ORIGINAL ARTICLE

Six-month clinical follow-up of the self-apposing coronary stent system in patients with hemodynamically significant stenosis of unprotected left main

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Abstract: **Premises –** Left main coronary artery disease is the highest-risk lesion subset of ischemic heart disease, and has traditionally been an indication for coronary artery bypass grafting. In recent years, many interventional techniques have been proposed for the treatment of such lesions. Implantation of self-apposing stents is one of them. These stents have a conical shape and open cells, which allows us to restore the bifurcation of left main and achieve anatomy close to the physiological. **Material and methods –** Thirty-three patients with left main bifurcation lesions treated with self-apposing coronary, nitinol, sirolimus-eluting stent using stent with balloon technique were enrolled in this study. These patients were admitted in hospital during 2016. Primary endpoints were a procedural success, defined as favourable technical and angiographic result in the absence of a major adverse cardiac event (MACE) at hospital discharge and cumulative MACE at six months follow-up. **Results –** Post-procedural TIMI III flow was reached in both vessels. One recorded stent with balloon technique failure (3.0%) was attributed to impossibility of rewiring due to extremely tortuous circumflex artery, and calcified ostium. There were 2 patients (6.1%) with in-stent thrombosis during hospitalisation and 2 patients (6.1%) with in-stent restenosis during six-month follow-up after intervention. All these events were confirmed angiographically. The cumulative MACE at six-month rate was 12.0% ($p<0.05$). **Conclusions –** This study demonstrates that the self-apposing coronary stent can be safely deployed with excellent procedural success of 97% for the treatment of hemodynamically significant stenosis of unprotected left main. It is also feasible for using the stent with balloon technique in most cases. A relatively high cumulative MACE was registered at six months (12.0%). To minimize the rate of MACE, it is probably important to analyse the anatomy of the vessels and the lesions characteristics.
Keywords: left main disease, self-apposing stent, angioplasty, coronary angiography.

Rezumat: **Premize –** Leziunile de trunchi comun ale arterei coronare stângi sunt afecţiuni cu risc major ale cordului şi, în mod tradiţional, au fost privite ca indicaţie de tratament chirurgical prin by-pass aorto-coronarian. În ultimii ani au fost propuse multe tehnici intervenţionale de tratament a acestor leziuni. Una din ele este implantarea stenturilor autoexpandabile. Aceste stenturi au formă conică şi celule deschise, care permit restabilirea bifurcaţiei de trunchi comun in modul cel mai fiziologic. **Material şi metode –** 33 de pacienţi cu leziune de trunchi comun au fost trataţi prin implantarea stentului autoexpandabil, farmacologic active, din nitinol, folosind tehnica stent-balon. Toţi pacienţii au fost trataţi pe parcursul anului 2016. Obiectivul final al studiului a fost aprecierea succesului procedural manifestat prin rezultatul angiografic şi rata evenimentelor cardiace majore în timpul spitalizării şi la şase luni după intervenţie. **Rezultate –** Fluxul TIMI III a fost obţinut în toate cazurile pe ambele vase principale. Un eşec tehnic (3,0%) a fost atribuit imposibilităţii efectuării reghidării spre ramul secundar din cauza tortuozitatii excesive a vasului şi calcifierea ostiului. Au fost înregistrate două cazuri (6,1%) de tromboză precoce şi două cazuri (6,1%) de restenoză intrastent, aproximativ la 4 luni post-intervenţie, toate cazurile fiind confirmate angiografic. Rata totală a evenimentelor cardiovasculare majore a constituit 12,0%. **Concluzii –** Acest studiu a demonstrat că stenturile autoexpandabile pot fi aplicate în tratamentul hemodinamic al leziunilor semnificative de trunchi comun cu o rată înaltă de succes procedural (97%) cu aplicarea tehnicii stent-balon. O rata relativ crescuta de evenimente cardiovasculare majore (12,0%) a fost înregistrată la şase luni de supraveghere. Pentru reducerea riscurilor de evenimente cardiovasculare majore se recomandă selectarea mai riguroasă a cazurilor cu anatomie şi morfologie favorabilă a leziunilor.
Cuvinte cheie: leziuni de trunchi comun, stent autoexpandabil, angioplastie, coronarografie.

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INTRODUCTION

Patients with hemodynamically significant left main (LM) coronary artery disease have a poor prognosis and increased mortality over the next three years[1]. Compared with medical therapy, coronary artery bypass graft surgery improves survival in these patients by about 66%. Accordingly, the European guidelines on myocardial revascularization have assigned a class I recommendation to CABG surgery to improve survival in patients with left main disease[2]. Percutaneous Coronary Intervention is a mini-invasive alternative for the treatment of left main disease, and is currently regarded as equivalent to CABG in several lesion subsets which previously were preferably treated by surgery[3].

