Journal of Thrombosis and Circulation Open Access

Editorial OMICS International

DES or BMS: Where do we Stand after NORSTENT

O Hamza[1], O Aitmokhtar[1,2]*, S Benamara[1], A Azaza[1], M Kara[1] and S Benkhedda[1]

[1]University Hospital Mustapha, Algiers, Algeria
[2]Department of Cardiology, Hopital Européen de Marseille, France

Percutaneous coronary intervention (PCI) is one of the most frequently performed procedures worldwide reflecting the burden extent of coronary atherosclerosis disease. These past decades have witness a tremendous evolution in pci techniques from balloon angioplasty alone to newer generation of drug eluting stents.

Bare metal stents (BMS) were a major advance over balloon angioplasty by decreasing acute arterial recoil and reducing target lesion restenosis rates to up to 20%. However BMS came with a new challenge known as intrastentrestenosis [1].

After that Drug eluting stents (DES) were developed in response to the high rates of restenosis and subsequent need for repeat revascularization with BMS. Though early generation DES has shown benefits in term of efficacy, they are associated with delayed vessel healing and late stent thrombosis not present after BMS implantation [2-4]. Therefore DES likely requires a longer dual antiplatelet therapy period.

Lately the second generation of DES came up with improved designs, reduced strut thickness, higher biocompatibility and newer anti-proliferative drug translating in better safety and efficacy compared to the earliest generation or BMS [5,7].

With newer generation DES the necessary dual antiplatelet therapy period was shortened demonstrating not only efficacy over BMS but also safety leaving little room for BMS implantation. In fact many meta-analysis and randomized trials have proven decreased mortality rates in favor of DES. However, there was no head to head comparison between the modern versions of DES and BMS.

That is what motivated the NORSTENT investigators to design the largest randomized trial to compare latest generation DES to modern BMS which results were presented at the latest European Society of Cardiology (ESC) meeting at Rome while simultaneously published at the new England journal of medicine [8].

This Norwegian fully funded by non-for-profit organizations trial enrolled 9013 patients from September 2008 to February 2011 largely included patients with stable coronary disease or acute coronary syndrome and lesions in native coronary arteries or coronary artery grafts. The patients were randomly assigned to second generation DES (82.9% everolimus-eluting stents, 13.1% zotarolimus-eluting stents) or modern BMS.

Unsurprisingly there was a significant difference in target lesion revascularization rates (5.3% *vs.* 10.3%; HR 0.47; 95% CI (0.40-0.56); P<0.001), and any revascularization rates (16.5% *vs.* 19.8%; HR 0.76; 95% CI (0.69-0.85); P<0.001) in favor of DES. As for stent thrombosis the authors report low rates in both groups 0.8% for the DES assigned group and 1.2% for the BMS group and BMS with a p value in the limit of significance (P=0.0498). These results were expected and have been shown in previous randomized trials and meta-analysis.

The particularity of Norstent was that it showed no difference in the primary composite endpoint of all cause death/spontaneous MI after a median follow-up of 5 years which can make one thinks that DES did not do better than BMS. But still DES is doing what they are designed for: reduce the need of revascularization and still be safe in terms of stent thrombosis events. Nor stent is the largest trial to ever compare head to head modern DES and BMS, properly designed and maybe one of the most sensitive points non industry funded. But the chosen primary endpoint of all-cause mortality/spontaneous MI cannot reflect by itself the efficacy of a stent. A device can only prevent device related events and device related-deaths are a very limited proportion of the overall mortality implying the need of an even larger number of patients to be able to demonstrate any significant difference in stent related deaths between the two groups.

Therefor we should be careful in interpreting the NORSTENT results and not quickly jump to the conclusion that DES failed to show mortality benefit over BMS. Contemporary DES are doing what they are supposed to do with a sustaining benefit on the median of 5 yrs follow-up on revascularization and stent thrombosis.

Economic reasons

DES will remain the preferred choice for our daily patients given there proven efficacy and safety and are becoming more attractive with the shorter period of dual antiplatelet therapy but as pointed out by Bates [9], after NORSTENT interventional cardiologists to be more confident in their choices for BMS in selected patients.

References

1. Morice MC, Serruys PW, Sousa JE, Fajadet J, Ban Hayashi E, et al. (2002) A randomized comparison of a sirolimus-eluting stent with a standard stent for coronary revascularization. N Engl J Med 346: 1773-1780.
2. Pfisterer M, Brunner-La Rocca HP, Buser PT, Rickenbacher P, Hunziker P, et al. (2006) Late clinical events after clopidogrel discontinuation may limit the benefit of drug-eluting stents: an observational study of drug-eluting versus bare-metal stents. J Am Coll Cardiol 48: 2584-2591.
3. Camenzind E, Steg PG, Wijns W (2007) Stent thrombosis late after implantation of first-generation drugelutingstents: a cause for concern. Circulation 115: 1440-1455.
4. McFadden EP, Stabile E, Regar E, Cheneau E, Ong AT, et al. (2004) Late thrombosis in drug-elutingcoronary stents after discontinuation of antiplatelet therapy. Lancet 364: 1519-1521.
5. Daemen J, Wenaweser P, Tsuchida K, Abrecht L, Vaina S, et al. (2007) Early and latecoronary stent thrombosis of sirolimus-eluting and paclitaxel-eluting stents in routine clinical practice: data from a large two-institutional cohort study. Lancet 369: 667-678.
6. Valgimigli M, Sabaté M, Kaiser C, Brugaletta S, de la Torre Hernandez JM, et al. (2014) Effects of cobalt-chromium everolimus eluting stents or bare metal

***Corresponding author:** Ait Mokhtar Omar, University hospital Mustapha, Place du 1er Mai Algiers Algeria, Tel: 0021321932323, Fax: 0021321932323; E-mail: aitmokhtar1@yahoo.fr

Received: October 03, 2016; **Accepted:** October 06, 2016; **Published:** October 13, 2016

Citation: O Hamza, O Aitmokhtar, Benamara S, Azaza A, Kara M, et al. (2016) DES or BMS: Where do we Stand after NORSTENT. J Thrombo Cir 2: e104.

stent on fatal and non-fatal cardiovascular events: patient level meta-analysis. BMJ 349: g6427-g6427.

7. Palmerini T, Benedetto U, Biondi-Zoccai G, Riva DD, Bacchi-Reggiani L, et al. (2015) Long-term safety of drug-eluting and bare-metal stents: evidence from a comprehensive network meta-analysis. J Am Coll Cardiol 65: 2496-2507.

8. Bønaa KH, Mannsverk J, Wiseth R, Aaberge L, Myreng Y, et al. (2016) Drug-eluting or bare-metal stents for coronary artery disease. N Engl J Med 375: 1242-1252.

9. Eric RB (2016) Balancing the Evidence Base on Coronary Stents. N Engl J Med 375:1286-1288.