In-hospital and Intermediate Term Prognosis of High-Nickel Content Cobalt Chromium Alloy Stents versus Low-Nickel Content Cobalt Chromium Alloy Stents In Diabetic Patients

Thesis

Submitted for partial fulfillment
of master degree in cardiology

By

Ahmad Mohamad Abdulradi

M.B.B.CH

Supervised by

Doctor\ Ahmed Ahmed Khashaba

Assistant Professor of cardiology
Ain shams university

Doctor\ Mazen Tawfik Ibrahim

Lecturer of cardiology
Ain shams university

Ain Shams University
Faculty of Medicine
Cardiology Department
2010

Contents

List of Tables

List of Figures

List of Abbreviations

ACS	Acute Coronary Syndrome
AGE	Advanced Glycation End Products
ARTS	Arterial Revascularization Therapy Study
ASTM	American Society For Testing And Materials
BMS	Bare Metal Stent
BP	Blood Pressure
C	Carbon
CABG	Coronary Artery Bypass Grafting
CAD	Coronary Artery Disease
CC	Cobalt Chromium
CCS	Cobalt-Chromium Stents
CDC	Centers for Disease Control
CKD	Chronic Kidney Disease
Co	Cobalt
Cr	Chromium
CR-ISR	Chronic Resistant In-Stent Restenosis
DES	Drug-Eluting Stent
DM	Diabetes Mellitus
ECG	Electrocardiography
EES	Everolimus-Eluting Stent
EF	Ejection Fraction
FDA	Food And Drug Administration
Fe	Iron
GP IIb/IIIa	Glycoprotein IIb/IIIa
HbA1c	Glycosylated Hemoglobin

HR	Heart Rate
IDDM	Insulin-Dependent Diabetes Mellitus
ISAR-Diabetes	Paclitaxel-Eluting Stent or Sirolimus-Eluting Stent for the Prevention of Restenosis in Diabetic Patients
ISAR-REACT	Intracoronary Stenting and Antithrombotic Regimen - Rapid Early Action for Coronary Treatment
ISAR-STEREO	Intracoronary Stenting and Angiographic Results - Strut Thickness Effect on Restenosis Outcome
ISAR-SWEET	Intracoronary Stenting and Antithrombotic Regimen: Is Abciximab a Superior Way to Eliminate Elevated Thrombotic Risk in Diabetics
ISR	In-Stent Restenosis
LAD	Left Anterior Descending Coronary Artery
LCX	Left Circumflex Coronary Artery
LM	Left Main Coronary Artery
LV	Left Ventricle
MACE	Major Adverse Cardiac Events
MAPK	Mitogen Activated Protein Kinase
MI	Myocardial Infarction
Mn	Manganese
MRI	Magnetic Resonance Imaging
Ni	Nickel
NIDDM	Non Insulin-Dependent Diabetes Mellitus

OM	Obtuse Marginal
PCI	Percutaneous Coronary Intervention
PDA	Posterior Descending Artery
PES	Paclitaxel-Eluting Stent
PI3	Phosphatidylinositol 3 Kinase
PKC	Protein Kinase C
PTCA	Percutaneous Transluminal Coronary Angioplasty
PTFE	Poly-tetra-fluoro-ethylene
RCA	Right Coronary Artery
RVD	Reference Vessel Diameter
SCORPIUS	CYPHER Sirolimus-Eluting Stent in the Treatment of Diabetic Patients with De Novo Native Coronary Artery Lesions
SES	Sirolimus-Eluting Stent
Si	Silicon
SIRIUS	Sirolimus-Eluting Stent in De-Novo Native Coronary Lesions
SIRTAX	Sirolimus-Eluting Stent Compared With Paclitaxel-Eluting Stent For Coronary Revascularization
SMC	Smooth Muscle Cell
SPIRIT FIRST	XIENCE V® Everolimus Eluting Coronary Stent System in the Treatment of Patients With de Novo Native Coronary Artery Lesions
SS	Stainless Steel
SSS	Stainless Steel Stents

Ta	Tantalum
TAXUS	Paclitaxel-eluting coronary stents in patients with diabetes mellitus
Ti	Titanium
TLR	Target Lesion Revascularization
TVR	Target Vessel Revascularization
VCAM-1	Vascular Cell Adhesion Molecule 1

Acknowledgment

It is a great thing to feel success and have the pride of achieving all what is always aspired. Nevertheless, one must not forget all those who usually help and push him onto the most righteous way that inevitably ends with fulfillment and perfection.

I mention ***Prof. Dr. Ahmad Khashaba***, Assistant Professor of Cardiology, Ain Shams University, the person who gave me the honor to be his student. He really helped me by his precious opinions and contributive comments that served much in the construction of this work.

Great thanks are also due to ***Dr. Mazen Tawfik***, Lecturer of Cardiology, Ain Shams University. He was always there to care, support, encourage and provide constructive pieces of advice in every possible way.

I would also like to record endless and forever love to my family whom I'm honored to belong to, my wife who aided me a lot, and my little son whose smile was inspiring.

Introduction

Coronary stents were developed in the late 1980s to improve on the limitations associated with balloon angioplasty. They scaffold arterial dissection flaps, thereby lowering the incidence of vessel closure and need for emergency CABG surgery. They also prevent arterial constriction, thus lessening the frequency of restenosis.

The most widely used metal in balloon-expandable stents is 316L stainless steel. Stainless steel is predominately composed of iron, which is biologically inert but also contains approximately 5% nickel, allergy to which may be linked to an increased risk of in-stent restenosis ***(Koster et al., 2000)*** which ranged from 16% to 32% ***(Kastrati et al., 2000)***. Efforts to reduce restenosis included coating of conventional stents and use of alternative materials (e.g., cobalt chromium or layered metals) and design.

Recently, cobalt-chromium (Co-Cr) alloys have been increasingly introduced into clinical practice (Guidant Multi-Link Vision™/Guidant Corporation, Driver-Stent™/Medtronic). Due to favorable mechanical properties, the use of Co-Cr alloys allows reduction of stent strut thickness without affecting radial strength or radio-opacity ***(Kastrati et al., 2003; Sketch et al., 2005)***. Reduced strut thickness increased their flexibility, and consequently facilitated stent implantation into tortuous vascular segments or severe obstructive lesions. It may also be of importance in lowering the risk of restenosis ***(Pache et al., 2003)***.

Nickel content in most currently available Co-Cr stents is 9-11%, but it increases in some brands (Driver-Stent™/Medtronic) to reach 35%. Effect of this variation on clinical and angiographic outcome is the aim of this study.

Diabetes mellitus (especially insulin-requiring diabetes) is unequivocally associated with increased clinical and angiographic restenosis rates after bare metal stent implantation ***(Cutlip et al., 2002)***. This is related to smaller vessel size, greater negative remodeling, and increased neointimal hyperplasia in diabetic compared with nondiabetic vessels ***(Kornowski et al., 1997)***.

In particular, diabetics are prone to a diffuse and rapidly progressive form of atherosclerosis highly implying the need for revascularization ***(Goraya et al., 2002)***. Over the last 3 decades, coronary stenting has improved clinical outcome compared with balloon angioplasty, namely decreasing acute complications and restenosis rate.

Aim of the Work

The Aim of this work was to determine in-hospital and intermediate term prognosis of high-nickel content cobalt-chromium alloy stents versus low-nickel content cobalt chromium stents in diabetic patients.