

# The Doctor the Surgeon and the Device Installer: Nor Stent #EscCongress 2016 Rome

## Abstract

**Objectives:** Scientific innovative technology served healthcare providers throughout medical history, monitored and validated by unbiased clinical trials for regulations to avoid harm as well as financial abuse. One of revolutionary recent innovations is the utilization of stents for revascularization in coronary artery disease (CAD). Robust evidence clearly supported the use of drug eluting stent (DES) as per guidelines, however, the NorStent trial demonstrated failure of DES supremacy compared to bare metal stent (BMS) which implicates waste of financial resources due to unjustified high price of DES. The aim of this article is to compare evidence to guidelines in clinical practice.

**Methods:** Analysis of the available current evidence through Google scholarly article search validated by standard reliable medical databases to evaluate the question raised by NorStent trial at ESC congress 2016 stating the lack of robust justification of any difference between drug eluting stent (DES) compared to bare metal stent (BMS) in survival benefits except the marked high price of DES.

**Results:** Please read the article for brief results.

**Conclusion:** In this article, the facts will be presented for readers to reach a verdict on whether doctors are evolving into device installers without obvious justifications of device implantations.

**Keywords:** Cardiology; DES; PCI; Surgeon; BMS; CAD; Patients; Guidelines; Ethics; Device implantations

## Review Article

Volume 4 Issue 3 - 2016

**Mohamed Z Khalil\***

*AirMidVest, British Medical Center, Egypt*

**\*Corresponding author:** Mohamed Z Khalil, Professor of Medicine, AirMidVest, British Medical Center, Cairo, Egypt, Tel: 00201100800262; Email: prof.mzkhalil@gmail.com

**Received:** September 03, 2016 | **Published:** November 18, 2016

**Abbreviations:** CAD: Coronary Artery Disease; DES: Drug Eluting Stent; BMS: Bare Metal Stent; ACS: Acute Coronary Syndromes; MI: Myocardial Infarction

## Introduction

DES are clearly used by most of practicing interventional cardiologists for the management of CAD, particularly, in acute coronary syndromes (ACS) based on current guidelines based on mount evidence of clinical trials comparing different DES to BMS with clear superiority in favor of DES [1-16]. CAD is prevalent worldwide with variable presentations necessitating appropriate management guidelines that supported that superiority is convincing justification of the high price of DES [17-28].

“Stenosis of the coronary arteries may be treated by balloon dilatation followed by the implantation of a metal stent. However, restenosis occurs in 10-20% of patients treated with bare metal stents (BMS). Restenosis and treatment of restenosis is associated with risk of myocardial infarction (MI) and death. Drug eluting stents (DES) release drugs to the vessel wall that delay or inhibit the process of restenosis. Some reports have found that DES is associated with risk of acute stent thrombosis, MI and death. The precise magnitude of this risk is not known. Current evidence is therefore insufficient to balance the long-term risk and benefit of BMS compared to DES in similar set of patients with CAD either stable (elective) or ACS (Acute Coronary Syndrome).”

## Methods

NorStar trial results are compared to previous published evidence supporting the classical first choice of DES in most patients. All-cause mortality and non-fatal spontaneous MI rates were not significantly different between DES and BMS with 6 years follow up. Trial of Drug Eluting Stent Versus Bare Metal Stent to Treat Coronary Artery Stenosis (NORSTENT) This study is ongoing.

## Sponsors

- University of Tromso Collaborators
- The Research Council of Norway
- The Royal Norwegian Ministry of Health
- Norwegian Council on Cardiovascular diseases
- Information provided by (Responsible Party)
- University of Tromso
- ClinicalTrials.gov Identifier: NCT00811772 First received: December 18, 2008
- Purpose: Safety/Efficacy Study Intervention Model: Parallel Assignment

- i. Inclusion Criteria: Men and women >18 years with stable angina pectoris or acute coronary syndrome.
- j. Exclusion Criteria: Previous implantation of a coronary bare metal stent or coronary drug eluting stent, planned intervention of a bifurcation lesion with overlapping 2-stent technique Patient is receiving chronic anticoagulation therapy.

## Results

There were no significant between-group differences in the rates of the individual components of the primary outcome. There were no significant differences between the study groups in the rates of death from cardiac, vascular, or noncardiovascular causes, in the rates of stroke.

## Discussion

The standard evaluation of new therapeutic modality is by refuting the null hypothesis of no difference between the new therapeutic modality compared to other options by controlling the variables in peer reviewed published unbiased clinical trials. This evaluation is performed by the outcomes of: A) Survival benefits, B) Safety profile, C) Efficacy, D) Cost effectiveness.

The variables A & B is similar comparing DES to BMS (Nor Stent trial NEJM), however, the C variable is in favor of DES while the D variable is in favor of BMS.

The point here is that cardiologists have evolved from clinicians into interventionalists in order to maintain the opening of stenosed or occluded coronary artery in patients with CAD or implanting pacemakers in selected patients. In real clinical practice, the initial focus by the doctor is on the patient, nonetheless, PCI is shifting the focus of the treating doctor from the patient to the procedure, similar to a surgeon mastering a procedure, interventionalists on the other hand are different compared to surgeons as the nature of CAD is requiring longitudinal healthcare rather than cross sectional and patient is cured [29-33].

