SciMedCentral

Journal of Translational Medicine & Epidemiology

Editorial

Coronary Balloon-Expandable Drug-Eluting Stents for Focal Superficial Femoral Artery Disease: When is the Time Ripe for Challenging Conventional Wisdoms?

Arturo Giordano[1,2]*, Giuseppe Biondi-Zoccai[3] and Gabriele Giordano[1,2]

[1]*Unit of Cardiovascular Interventions, Presidio Ospedaliero Pineta Grande, Castel Volturno, Italy*

[2]*Hemodynamics Unit, Casa di Salute Santa Lucia, San Giuseppe Vesuviano, Italy*

[3]*Department of Medical-Surgical Sciences and Biotechnologies, Sapienza University of Rome, Latina, Italy*

Abstract

The management of patients with peripheral artery disease (PAD) largely depends on symptom status and disease location. Those symptomatic for lower limb atherosclerotic disease are often offered revascularization if medical therapy does not suffice in ameliorating such symptoms. Despite the inherent advantages of surgical revascularization, endovascular therapy appeals many patients given the low invasiveness. However, a plethora of devices and techniques is available, which complicates substantially decision making, especially for lesions located in the femoral vessels. Despite mounting evidence and experience that dedicated self-expandable drug-eluting stents (DES) represent the most favorable choice for many patients, we hereby make the case that in selected subjects with focal superficial femoral artery (SFA) disease, implantation of balloon-expandable drug-eluting stents originally developed for percutaneous coronary intervention (PCI) can prove remarkably safe and effective.

Corresponding author

Arturo Giordano, Unit of Interventional Cardiovascular, the Hospital Pineta Grande, State Road Domiziana Km 30, 81030 Castel Volturno, CE, Italy, Email: arturogiordano@tin.it

Submitted: 20 August 2013

Accepted: 20 August 2013

Published: 23 August 2013

Keywords

- Coronary artery disease
- Drug-eluting stent
- Peripheral artery disease
- Superficial femoral artery

INTRODUCTION

Despite momentous efforts in the prevention, diagnosis, and management of atherosclerosis, the burden of peripheral artery disease (PAD) continues to increase worldwide [1]. Symptomatic PAD failing maximal medical therapy is particularly troublesome, and surgical revascularization (usually based on venous or synthetic bypass grafts), has traditionally been considered the definitive palliative treatment for such cases [2]. However, surgery is fraught with an increased short-term risk of adverse events, mainly due to its invasiveness [2,3]. Accordingly, endovascular therapy has been proposed as early as 1964 by Dotter and Judkins as a means to achieve effective revascularization in minimally invasive fashion [4]. Despite the success rates which remain at least moderately lower than those of surgery, [2,5] endovascular revascularization is being used more and more commonly in clinical practice, and currently outnumbers surgery in case volume in most practices.

In this respect, the superficial femoral artery (SFA) represents a prototypical example of the ongoing challenges faced by endovascular specialists. The SFA is often a cause of troubling symptoms (most commonly claudication, but occasionally, and especially when infra-popliteal disease is also present, critical limb ischemia). In addition, it is typically affected by very extensive, advanced, and calcific atherosclerotic disease, and has several unique mechanical features which make it a very challenging treatment target [6]. In light of these factors and the setbacks associated with simple Dotter techniques or standard balloons, [4,7] several devices have been proposed for SFA revascularization, with heterogeneous results [8].

Table 1: Pros and cons of coronary balloon-expandable drug-eluting stents (*italicized*) for focal superficial femoral artery disease in comparison to the other available devices.

