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

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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

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INTRODUCTION

oronary 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 instent 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

he 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.