to February 2013, recorded in our coronary intervention registry were enrolled in the study. A study sample of 100 was expected and considered adequate. The reported hospital based prevalence of MACE (death, MI, TLR) was assumed to be 10% at Batra Hospital in the pilot study. The optimum sample size was calculated based on the following formula: $4Pq/d^2$. Therefore the minimum 100 patients were required to follow-up during the study period.

Data Collection Technique: Patient case file and records were reviewed from the cath lab and record section of our hospital. Coronary angiography reports were reviewed for lesion characteristics. Mode of presentation, past history, course in hospital and lab reports were recorded as per the documents available. Coronary angiograms were reviewed if needed Clinical follow-up was performed by telephone contact or office visit at 12 months after the index procedure. Patients who visited the follow up clinics at 1 year, clinical status was recorded by clinical history, physical examination, laboratory tests and ECG. Non-invasive investigations like TMT or stress echocardiography were done only if clinically indicated. Coronary angiography was done only if required and indicated, based on clinical judgement. Other patients were followed up telephonically at 1 year. Clinical status was judged from a questionnaire .Clinical events like Death, MI, recurrence of symptoms were recorded. For patients who suffered an adverse event at another center, medical records or discharge letters from the other institutions were systematically reviewed. General practitioners and referring physicians were contacted for additional information if necessary. The clinical end points

analysed were Death, MI, target vessel revascularization (TVR), target lesion revascularization (TLR), and major adverse cardiac events (MACE). The MACE (major adverse cardiac events) was defined, as it was in the SPIRIT trials as a composite of cardiac death, MI, and TLR during the follow-up period, which were evaluated on a per-patient basis. We also analysed TLR separately on a per-lesion basis. Target Vessel revascularization TVR was defined as repeat revascularization of a lesion in the same epicardial vessel treated in the index procedure.

Target lesion revascularization: TLR was defined as a repeat intervention in the stent or within 5 mm proximal or distal to the stent or CABG of the target vessel. TLR and TVR were only ischemia driven and there was no routine angiography of the patients on follow up. MI was defined as per universal definition of MI 2007.

Data Analysis: Categorical variables are presented as frequencies with corresponding proportions and continuous variables are presented as mean±SD. The normality of the distribution of the continuous variables was tested by the Kolmogorov-Smirnov goodness-of-fit test. Pie chart, bar diagram and histograms were made for graphical presentation of data. Continuous variables were compared with independent sample Student-t or Mann-Whitney U test. Categorical variables were compared with chi-square statistic or Fisher exact test when appropriate. Z test for proportion is also used for lesion wise comparisons of outcomes. A p value < 0.05 was considered statistically significant, and all reported p values are 2-sided. Data were coded and in MS Excel (2007) and statistical analysis was performed with IBM SPSS software (version 21, Chicago, Illinois).

Results and Discussion: Ours was an observational follow up study. A total of 128 patients were selected retrospectively and followed up after 1 year of the index procedure. Baseline characteristics of patients and

outcomes are shown in the table 1. Percentage of outcomes is showing in Figure 1. In a total of 128 patients, 154 lesions were treated with 165 stents. 3 patients (2.3%) died. 6 patients (4.7%) had an MI during the follow up period. 8(6.3%) patients had target lesion revascularization during the follow up period. 10 patients (7.8%) had to undergo target vessel revascularization in total during the follow up period. MACE as an end point was seen in 9.4% of the patients. All the patients were on dual antiplatelet at one year. Only in one patient it had to be stopped temporarily as he had developed ICH. A total of 3 patients (2.3%) died over one year. One of them died within 48 hrs of procedure when he developed VT and could not be resuscitated. The two others died at 2 and 5 months suddenly, one of them having chest pain before death. All of these deaths were taken as cardiac deaths. A total of six patients (4.7%) developed MI. Out of these one patient developed STEMI 24 hrs after the index procedure. Patient had stent thrombosis and was treated by repeat angioplasty of the lesion. The rest of the five patients who developed MI were NSTEMI with biomarker rise, and they developed MI on an average of 5 months after the index procedure. Four out of these five patients had significant restenosis of the lesion and were revascularised either with stenting or CABG. One patient had development of new significant lesion in the target vessel but no restenosis of the stent. The patient was revascularised with repeat PCI. Eight patients (6.3%) had to undergo revascularization because of significant in-stent restenosis of the target lesion (TLR). Five of these patients had developed MI, while as rest of three patients had developed recurrence of symptoms of angina on exertion or exertional breathlessness. Two more patients had to undergo revascularization in the same vessel but in the region other than that of target lesion. one of them had presented as MI while as other had recurrence of symptoms. In total 10 patients had to undergo revascularization of the target vessel (TVR). MACE (major adverse cardiac events)