Class	Standard devices			Drug-eluting devices				Other devices			
Device	**Balloons**	**Balloon-expandable BMS**	**Self-expandable BMS**	**Self-expandable DES**	***Balloon-expandable DES***	**Drug-eluting balloons**	**Bioresorbable DES**	**Atherectomy**	**Cryoplasty**	**Bioresorbable BMS**	**Self-expandable covered stents**
Support	-	+	+	+	+	-	+/-	-	-	+/-	+
Anti-restenotic effect	-	-	-	+	+	+	+	+/-	+	-	+/-
Flexibility	+	-	+	+	-	+	-	+	+	-	+
Applicable to large vessels	+	+	+	+	-	+	-	+	+	+	+
Cost	-	+/-	+/-	+	+/-	+/-	+	+	+	+	+

BMS=bare-metal stent; DES=drug-eluting stent

Conventional and non-conventional endovascular tools for focal superficial femoral artery disease

The standard treatment of SFA lesions is based on extensive balloon dilation followed by elective or bail-out implantation of self-expandable bare-metal stents (BMS; Table 1) [9]. This approach is safe and effective, especially at short-term, but is fraught with a substantial risk of restenosis given the often exuberant neointimal hyperplasia which develops inside these metallic prostheses [10,11]. Accordingly, alternative devices include drug-eluting balloons (DEB), self-expandable drug-eluting stents (DES), covered stents, atherectomy, and cryoplasty [12-14]. Each of these devices and techniques is associated with some unique pros and cons, which lead in many cases to tailored and individualized decision making.

In general, however, we can succinctly state that devices or techniques lacking a permanent supportive platform, such as DEB, cryoplasty, atherectomy, and other cutting devices may be associated with less aggressive long-term restenosis but may be fraught with an increased risk of short-term adverse events (including vessel closure), as they do not provide adequate mechanical protection from recoil or dissection [15,16]. Conversely, devices which provide substantial radial support to tackle severe dissections, highly calcific lesions, or prolapsing plaques, may also lead to substantial neointimal hyperplasia. In addition, stiff metallic prostheses may be prone to fracture or get otherwise damaged [10].

While indeed angioplasty was invented and first tested having in mind PAD, it is sobering to recall that the greatest developments of angioplasty have been due to its momentous uptake for percutaneous coronary intervention (PCI). In this sense, we believe that the major successes and developments obtained in coronary stent technology can also now be applied successfully to selected patients with SFA disease.

The case for coronary drug-eluting stents

Coronary DES (almost all balloon-expandable with the notable exception of the Devaxx, Stentys, and Sparrow devices), [17-19] have been remarkably refined since their introduction in mainstream practice in 2002 [20]. Current generation DES are more effective and safer than their bare-metal counterparts, [21,22] they come in ample ranges of sizes, and have been proved beneficial also in non-coronary settings, such as infra-popliteal arteries [23,24]. Accordingly, we have hypothesized that they can also be used safely and effective in selected patients with focal SFA disease.

It is important to envision their use in such fashion for lesions which can be successfully crossed, can be covered by no more two overlapping DES (thus usually <60-65 mm), and in vessels which are no larger than 5.0-5.5 mm. Indeed, even if some undersizing occurs, the typical stent diameters obtained with high (>20 atmospheres) inflations are enough to yield adequate blood flow to the distal limb. Conversely, it is important to avoid ostial or distal SFA disease as these locations may be more prone to stent crush or fracture. Exploiting such pragmatic approach, our own group as well as others has used so far coronary DES in several patients with remarkably favorable outcomes. As these devices are also currently rather cheap, at least in comparison to the other devices and techniques approved for SFA usage, they may appear even more appealing to endovascular specialists.

Of course, it should be clearly borne in mind that no study is yet available in the scholarly literature in favor or against the use of coronary balloon-expandable DES in the SFA. Accordingly, their usage for this indication should be based on sound clinical judgment. However, it is difficult to state clearly when a given scientific or clinical dogma (such the one forbidding the use of balloon-expandable stents in the SFA) can be tentatively challenged, and when an off-label use may become clinically sound [25].

CONCLUSIONS

Despite the plethora of devices and techniques currently available for SFA revascularization, no perfect device exists yet. We hereby make the case that coronary balloon-expandable DES, given their outstanding efficacy and safety profile as far as clinical evidence on coronary artery disease is concerned, could prove similarly useful for selected patients with focal SFA disease. Dedicated studies are eagerly awaited to clarify if it is wise to challenge the dogma that balloon-expandable stents should not be used in the SFA district.