However, the mechanical properties of balloon expandable stents (Bx) may be limited in case of patients with lesions of left main and are frequently not well adapted to the requirements of the biological system. Consequently, there is evidence that the mechanical shortcomings of Bx stents, such as conformability to the vascular wall, stent under expansion or oversizing, adaptability to vessel tapering, scaffolding of bifurcated lesions, inability to address vessel remodeling, and achieving optimal drug delivery, could translate into adverse clinical events. New, enhanced technology now allows the application of a number of self-apposing (Sa) coronary stents to treat left main disease. Various clinical trials have proven coronary applicability and the clinical safety and efficacy of Sa stents. It is expected that this new generation of endovascular prostheses that are specifically tailored to the needs of the coronary arteries can overcome some of the limitations that are associated with Bx stents, while maintaining their valuable, traditional features. Clinical results of Sx stents may be further improved by continuous development of these devices.

METHODS

The purpose of this study is to assess the particularities of the percutaneous coronary interventions (PCI) using self-apposing coronary stent system The Xposition S™ by STENTYS in patients with hemodynamically significant stenosis of unprotected left main.

The overall study objectives are to assess the safety and efficacy of stenting in patients with significant stenosis of unprotected LM coronary artery using self-apposing coronary stent and to evaluate the applicability of the stent with balloon technique (SBT) depending on the type of bifurcation lesions (Medina classification).

The Xposition S™ stent is a self-apposing, conical, nitinol, drug (Sirolimus) eluting stent with small interconnections that can be disconnected by balloon angioplasty to provide access to the side branch and full ostium coverage.

33 patients with LM bifurcation lesions treated with self-apposing coronary stent using SBT were enrolled in this study.

These patients were admitted in Polivalent Hospital Novamed, Chisinau, Republic of Moldova during 2016. All patients presented on admission stable angina functional class III or IV.

The patient population consisted of 90,9% males with an average age of 60,6 years (minimum – 33 years, maximum – 77 years).

According to the Medina classification, Medina 1.0.0 type of bifurcation lesion was found in 12.1% of patients, Medina 1.1.0 – in 63.6%, Medina 1.1.1 – in 18.2%, and Medina 1.0.1 – in 6.1% of cases.

Primary endpoints were a procedural success, defined as favourable technical and angiographic result in the absence of a major adverse cardiac event (MACE) at hospital discharge and cumulative MACE at six months follow-up.

RESULTS

One stent technique was performed in all (100%) patients, including the stent with balloon technique (SBT)in 97.0% of cases. Average length of deployed stents was 23.1 mm. In 57.6% of cases the diameter of stent was 3.0-3.5 mm, in 42.4% of cases – 3.5-4.5 mm. In 36.4% of patients it was needed to implant a drug eluting stent (DES) in other segments of coronary arteries.

The overall procedural success rate was high – 97.0%, comprising 32 of 33 cases. Post-procedural TIMI III flow was reached in both vessels (side branch and main branch)[4]. One recorded SBT failure was attributed to impossibility of rewiring due to extremely tortuous circumflex artery, and calcified ostium. One female patient with Medina 1.1.1 lesion developed STEMI in two hours after stenting procedure. It was caused by acute thrombosis of circumflex artery and was followed by thrombus aspiration. Also, one male patient with severe three vessel coronary disease and Medina 1.1.1 type of bifurcation lesion died in eight hours after the intervention. In-stent thrombosis was confirmed angiographically in this case. The cumulative MACE at six-month (including in-hospital MACE) rate was 12.0 % ($p<0.05$). There were two pa-

tients with in-stent thrombosis during hospitalisation and two patients with in-stent restenosis during six-month follow-up after intervention. All these events were confirmed angiographically.

CONCLUSIONS

1. This study demonstrates that the Self-apposing Coronary Stent (Xposition S ™ by STENTYS) can be safely deployed with excellent procedural success of 97% for the treatment of hemodynamically significant stenosis of unprotected left main. It is also feasible for using SBT in most cases.
2. A relatively high cumulative MACE was registered at six months (12.0%). To minimize the rate of MACE, it is probably important to analyse the anatomy of the vessels and the lesions characteristics.

The authors have no conflict of interest to declare.

References

1. Boersma H, Doornbos G, Bloemberg BPM, Wood DA, Kromhout D, Simoons ML. Cardiovascular diseases in Europe. European Society of Cardiology, 1999.
2. Stone GW, Sabik JF, Serruys PW, et al. Everolimus-Eluting Stents or Bypass Surgery for Left Main Coronary Artery Disease. N Eng J Med 2016;375:2223-35.
3. Mäkikallio T, Holm NR, Lindsay M, et al. Percutaneous coronary angioplasty versus coronary artery bypass grafting in treatment of unprotected left main stenosis (NOBLE): a prospective, randomised, open-label, non-inferiority trial. Lancet 2016;388:2743-52.
4. Gibson CM, Cannon 4. CP, Daley WL, et al. TIMI frame count: a quantitative method of assessing coronary artery flow. Circulation 1996; 93:879-888.