

**BIOABSORBABLE POLYMER-BASED  
PACLITAXEL-ELUTING INFINNIUM STENT FOR  
MULTIVESSEL CORONARY ARTERY DISEASE :  
ONE YEAR FOLLOW-UP RESULTS OF  
SIMPLE 3 REGISTRY**



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# THREE COMPONENT SYSTEM

## Stent Design

(Matrix<sup>™</sup>)

**Pharmacologic Agent**

**Paclitaxel**

**Drug-Eluting Stent**

**Drug Carrier Vehicle**

**Biodegradable Polymer**

# INFINNIIUM STENT : CLINICAL TRIALS

STENT	CLINICAL TRIAL	NO. OF PATIENTS	ENROLLMENT AND STATUS
Infinnium Paclitaxel-Eluting Stent (3.0 µg/mm <sup>2</sup> )	<b>SIMPLE I</b> In Real World Lesions	282	<ul style="list-style-type: none"> <li>● Completed</li> <li>● Three Years FU Available</li> </ul>
Infinnium Paclitaxel-Eluting Stent (1.4 µg/mm <sup>2</sup> )	<b>SIMPLE II</b> Single de Novo Focal Lesions	103	<ul style="list-style-type: none"> <li>● Completed</li> <li>● 9 Month Results Published</li> </ul>
Infinnium Paclitaxel-Eluting Stent (1.4 µg/mm <sup>2</sup> )	<b>SIMPLE III</b> Multivessel Disease with MV Stenting	123	<ul style="list-style-type: none"> <li>● Completed</li> <li>● One Year FU Results Being Presented</li> </ul>

# THE INFINNIIUM PACLITAXEL-ELUTING CORONARY STENT

## Cumulative Paclitaxel Release 1.4 $\mu\text{g}/\text{mm}^2$



## OBJECTIVES

To Assess the **Safety and Efficacy** of **Bioabsorbable Polymer-Based** Paclitaxel-Eluting **INFINNIUM** Stent in “**Real World Lesions**” in Patients with **Multivessel Coronary Artery Disease** Requiring **Multivessel Stenting**

- **Safety** : MACE at One Month  
: Acute / Subacute / Late Stent Thrombosis
- **Efficacy** : MACE at 6 Months and One year  
: Need for TLR – Re PTCA / CABG

## STUDY DESIGN

- Included All Consecutive Patients of **Multivessel CAD** Between Nov. 2003 to June 2005, Requiring Treatment by **Multivessel Stenting**
- Single Centre, Prospective Observational Registry with Clinical Follow-up at One, Six and 12 Months

# **INFINNIIUM FOR MULTIVESSEL STENTING IN CAD PATIENTS**

- **Number of Patients** : 123
- **Period** : Nov. '03 - June '05
- **Age Range** : 31-73  
**(Yrs.) Mean** : 54±13
- **Sex**
  - Males** : 101 (82.1%)
  - Females** : 22 (17.9%)

# INFINNIIUM FOR MULTIVESSEL STENTING IN CAD

## CLINICAL PROFILE : INDICATIONS

	<b>N = 123</b>	<b>%</b>
● <b>ACS / Unstable Angina</b>	<b>48</b>	<b>39.0</b>
● Ch. Stable Angina	<b>24</b>	<b>19.5</b>
● Post-MI Angina	<b>20</b>	<b>16.3</b>
● Asymptomatic, Positive Stress Test After MI	<b>19</b>	<b>15.4</b>
● <b>Acute MI</b>	<b>10</b>	<b>8.1</b>
● Acute LVF	<b>2</b>	<b>1.6</b>