The ugly component of this evolution is the tricky part of choosing certain therapy declined by patient for less convincing option based on financial abilities in both insured as well as self funded patients. Medical education include Ethics, that clearly educate doctors to provide the best slandered of certain therapy, while in our current daily practice cardiologists are left with no choice but to consider cost as a strong variable leading to evolution of "Device installers" that usually take no responsibilities as long as the evidence is grey with multiple appropriate options.

This term of "Device installers" was used by an imminent medical editor at reputable organization indicating another meticulous look of the evidence prior to proceeding with the procedure of installing a therapeutic device.

Finally, #Ethics\_All\_The\_Way is suggested in answering a question choosing between money and ethics, with very rare unusual exceptions, who tend to forget the medical profession oath.

## References

1. Stone GW, Lansky AJ, Pocock SJ, Gersh BJ, Dangas G, et al. (2009) HORIZONS-AMI Trial Investigators. Paclitaxel-eluting stents versus bare-metal stents in acute myocardial infarction. *N Engl J Med* 360(19): 1946-1959.
2. Di Lorenzo E, Sauro R, Varricchio A, Carbone G, Cortese G, et al. (2009) Long-Term outcome of drug-eluting stents compared with bare metal stents in ST-segment elevation myocardial infarction: results of the paclitaxel- or sirolimus-eluting stent versus bare metal stent in Primary Angioplasty (PASEO) Randomized Trial. *Circulation* 120(11): 964-972.
3. Hillegass WB (2016) End of the bare metal stent era? *Catheter Cardiovasc Interv* 88(1): 49-50.
4. Palmerini T, Benedetto U, Biondi-Zoccai G, Della Riva D, 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(23): 2496-507.
5. Olafiranye O, Vlachos H, Mulukutla SR, Marroquin OC, Selzer F, et al. (2015) Comparison of long-term safety and efficacy outcomes after drug-eluting and bare-metal stent use across racial groups: Insights from NHLBI Dynamic Registry. *Int J Cardiol* 184: 79-85.
6. Kereiakes DJ, Cannon LA, Dauber I, Ball M, Bertolet B, et al. (2015) Long-term follow-up of the platinumchromium TAXUS Element (ION) stent: The PERSEUS Workhorse and Small Vessel trial five-year results. *Catheter Cardiovasc Interv* 86(6): 994-1001.
7. Chan CY, Vlachos H, Selzer F, Mulukutla SR, Marroquin OC, et al. (2014) Comparison of drug-eluting and bare metal stents in large coronary arteries: findings from the NHLBI dynamic registry. *Catheter Cardiovasc Interv* 84(1): 24-29.
8. de Belder A, de la Torre Hernandez JM, Lopez-Palop R, O'Kane P, Hernandez F, et al. (2013) A prospective randomized trial of everolimus-eluting stents versus bare-metal stents in octogenarians: the XIMA Trial (Xience or Vision Stents for the Management of Angina in the Elderly). *J Am Coll Cardiol* 63(14): 1371-1375.
9. Valgimigli M, Patialiakas A, Thury A, Colangelo S, Campo G, et al. (2013) Randomized comparison of Zotarolimus-Eluting Endeavor Sprint versus bare-metal stent implantation in uncertain drug-eluting stent candidates: rationale, design, and characterization of the patient population for the Zotarolimus-eluting Endeavor Sprint stent in uncertain DES candidates study. *Am Heart J* 166(5): 831-838.
10. Kubo S, Kadota K, Shimada T, Ozaki M, Ichinohe T, et al. (2013) Seven-year clinical outcomes of unprotected left main coronary artery stenting with drug-eluting stent and bare-metal stent. *Circ J* 77(10): 2497-504.
11. De Felice F, Fiorilli R, Parma A, Musto C, Nazzaro MS, et al. (2012) Five-year outcomes in patients with chronic total coronary occlusion treated with drug-eluting vs bare-metal stents: a case-control study. *Can J Cardiol* 29(8): 945-950.
12. Geng DF, Meng Z, Yan HY, Nie RQ, Deng J, et al. (2013) Bare-metal stent versus drug-eluting stent in large coronary arteries: meta-analysis of randomized controlled trials. *Catheter Cardiovasc Interv* 81(7): 1087-1094.
13. Stella PR, Belkacemi A, Dubois C, Nathoe H, Dens J, et al. (2012) A multicenter randomized comparison of drug-eluting balloon plus