defined in our study as composite of Death, MI and TLR was seen in 12 patients (9.4%). In total two patients (1.5%) developed stent thrombosis. One had definite stent thrombosis and one had probable stent thrombosis. Most of these outcomes had already occurred at the time of follow up contact, so the information regarding the adverse outcome was obtained by going through the records of that particular hospital and checking hospital discharges regarding cause of admission, CAG report, biomarker results, hospital course and the intervention done.

Our study showed that the use of Xience V EES in the treatment of coronary artery disease in unselected patients was associated with low rates of adverse outcomes in the form of death, MI, TLR and TVR. The outcome in our study particularly MACE, TLR and TVR were slightly higher as compared to some of the other studies but this difference was not marked. The cause of this slightly higher outcomes could be multifactorial. One reason could be that the baseline patient characteristics varies across our study and these mostly European studies and the fact that the Indian population is considered more likely to present with the known predictors of restenosis and TLR. The other factor being difference in the total number of patients studied as our study was based on small number of patients. One more reason could be that our study was looking at the outcomes in the real world patients/lesions in daily practice that were excluded in many randomized trials. Difference in the use of cardiac biomarkers could possibly play a role as more routine use of biomarkers leads to more diagnosis of MI and hence TLR which in our study was ischemia driven. Yet another reason could be that at the time of index procedure the angiographic success was not quantified by IVUS in our study while as it was in some of the above studies and also pre and post stent dilatation at different pressures could also play a role as these variables were not looked at. Ours was an observational follow up study of everolimus Xience V stents in coronary artery diseases. The

only patients that were excluded were the ones in which stents were put to treat an in-stent lesion and the ones in which any other type of stent was put in addition to Xience V stent (mixed stents). Rest all the patients were studied regardless of the way of presentation (STEMI, NSTEMI, UA, Stable angina or exertional breathlessness), or the type of lesion morphology, or the number of vessels diseased or treated. In short we studied outcomes in unselected patients in clinical practice. Many of these complex patients/lesions have been excluded in many randomised trials. However there are some European and a few Indian all comer studies that have looked at the outcomes in unselected patients in daily practice as well.

MACE rate in our study was 9.4% and TLR rate was 6.3% which was not markedly different from SPIRIT III trial of 6 and 3.4%^(13,14). This was in spite of increased complexity of patients and lesions treated in our study (there were many type B2 and C lesions in our study, many lesions were long, more than 40mm and the patient presentation also included STEMI). In a study done by Azeemlatib et al⁽¹⁴⁾ where outcomes were evaluated after unrestricted implantation of everolimus eluting stent MACE occurred in 10.6% and TLR in 7.9%. This was similar to our study (9.4% and 6.3%). MI rates were 2.1% in Azeem Latib et al study while as it was 4.7% in our study.