# INFINNUM FOR MULTIVESSEL STENTING IN CAD

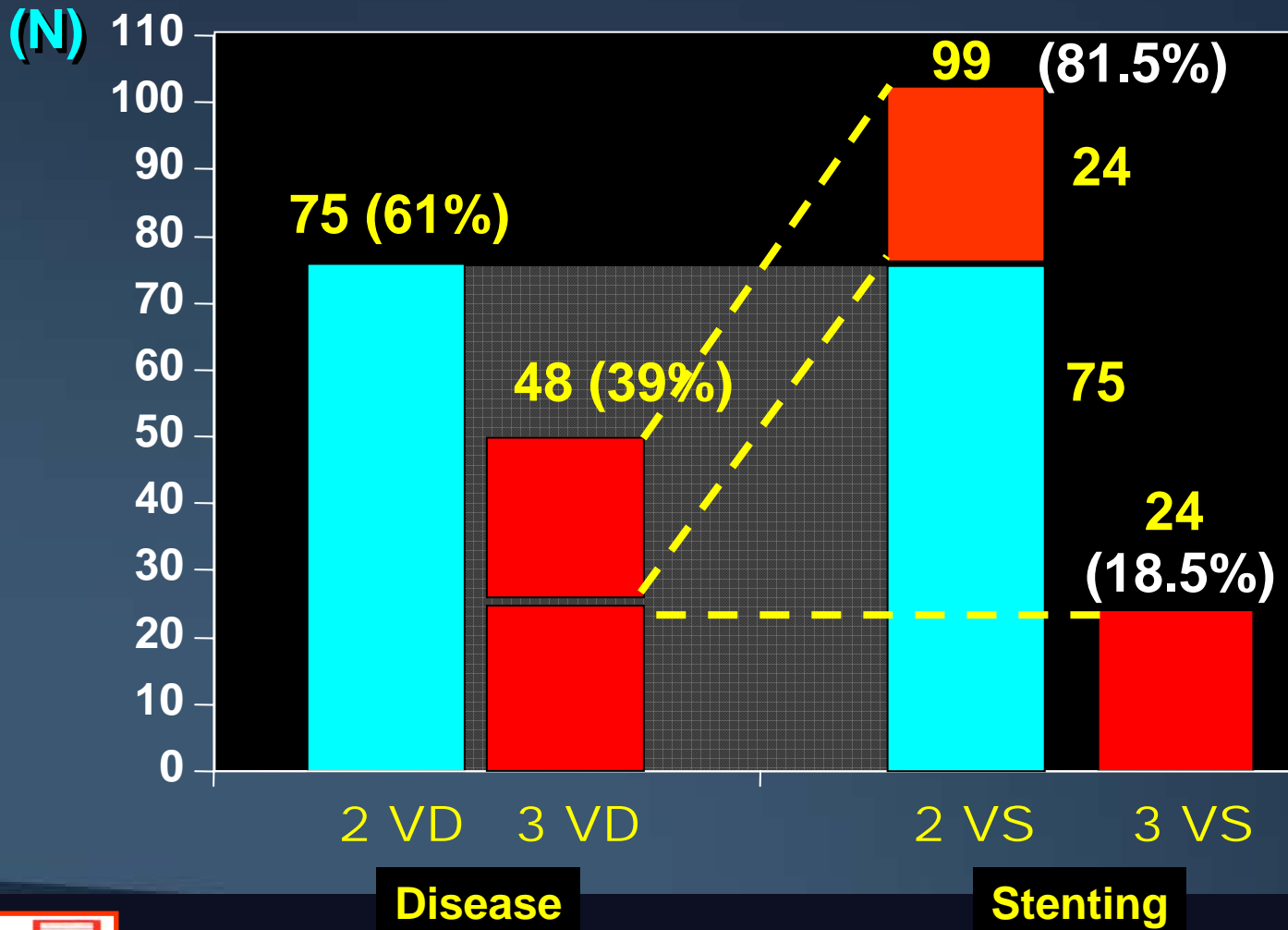
## RISK FACTOR PROFILE

- Hypertension : 69 (56.1%)
- Diabetes : 41 (33.3%)
- Smoking : 16 (13%)
- Dyslipidemia : 12 (9.7%)
- Family H/O CAD : 11 (8.9%)

## **INFINNIUM FOR MULTIVESSEL STENTING IN CAD STRATEGY FOR DES SELECTION**

- All Patients Informed of the Need and Significance of Using DES
- Written Consent Obtained Prior to Procedure
- Following Strategies / Options Used for Deployment of DES
  - **Option I** : Infinnium Stent for All Target Lesions
  - **Option II** : Infinnium Stent in Combination with other DES :
    - Cypher
    - Supralimus
- Choice of Non-Infinnium DES Influenced by Patient Preference and Availability of a Particular Size

