VIA MEDICA

ORIGINAL ARTICLE

Justas Keršulis, Robertas Pranevičius, Kasparas Briedis, Ramūnas Unikas, Ąžuolas Sirtautas, Norvydas Zapustas

Lithuanian University of Health and Sciences

Evaluation of two years' treatment results after implantation of Biolimus A9 stents in coronary arteries

Corresponding author:

Robertas Pranevičius LSMU SA

Tel.: 861290437

E-mail:
pranevicius.robertas@gmail.com

Medical Research Journal 2016;
Volume 1, Number 2, 92–94
10.5603/MRJ.2016.0015

ISSN 2451–2591

ABSTRACT

Introduction. Stenting is a widespread procedure for patients suffering from coronary artery disease. The use of drug-covered stents has improved stenting safety and treatment efficiency. Using second-generation Biolimus drug-covered A9 stents is associated with reduced risk of stent thrombosis compared with first-generation ones. The aim of the study was to evaluate two years' treatment results after implantation of Biolimus A9 stents in coronary arteries in patients who suffer from coronary artery disease.

Methods. The study included 216 patients who suffered from coronary artery disease and were treated using Biolimus A9 drug-covered stents, in order to eliminate all greater-than-50% stenoses. Patients' data were collected from hospital case histories and e-Biomatrix PMR questionnaire. Decisions regarding whether to use Biolimus A9 stents during percutaneous coronary intervention were made by the respective operators. The rate of complication after stenting was evaluated when stenosis was eliminated or reduced to 30% or TIMI 3 flow was determined.

Results. Out of 216 patients included in the study, 151 were males (69.91%) and 30.09% (65) were females. Mean of age of patients was 60.2 ± 10.1 years; 19% of patients had diagnosed diabetes. The success rate of implanting Biolimus A9 stents was 100% with no complications during hospital stay.

Key words: Biolimus, stents, coronary artery disease

Med Res J 2016; 1 (2): 92–94

Introduction

Stenting is a widespread procedure for patients suffering from coronary artery disease. The possibility of using drug-covered stents has improved stenting safety and treatment efficiency. The use of second-generation Biolimus drug-covered A9 stents is associated with reduced risk of stent thrombosis when compared with first-generation ones. Drug-eluting stents (DES) have greatly reduced the risk of restenosis compared with bare-metal stents and have become the standard of care for patients undergoing percutaneous coronary intervention (PCI). However, the durable polymer within the vessel is considered responsible for ongoing inflammation, leading to late complications such as stent thrombosis. From these innovations, the second-generation everolimus-eluting stent (EES) using a biocompatible durable polymer (fluorinated copolymer) with thin strut (81 mm) and the third-generation biolimus-eluting stent (BES) using an abluminally coated biodegradable polymer (polylactic acid) with relatively thick strut (112 mm) are currently considered the safest DESs.

PCI is the preferred treatment for patients with acute myocardial infarction (AMI) [1, 2]. In both elective and primary PCIs, DES showed reduced restenosis rates compared with bare metal stents, but still it is not clear whether late restenosis is possible [3–6]. Because AMI is a predictor of thrombotic stent complications occurring late after DES implantation in the presence of a high thrombus burden, careful consideration of both the risks and benefits of DES is necessary, especially in the clinical practice for AMI patients [7, 8]. The biodegradable polymer BES (BioMatrix, Biosensors; Nobori, Terumo) is composed of stainless steel alloy and an abluminally-coated biodegradable polymer eluting Biolimus A9, a highly lipophilic analogue of sirolimus. Use of second-generation Biolimus drug-covered A9 stents is associated with reduced risk of stent thrombosis com-

pared with the first generation. Additionally, the high degree of lipophilicity may provide a more potent local effect on lipid-rich plaques in lesions causing AMI [9, 10]. The goals of using a biodegradable polymer BES are to reduce the risk of late-onset thrombosis with non-inferiority with respect to target vessel revascularisation compared with other DESs. However, there are limited data regarding clinical outcomes of biodegradable polymer BES in subjects presenting with AMI and late stent thrombosis. The aim of this study was to evaluate two-year treatment results after Biolimus A9 stent implantation in coronary arteries in patients who suffer from coronary artery disease.

Methods

Study population

A total of 216 patients who suffered from coronary artery disease were treated using Biolimus A9 drug-covered stents in order to eliminate all greater-than-50% stenoses. Patients' data were collected from hospital case histories and e-Biomatrix PMR questionnaires. Consecutive patients with ST-segment elevation myocardial infarction (STEMI) and non-ST segment elevation myocardial infarction (NSTEMI) underwent PCI using a BES. Decisions regarding whether to use a BES during PCI were made by the respective operators. The rate of complications after stenting was evaluated when stenoses were eliminated or reduced to 30% or TIMI 3 flows were determined.

All procedures were performed using standard interventional techniques. Loading doses of aspirin (300 mg) and clopidogrel (300 or 600 mg) were administered unless patients had previously received antiplatelet medications for more than one week. The type of DES, use of glycoprotein IIb/IIIa receptor antagonists, PCI performed on non-culprit vessels, and the duration of clopidogrel therapy after PCI were at the discretion of the physician.