In Spirit IV⁽¹⁵⁾ trial the primary endpoint was target vessel failure (a composite of target vessel MI and cardiac death), which was seen in 4.2% of the patients. Since in our study all deaths were cardiac and all MIs were related to target vessel, the composite of MI and death was 7.03%. This was not markedly higher than SPIRIT IV trial considering the increased complexity of lesions and inclusion of acute MIs and recent MIs in our study, as SPIRIT IV trial included simple lesions and also excluded Acute or recent MIs. In one more trial evaluating outcomes in everolimus eluting stent in real life practice and having inclusion criteria almost similar to our study was

COMPARE trial⁽¹⁶⁾ in which the rate of TLR, MI and death was 5% while as in our study it was 9.4%. This difference was also not large however this difference could be explained because of large number of patients (n=1797) in COMPARE trial as compared to our study (n=128). Xience v Registry USA (39) reported a rate of 0.85% of probable and definite stent thrombosis while as our study had stent thrombosis of 1.5%. In our study death and MI amounted to 7.03 % while as in Xience V registry USA this composite endpoint was 6.5%. Again this was not markedly different. In Resolute trial⁽¹⁷⁾ the endpoint of cardiac death, MI and TLR was 8.3% in everolimus arm which is not markedly different from our composite endpoint of death, MI and TLR (9.4%) (All deaths in our study being cardiac). In ISAR-4 study⁽¹⁸⁾ the outcome of cardiac death, MI related to target vessel and TLR was 13.8% in everolimus Xience stent arm which is again not markedly different from our study (9.4%).

The slightly higher rates of TLR and MACE in our study as compared to some of the above studies could be multifactorial. One reason could be that the baseline patient characteristics varies across our study and these mostly European studies and the fact that the Indian population is considered more likely to present with the known predictors of restenosis and TLR. The other factor being difference in the number of patients studied as our study contained small number of patients.

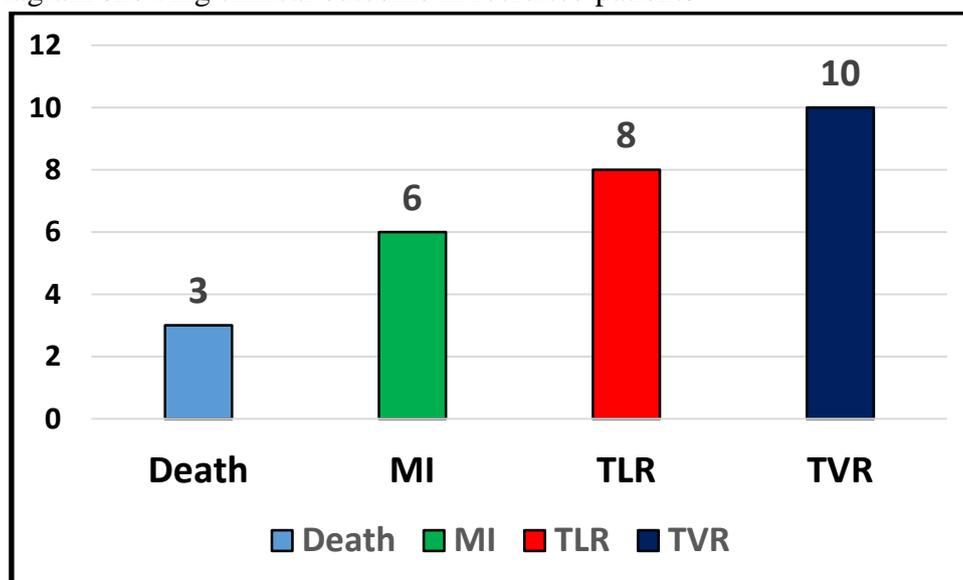
One more reason could be that our study was looking at the outcomes in the real world patients/lesions in daily practice that were excluded in many randomized trials. Yet another reason could be that at the time of index procedure the angiographic success was not quantified by IVUS in our study while as it was in some of the above studies and also pre and post stent dilatation at different pressures could also play a role as these variables were not looked at. Ashok Seth et al⁽¹⁹⁾ reported 1.9% rate of composite end point of MI and death at one year in an Indian study where patients were followed for three years. In our study MI and death occurred in 7.03% of patients. This difference could be explained by small number of patients in our study as compared to Ashok Seth's study. Also this difference could be because of the difference in the frequency by which cardiac markers were done, leading to increased diagnosis of MI and hence TLR (which was ischemia driven). The primary endpoint of this large Indian study was stent thrombosis which was seen in 0.5 % of patients at 1 year while as in our study definite/probable stent thrombosis was seen in 1.5% which again is not markedly different from the Ashok Seth et al study. Since the frequency in each outcome group like death, TLR, TVR is relatively low, all the significant results in our study, though providing some useful clinical information need to be interpreted cautiously.