**ANGIOGRAPHIC PROFILE VS NUMBER OF VESSELS STENTED**



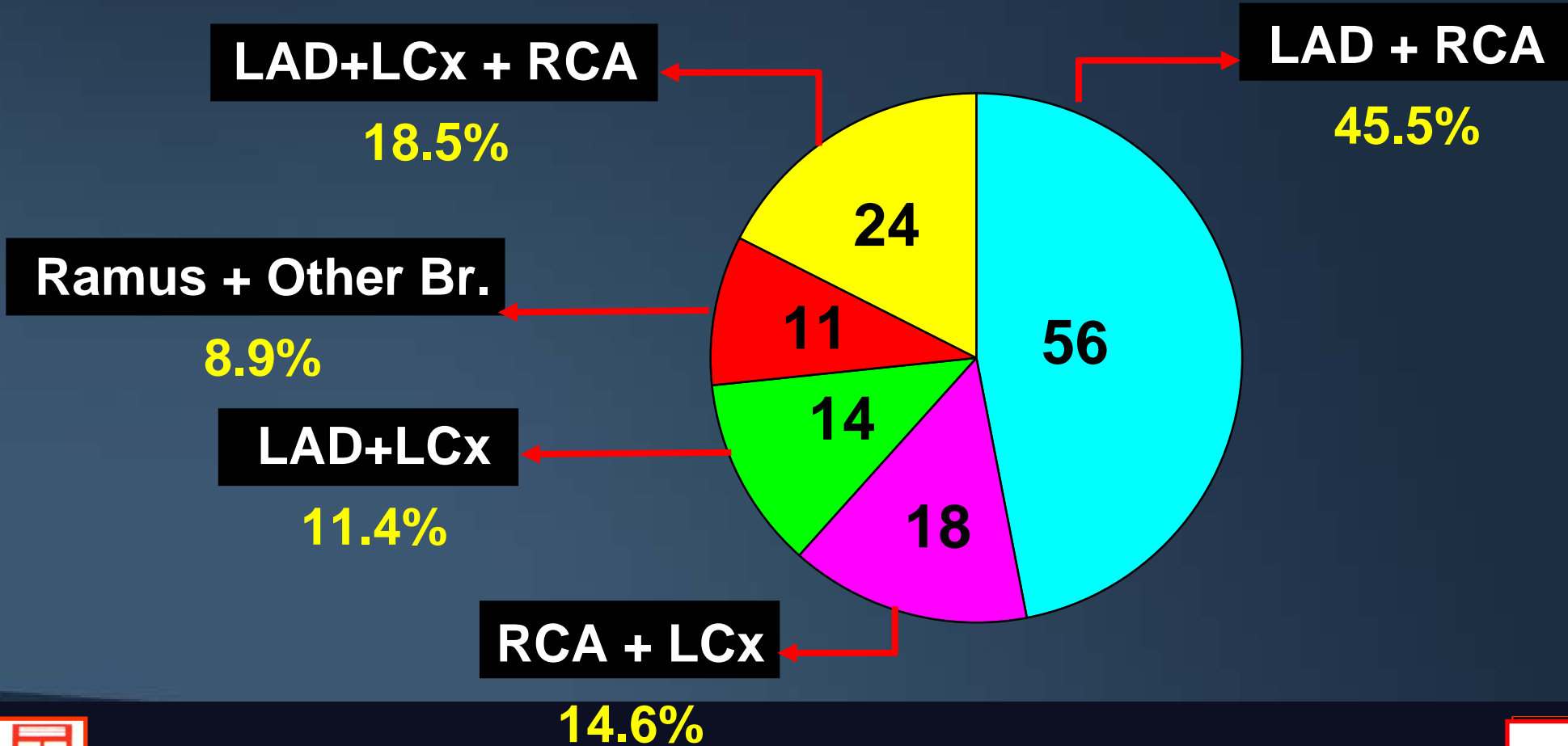
**Vessel Disease**

- 2-VD : 75 (61%)
- 3-VD : 48 (39%)

**Vessel Stented**

- 2-Vs Stenting  
 N = 99 (81.5%)
- 3-Vs Stenting  
 N = 24 (18.5%)

