

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

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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.

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- ClinicalTrials.gov Identifier:** NCT00811772 First received: December 18, 2008
- Purpose:** Safety/Efficacy Study Intervention Model: Parallel Assignment
- Inclusion Criteria:** Men and women >18 years with stable angina pectoris or acute coronary syndrome.
- 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.

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Conflicts of interest

Author declares there are no conflicts of interest.

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