Table 1: Baseline characteristics of all the patients recruited for the study.

Patient Characteristics	Frequency (n) N=128	Percentage (%)
Mean age (years) (mean \pm SD)	58.1 \pm 10.6	
Sex		
Male	105	82.0
Female	23	18.0
Hypertension	78	60.9
Diabetes Mellitus	52	40.6
Lipid Profile		
Normal	32	25.0
Dyslipidaemia	41	32.0
Prior MI	24	18.8
Prior PCI	13	10.2
Prior CABG	4	3.1
LV function category		

<30	1	0.8
30-44	18	14.1
45-54	54	42.2
≥ 55	55	43.0
Clinical Presentation		
STEMI	19	14.8
NSTEMI	13	10.2
UA	36	28.1
Stable Angina/DOE	60	46.9
Number of Vessel Disease		
One	72	56.3
Two	40	31.3
Three	16	12.5
Number of Target Vessels		
One	115	89.8
Two	13	10.2
Number of Stent Used		
One	95	74.2
Two	29	22.7
Three	4	3.1
Lesion type (n=154)		
A	8	5.2
B1	31	20.1
B2	39	25.3
C	76	49.4
Number of Lesion Treated		
One	103	80.5
Two	24	18.8
Three	1	0.8
Outcomes		
Death	3	2.3
MI	6	4.7
TLR	8	6.3
TVR	10	7.8

Figure 1: Bar Diagram showing clinical outcome in recruited patients



Conclusion

Our study showed that in unrestricted daily practice , implantation of Xience V EES was

associated with low rates of adverse outcomes like MI and death, just as has been reported from various randomised controlled trials and

some registries. Although composite outcome MACE (composite of death, MI and target lesion vascularisation) was slightly higher as compared to randomized controlled trials like SPIRIT trials, the difference was not marked. Our study provides important complementary information about the outcomes in the real world patients /lesions that were excluded in many randomized trials and it provides insight about the clinical spectrum and clinical outcomes of patients with de novo lesions being currently treated with this second generation drug eluting stent. However our study was limited due to following reasons: - Our study has a limitations of being observational nonrandomized study. It involved small number of patients in total. The lack of routine angiographic follow up precludes any comments about the antirestenotic efficacy of Xience V EES and follow up of many of the patients was done telephonically.

Recommendation

The superiority of Xience V EES has been documented in many randomised trials .The use of Xience V EES has been associated with low rates of death and MI in these studies. Our study also demonstrated low rates of death, MI and TLR in unselected patients encountered in general cardiology practice, which are usually excluded from many randomised trials. Hence Xience V EES is one of the better choices for stenting in coronary artery lesions. IVUS had not been used to assess the angiographic success at the time of index procedure in our study. The use of techniques like IVUS to assess angiographic success may further decrease the rate of outcomes. The use of EES with slightly different stent platforms (promus element) need to be looked at in detail as the increased trachability, radial strength and a different stent platform may have some effects on outcomes. Study of Outcomes in the form of instent restenosis needs a study which will incorporate routine angiography on follow up and will assess anti restenotic properties of Xience V EES. Finally, more such studies,

evaluating outcomes in unselected patients in daily routine practice in Indian scenario, with increased number of patients are recommended.

Ethical Consideration

The study had no ethical issues pertaining to human or animal experimentation.

Source of Funding: None

Conflict of Interest: None

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