**TARGET VESSELS STENTED**

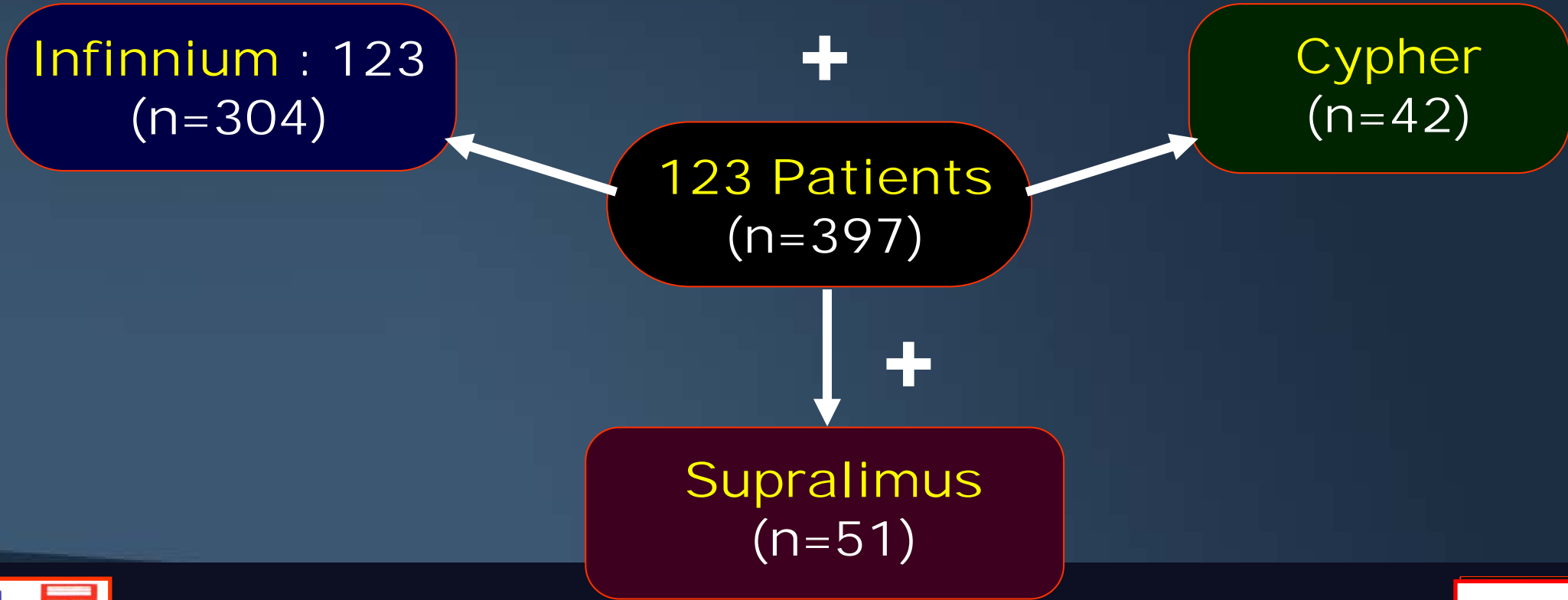


## **INFINNIUM FOR MULTIVESSEL STENTING IN CAD**

- **Number of Lesions Stented** : 381
- **Morphological Type of Lesions**
  - **Type A** : 79 (20.7%)
  - **Type B<sub>2</sub>** : 205 (53.8%)
  - **Type C** : 97 (25.5%)

# INFINNIIUM FOR MV STENTING IN CAD

## USE OF OTHER DES



## **INFINNIUM FOR MV STENTING IN CAD** **STENT DETAILS**

- **Number of Patients** : **123**
- **Number of Vessels Stented** : **272**
- **Number of DES Deployed** : **397**
- **Stents Deployed per Patient** : **3.22**
- **Stents Deployed per Vessel** : **1.46**

## **INFINNIUM FOR MV STENTING IN CAD**

### **STENT CHARACTERISTICS**

- **Stent Length (mm)**
  - Range : 11-39
- **Stent Diameter (mm)**
  - Range : 2.5 - 3.5
- **Length of Stented Segment (mm) in the Target Vessels**
  - Range : 16-110
  - Mean :  $31.5 \pm 16$



## **INFINNIIUM FOR MV STENTING IN CAD**

### **PROCEDURAL RESULTS**

- **Number of Target Vessels** : 272
- **Successful Deployment of Stent in the Target Vessel** : 270 (99.2%)
- **Angiographic Success** : 269 (98.9%)
- **Clinical Success** : 121 (98.4%)

## **INFINNium FOR MV STENTING IN CAD MACE AT 30 DAYS**

- **Death** : 3 (2.4%)
- **MI** : 2 (1.62%)
- **CABG** : 0 (0.0)
- **Reintervention** : 0 (0.0)
- **Angiographic Subacute Stent Thrombosis** : 1 (0.8%)
- **CVA** : 1 (0.8%)
- **Overall MACE** : 4 (3.25%)

