Comparison between Drug Eluting Balloons (DEB) and Drug Eluting Stents (DES) in the treatment of de novo coronary lesions

Thesis

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وأنزل الله عليك
الكتاب والحكمة
وعَلَّمَكَ مَا لَمْ تَكُن
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عَلَيْكَ عَظِيماً

صدق الله العظيم

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List of Abbreviations

Abbrev.	Full term
BMS	: Bare matal stent
BVS	: Bioabsorbable drug eluting vascular scaffolds
CoCr	: Cobalt chromium
CT	: Computed tomography
DAT	: Dual anti-platelet therapy
DCB	: Drug coated ballon
DEB	: Drug eluting ballon
DES	: Drug eluting stent
DP	: Durable polymer
EES	: Everolimus-eluting stents
ISR	: In-stent restenosis
IVUS	: Intravascular ultrasound
LAD	: Left anterior desending artery
LCX	: Left circumflex artery
LLL	: Late lumen loss
MACE	: Major adverse cardiac events
mCi	: Millicurie
MI	: Myocardial infarction
MPI	: Myocardial perfusion imaging
MRI	: Magnetic resonance imaging
PCI	: Percutaneous coronary intervention
PES	: Paclitaxel-eluting stent

PLA : Poly lactic acid

PLLA : Poly levo lactic acid

PTCA : Percutaneous transluminal coronary angioplasty

PtCr : Platinium chromium

RCA : Right coronary artery

SES : Serolimus-eluting stents

SPECT : Single photon emission computed tomography.

ST : Stent thrombosis

Tc-99m : Technetium 99m

Ti-201 : Thallium 201

TLR : Target lesion revascularisation

TVR : Target vessel revascularization

VBT : Vascular brachytherapy

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ABSTRACT

TITLE:

Comparison between drug eluting balloons and drug eluting stents in the treatment of de novo coronary lesions.

OBJECTIVES:

This Study sought to compare the effectivness of local drug delivery with DEB (PTCA only) against PCI with DES in de novo coronary lesions.

BACKGROUND:

The frequency of restenosis after PCI and need for repeat revascularization have been reduced with advent of drug eluting stents (DES).

The major disadvantage of DES is the need for longer term dual anti platelet therapy of usually 12 months duration compared to only one month of bare metal stent (BMS), also DES come with worrying risk of stent thrombosis, due to this limitation there is a proportion of about 20 to 30 % of patient where BMS are preferred .

It would be optimal if PCI could be performed without leaving behind a permanent device, one option is the use of bioabsorbable scaffolds, another alternative includes the use of drug elluting balloon (DEB).

DEB has been of proven benefit for the treatment of in-stent restenosis in several small randomized trials. However, the use of DEB in the setting of de novo coronary lesions has only been addressed in few small-randomized trials with limited power for clinical endpoints.

METHODS:

50 patients were randomized to either PTCA (DEB) group 1 or PCI (DES) group 2 with follow up after three months clinically and by myocardial perfusion imaging.

RESULTS:

Angiographic and clinical success was high (>88%) in both two groups.

CONCLUSION:

Current work suggests DEB efficacy and safety in coronary de novo lesions but does not support superiority or even equivalence to the best in class DES.

Key Words :

Drug eluting balloons

Drug eluting stents

Introduction

Percutaneous coronary intervention (PCI) has seen a tremendous increase and tends to be the most frequently used method for myocardial Revascularization.

An impressive array of stent improvements, newer drug regimens and technological advances have emerged and broadened the therapeutic spectrum for interventional cardiologists worldwide.

The recurrence of luminal narrowing due to recoil, arterial vessel remodeling and intimal hyperplasia induced by artery injury and disease progression, has compromised the results of balloon angioplasty.

The use of stents during PCI achieved both a significant decrease in the Incidence of acute complications and an improvement in patients' outcomes ***(Mack et al., 2004).***

An elevated risk of thrombosis is present both shortly after percutaneous coronary intervention (PCI) and during the period when stent struts are exposed to the circulation, prior to re-endothelialization.

With the use of BMS, re-endothelialization occurs at one month after stent implantation. Due to the risk of stent

thrombosis with DES and BMS, all patients are prescribed with antiplatelet therapy to prevent clot formation.

The current guidelines mandate dual antiplatelet therapy (DAT) with aspirin and clopidogrel for at least 12 months after DES percutaneous coronary intervention, and it is sometimes continued as long as possible.

Aspirin is often continued through the patient's lifetime. The drugs in DES—sirolimus and paclitaxel—reduce the risk of restenosis by inhibiting the proliferation of endothelial cells. However, this inhibition of normal healing is associated with vessel-wall remodeling and sustained exposure of stent struts to the bloodstream for months or years after implantation, leading to late stent thrombosis three to five years after stent implantation.

Preliminary results show that the reduction of dual antiplatelet therapy back to bare metal stent protocol of three months appears safe.

Thus, in elderly patients and pregnant women patients with a high risk of bleeding, DEBs are likely to become the preferred therapy as they require a shorter antiplatelet therapy, in contrast to the 12 months needed for DES.

The shorter dual antiplatet therapy regimen that may be required by drug eluting balloons is expected to drive its adoption in the future.