Definitions and measured outcomes

We assessed two study endpoints, two years after stent placement: an efficacy endpoint and a safety endpoint. The efficacy endpoint was defined by target vessel failure, which was a composite of cardiac death, target vessel-related myocardial infarction (MI), and target vessel revascularisation. The safety endpoint was a composite of all cause death, MI, and stent thrombosis. Clinical outcomes measured after two years were all-cause death, cardiac death, AMI, target lesion revascularisation, target vessel revascularisation, and stent thrombosis. MI was defined as elevated cardiac biomarkers (troponin or CK-MB) with ischaemic symptoms or electrocardiographic findings indicative of ischaemia. Target lesion revascularisation was defined as repeat PCI of the lesion within 5 mm of stent deployment or bypass graft of the target vessel. Target vessel revascularisation was defined as any percutaneous or surgical revascularisation of the treated target vessel. Stent thrombosis was described as definite or probable according to the definitions set forth by the Academic Research Consortium [11]. Baseline clinical, angiographic, and procedural findings were collected retrospectively, and clinical outcome data were recorded in the dedicated PCI registry by research personel.

Statistical analyses

Categorical variables were summarised as frequencies with percentages and were compared using Chi-square test or Fisher's exact test. Survival curves were constructed using Kaplan–Meier estimates and were compared using log-rank test.

Results

Mean of age of 216 study patients was 60.2 ± ± 10.1 years. 19% of patients had diabetes. The success rate of implanting Biolimus A9 stents was 100%, with no complications whatsoever while the patients were in the hospital. After performing a follow-up on these patients, it was found that there were four cases with complications in the one-year period after stenting procedure. In one case of stent thrombosis was found, one patient suffered a stroke, and two patients needed revascularisation afterwards, so the complication rate was 1.4%. During the second year period after stenting was performed, the patient follow-up showed a complication rate of only 0.46%; one case needed revascularisation.

Discussion

The study of Biolimus A9 stents showed that they are highly effective with a relatively low complication rate. Therefore, they could be recommended for more frequent use. The biodegradable polymer BES is composed of stainless steel alloy and an abluminally-coated biodegradable polymer eluting biolimus A9, a highly lipophilic analogue of sirolimus; the drug is rapidly absorbed by surrounding tissue. Subsequent degradation of the polymer on the surface of the stent may help to avoid late-onset thrombosis by reducing local hypersensitivity reactions to the durable polymer [12, 13]. Additionally, the high degree of lipophilicity may provide

a more potent local effect on lipid-rich plaques in lesions causing acute myocardial infarction. The goal of using a biodegradable polymer BES are to reduce the risk of late-onset thrombosis with non-inferiority with respect to target vessel revascularisation compared with other DESs. The stent elutes biolimus (15.6 μg/mm) for up to 30 days. The coating design of the stent combined with the lipophilicity of the drug is thought to optimise local drug distribution and to reduce its release into the circulation. Biolimus inhibits proliferation of smooth muscle cells similarly to sirolimus. Moreover, biolimus may offer significant advantages compared with other "limus" agents because it may improve pharmacokinetics due to its high lipophilicity and, consequently, optimise bioavailability with rapid distribution into the arterial wall during the initial hours after stent implantation; this allows achievement of faster therapeutic concentrations and extended duration of treatment effect, which may counterbalance the potentially negative effects of boost release.

References

1. Task Force on Myocardial Revascularization of the European Society of Cardiology, European Association for Cardio-Thoracic Surgery, European Association for Percutaneous Cardiovascular Interventions, Guidelines on myocardial revascularization. Eur Heart J 2010; 31: 2501–2555.
2. Levine GN, Bates ER, Blankenship JC et al. 2011 ACCF/AHA/SCAI guideline for percutaneous coronary intervention. A report of the American College of Cardiology Foundation/American Heart Association Task Force on Practice Guidelines and the Society for Cardiovascular Angiography and Interventions. J Am Coll Cardiol 2011; 58: 44–122.
3. Moses JW, Leon MB, Popma JJ et al. Sirolimus-eluting stents versus standard stents in patients with stenosis in a native coronary artery. N Engl J Med 2003; 349: 1315–1323.
4. Stone GW, Ellis SG, Cox DA et al. A polymer-based, paclitaxel-eluting stent in patients with coronary artery disease. N Engl J Med 2004; 350: 221–231.
5. Spaulding C, Henry P, Teiger E et al. Sirolimus-eluting versus uncoated stents inacute myocardial infarction. N Engl J Med 2006; 355: 1093–1104.
6. Stone GW, Witzenbichler B, Guagliumi G et al. Heparin plus a glycoprotein IIb/IIIa inhibitor versus bivalirudin monotherapy and paclitaxel-eluting stents versus bare metal stents in acute myocardial infarction (HORIZONS-AMI): final 3-year results from a multicentre, randomised controlled trial. Lancet 2011; 377: 2193–2204.
7. Sianos G, Papafaklis MI, Daemen J et al. Angiographic stent thrombosis after routine use of drug-eluting stents in ST-segment elevation myocardial infarction: the importance of thrombus burden. J Am Coll Cardiol 2007; 50: 573–583.
8. Daemen J, Wenaweser P, Tsuchida K et al. Early and late coronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study. Lancet 2007; 369: 667–678.
9. Raber L, Windecker S. Current status of drug-eluting stents. Cardiovasc Ther 2011; 29: 176–189.
10. Virmani R, Burke AP, Farb A, Kolodgie FD. Pathology of the vulnerable plaque, J Am Coll Cardiol 2006; 47: C13–C18.
11. Cutlip DE, Windecker S, Mehran R et al. Clinical end points in coronary stent trials: a case for standardized definitions. Circulation 2007; 115: 2344–2351.
12. Virmani R, Guagliumi G, Farb A et al. Localized hypersensitivity and late coronary thrombosis secondary to a sirolimus-eluting stent: should we be cautious? Circulation 2004; 109: 701–705.
13. Joner M, Finn AV, Farb A et al. Pathology of drug-eluting stents in humans: delayed healing and late thrombotic risk. J Am Coll Cardiol 2006; 48: 193–202.