CONFLICTS OF INTEREST

Dr. Giordano has consulted for Medtronic. Dr. Biondi-Zoccai has consulted/lectured for Abbott Vascular, Boston Scientific, and Medtronic.

REFERENCES

1. Norgren L, Hiatt WR, Dormandy JA, Nehler MR, Harris KA, Fowkes FG, et al. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). Eur J Vasc Endovasc Surg. 2007; 33: S1-75.
2. Peruzzi M, Biondi-Zoccai G, Frati G. Commentary: Aortoiliac Arteries: Another Waterloo for Transcatheter vs. Open Surgical Therapy After Aorta, Cardiac Valves, Carotids, Coronaries, Femorals, and Tibials? J Endovasc Ther. 2013; 20: 456-460.
3. Adam DJ, Beard JD, Cleveland T, Bell J, Bradbury AW, Forbes JF, et al. Bypass versus angioplasty in severe ischaemia of the leg (BASIL): multicentre, randomised controlled trial. Lancet. 2005; 366: 1925-1934.
4. Dotter CT, Judkins MP. Transluminal treatment of arteriosclerotic obstruction. Description of a new technic and a preliminary report of its application. Circulation. 1964; 30: 654-70.
5. Sangiorgi G, Lauria G, Airoldi F, Godino C, Politi L, Colombo A, et al. Retrograde popliteal access as bail-out strategy for challenging occlusions of the superficial femoral artery: a multicenter registry. Catheter Cardiovasc Interv. 2012; 79: 1188-1193.
6. Otsuka F, Nakano M, Sakakura K, Ladich E, Kolodgie FD, Virmani R. Unique demands of the femoral anatomy and pathology and the need for unique interventions. J Cardiovasc Surg (Torino). 2013; 54: 191-210.
7. Grüntzig A, Kumpe DA. Technique of percutaneous transluminal angioplasty with the Grüntzig ballon catheter. AJR Am J Roentgenol. 1979; 132: 547-552.
8. Biondi-Zoccai G, Sangiorgi G, Modena MG. Devices for infrainguinal endovascular therapy: menu à la carte or table d'hôte? J Endovasc Ther. 2011; 18: 638-641.
9. Zeller T, Tiefenbacher C, Steinkamp HJ, Langhoff R, Wittenberg G, Schlüter M, et al. Nitinol stent implantation in TASC A and B superficial femoral artery lesions: the Femoral Artery Conformexx Trial (FACT). J Endovasc Ther. 2008; 15: 390-398.
10. Scheinert D, Scheinert S, Sax J, Piorkowski C, Bräunlich S, Ulrich M, et al. Prevalence and clinical impact of stent fractures after femoropopliteal stenting. J Am Coll Cardiol. 2005; 45: 312-315.
11. Chalmers N, Walker PT, Belli AM, Thorpe AP, Sidhu PS, Robinson G, et al. Randomized trial of the SMART stent versus balloon angioplasty in long superficial femoral artery lesions: the SUPER study. Cardiovasc Intervent Radiol. 2013; 36: 353-361.
12. Geraghty PJ, Mewissen MW, Jaff MR, Ansel GM; VIBRANT Investigators. Three-year results of the VIBRANT trial of VIABAHN endoprosthesis versus bare nitinol stent implantation for complex superficial femoral artery occlusive disease. J Vasc Surg. 2013; 58: 386-395.
13. Biondi-Zoccai G, Sangiorgi G, D'Ascenzo F, Zuffi A, Lotrionte M, Romagnoli E, et al. Drug-eluting balloons for peripheral artery disease: A meta-analysis of 7 randomized clinical trials and 643 patients. Int J Cardiol. 2013; 168: 570-1.
14. Dake MD, Scheinert D, Tepe G, Tessarek J, Fanelli F, Bosiers M, et al. Nitinol stents with polymer-free paclitaxel coating for lesions in the superficial femoral and popliteal arteries above the knee: twelve-month safety and effectiveness results from the Zilver PTX single-arm clinical study. J Endovasc Ther. 2011; 18: 613-23.