- bare-metal stent versus bare-metal stent versus drug-eluting stent in bifurcation lesions treated with a single-stenting technique: six-month angiographic and 12-month clinical results of the drug-eluting balloon in bifurcations trial. *Catheter Cardiovasc Interv* 80(7): 1138-1146.
14. Räber L, Kelbaek H, Ostojic M, Baumbach A, Tüller D, et al. (2012) Comparison of biolimus eluted from an erodible stent coating with bare metal stents in acute ST-elevation myocardial infarction (COMFORTABLE AMI trial): rationale and design. *EuroIntervention* 7(12): 1435-1443.
  15. Vogt A, Schoelmerich A, Pollner F, Schlitt M, Raaz U, et al. (2011) Comparison of outcome in 1809 patients treated with drug-eluting stents or bare-metal stents in a real-world setting. *Vasc Health Risk Manag* 7: 693-699.
  16. Puymirat E, Mangiacapra F, Peace A, Sharif F, Conte M, et al. (2011) Long-term clinical outcome in patients with small vessel disease treated with drug-eluting versus bare-metal stenting. *Am Heart J* 162(5): 907-913.
  17. Dake MD, Ansel GM, Jaff MR, Ohki T, Saxon RR, et al. (2011) Paclitaxel-eluting stents show superiority to balloon angioplasty and bare metal stents in femoropopliteal disease: twelve-month Zilver PTX randomized study results. *Circ Cardiovasc Interv* 4(5): 495-504.
  18. Siontis GCM, Piccolo R, Praz F, Valgimigli M, Räber L, et al. (2016) Percutaneous Coronary Interventions for the Treatment of Stenoses in Small Coronary Arteries: A Network Meta-Analysis. *JACC Cardiovasc Interv* 9(13): 1324-1334.
  19. Meraj PM, Jauhar R, Singh A (2015) Bare Metal Stents Versus Drug Eluting Stents: Where Do We Stand in 2015? *Curr Treat Options Cardiovasc Med* 17(8): 393.
  20. Nakazato K, Mizukami H, Ohtake H, Sakamoto N, Yamaki T, et al. (2015) Stenting Strategy And Follow-Up Results Of Multi-Center Registry In Fukushima City For Left Main Coronary Artery Disease: Bare Metal Stent Versus Drug-Eluting Stent. *Fukushima J Med Sci* 61(1): 79-85.
  21. Nojima Y, Yasuoka Y, Kume K, Adachi H, Hattori S, et al. (2014) Switching types of drug-eluting stents does not prevent repeated in-stent restenosis in patients with coronary drug-eluting stent restenosis. *Coron Artery Dis* 25(8): 638-644.
  22. Santos R, Pereira H (2005) Economic evaluation of drug-eluting stents in coronary angioplasty. *Rev Port Cardiol* 24(11): 1409-1418.
  23. Al-Nozha MM, Arafah MR, Al-Mazrou YY, Al-Maatouq MA, Khan NB, et al. (2004) Coronary artery disease in Saudi Arabia. *Saudi Med J* 25(9): 1165-1171.
  24. Khalil MZ, Al Nozha MM (2012) Appropriate Management of Coronary Artery Disease. *Adv Pharmacoeconom Drug Safety* 1:122.
  25. Groeneveld PW, Suh JJ, Matta MA (2007) The costs and quality-of-life outcomes of drug-eluting coronary stents: a systematic review. *J Interv Cardiol* 20(1): 1-9.
  26. Tamburino C, Barbagallo R, Capodanno D, di Matteo S, Colombo GL, et al. (2009) Cost-effectiveness of the real-world use of drug-eluting stents at 9-month follow-up: results from the Sicilian DES Registry. *J Cardiovasc Med (Hagerstown)* 10(4): 322-329.
  27. Neyt M, Van Brabant H, Devriese S, De Laet C (2009) Cost-effectiveness analyses of drug eluting stents versus bare metal stents: a systematic review of the literature. *Health Policy* 91(2): 107-120.
  28. Brophy JM, Erickson LJ (2005) Cost-effectiveness of drug-eluting coronary stents in Quebec, Canada. *Int J Technol Assess Health Care* 21(3): 326-333.
  29. Rinfret S, Cohen DJ, Tahami Monfared AA, Leloir J, Mireault J, (2006) Cost effectiveness of the sirolimus-eluting stent in high-risk patients in Canada: an analysis from the C-SIRIUS trial. *Am J Cardiovasc Drugs* 6(3): 159-168.
  30. Polanczyk CA, Wainstein MV, Ribeiro JP (2007) Cost-effectiveness of sirolimus-eluting stents in percutaneous coronary interventions in Brazil. *Arq Bras Cardiol* 88(4): 464-474.
  31. Romano M, Buffoli F, Tomasi L, Corrado L, Ferrari MR, et al. (2008) Safety and effectiveness of drug eluting stent in patients with ST elevation myocardial infarction undergoing primary angioplasty. *Catheter Cardiovasc Interv* 71(6): 759-763.
  32. Goeree R, Bowen JM, Blackhouse G, Lazzam C, Cohen E, et al. (2009) Economic evaluation of drug-eluting stents compared to bare metal stents using a large prospective study in Ontario. *Int J Technol Assess Health Care* 25(2): 196-207.
  33. Kong DF, Eisenstein EL (2005) Decision models for assessing the cost effectiveness of drug-eluting stents. *Expert Opin Pharmacother* 6(6): 965-974.