15. Poncyljusz W, Falkowski A, Safranow K, Rać M, Zawierucha D. Cutting-Balloon Angioplasty Versus Balloon Angioplasty as Treatment for Short Atherosclerotic Lesions in the Superficial Femoral Artery: Randomized Controlled Trial. Cardiovasc Intervent Radiol. 2013.
16. Werk M, Albrecht T, Meyer DR, Ahmed MN, Behne A, Dietz U, et al. Paclitaxel-coated balloons reduce restenosis after femoro-popliteal angioplasty: evidence from the randomized PACIFIER trial. Circ Cardiovasc Interv. 2012; 5: 831-40.
17. Giordano A, Corcione N, Polimeno M, Messina S, Biondi-Zoccai G, Ferraro P. No surprising forward jump when deploying a self-expandable stent: Two cases exploiting the combination of Emboshield Nav6 BareWire and Stentys devices. Int J Cardiol. 2013; .
18. Verheye S, Agostoni P, Dubois CL, Dens J, Ormiston J, Worthley S, et al. 9-month clinical, angiographic, and intravascular ultrasound results of a prospective evaluation of the Axxess self-expanding biolimus A9-eluting stent in coronary bifurcation lesions: the DIVERGE (Drug-Eluting Stent Intervention for Treating Side Branches Effectively) study. J Am Coll Cardiol. 2009; 53: 1031-9.
19. Agostoni P, Verheye S. Step-by-step StentBoost-guided small vessel stenting using the self-expandable Sparrow stent-in-wire. Catheter Cardiovasc Interv. 2009; 73: 78-83.
20. Biondi-Zoccai GG, Agostoni P, Abbate A, Testa L, Burzotta F, Lotrionte M, et al. Adjusted indirect comparison of intracoronary drug-eluting stents: evidence from a metaanalysis of randomized bare-metal-stent-controlled trials. Int J Cardiol. 2005; 100: 119-123.
21. Palmerini T, Biondi-Zoccai G, Della Riva D, Stettler C, Sangiorgi D, D'Ascenzo F, et al. Stent thrombosis with drug-eluting and bare-metal stents: evidence from a comprehensive network meta-analysis. Lancet. 2012; 379: 1393-1402.
22. Palmerini T, Biondi-Zoccai G, Della Riva D, Mariani A, Sabaté M, Valgimigli M, et al. Clinical Outcomes With Drug-Eluting and Bare-Metal Stents in Patients With ST-Segment Elevation Myocardial Infarction: Evidence From a Comprehensive Network Meta-Analysis. J Am Coll Cardiol. 2013; 62: 496-504.
23. Biondi-Zoccai GG, Sangiorgi G, Lotrionte M, Feiring A, Commeau P, Fusaro M, et al. Infragenicular stent implantation for below-the-knee atherosclerotic disease: clinical evidence from an international collaborative meta-analysis on 640 patients. J Endovasc Ther. 2009; 16: 251-60.
24. Feiring AJ, Krahn M, Nelson L, Wesolowski A, Eastwood D, Szabo A. Preventing leg amputations in critical limb ischemia with below-the-knee drug-eluting stents: the PaRADISE (PReventing Amputations using Drug eluting StEnts) trial. J Am Coll Cardiol. 2010; 55: 1580-1589.
25. Ansel GM, Jaff MR. The "art" of medicine and the "smokescreen" of the randomized trial off-label use of vascular devices. Catheter Cardiovasc Interv. 2008; 72: 998-1002.

Cite this article

Giordano A, Biondi-Zoccai G, Giordano G (2013) Coronary Balloon-Expandable Drug-Eluting Stents for Focal Superficial Femoral Artery Disease: When is the Time Ripe for Challenging Conventional Wisdoms? J Transl Med Epidemiol 1: 1003.