## **INFINNIIUM FOR MV STENTING IN CAD**

### **MACE AT 6 MONTHS FOLLOW-UP**

- **Death** : 5 (4.1%)
  - **Cardiac** : 4
  - **Non-Cardiac** : 1
- **MI** : 3 (2.4%)
- **TLR / TVR** : 3 (2.4%)
- **CABG** : 1 (0.8%)
- **Late Stent Thrombosis** : 0
- **Overall MACE** : 10 (8.1%)

**Event-Free Survival at 6 Months = 92%**

## **INFINNIIUM FOR MV STENTING IN CAD**

### **MACE AT ONE YEAR FOLLOW-UP**

- **Death** : 7 (5.7%)
  - **Cardiac** : 6 (4.9%)
  - **Non-Cardiac** : 1
- **MI** : 3 (2.4%)
- **TLR / TVR** : 3 (2.4%)
- **CABG** : 2 (1.6%)
- **Overall MACE** : 12 (9.7%)

**Event-Free Survival at One Year = 90.2%**

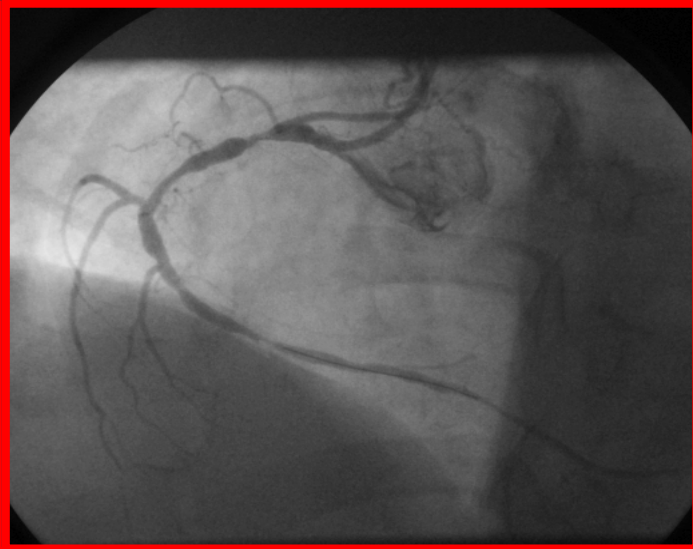
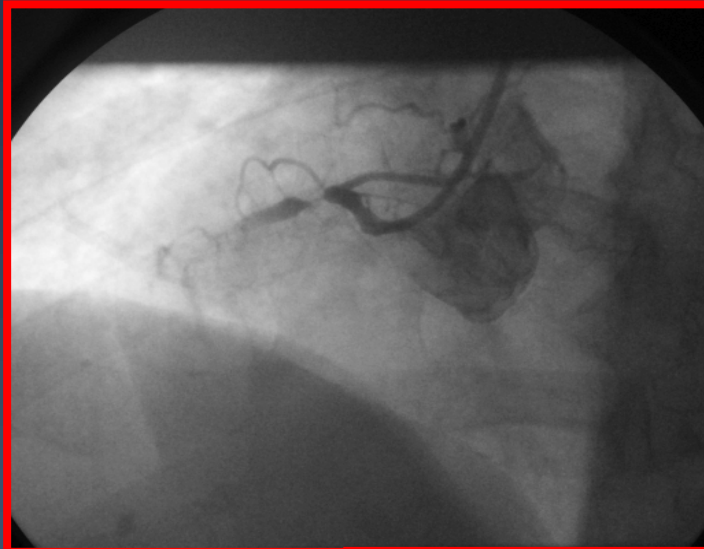
# INFINNium FOR MV STENTING IN CAD

## QCA DATA

- **Reference Vessel Diameter (mm)**
  - Pre :  $2.87 \pm 0.46$
  - Post :  $3.01 \pm 0.27$
- **Diameter Stenosis (%)**
  - Pre :  $76.78 \pm 15.29$
  - Post :  $2.42 \pm 3.13$
- **Minimum Lumen Diameter (MLD) (mm)**
  - Pre :  $0.72 \pm 0.38$
  - Post :  $2.95 \pm 0.51$
- **Length of Lesion (mm)**
  - Range : 11-32
  - Mean :  $24 \pm 13$

# INFINNIIUM FOR THREE VESSEL STENTING

Pre



Pre

**RCA - CTO**  
**WITH**  
**DIFFUSE**  
**DISTAL**  
**DISEASE**



Post

ZA

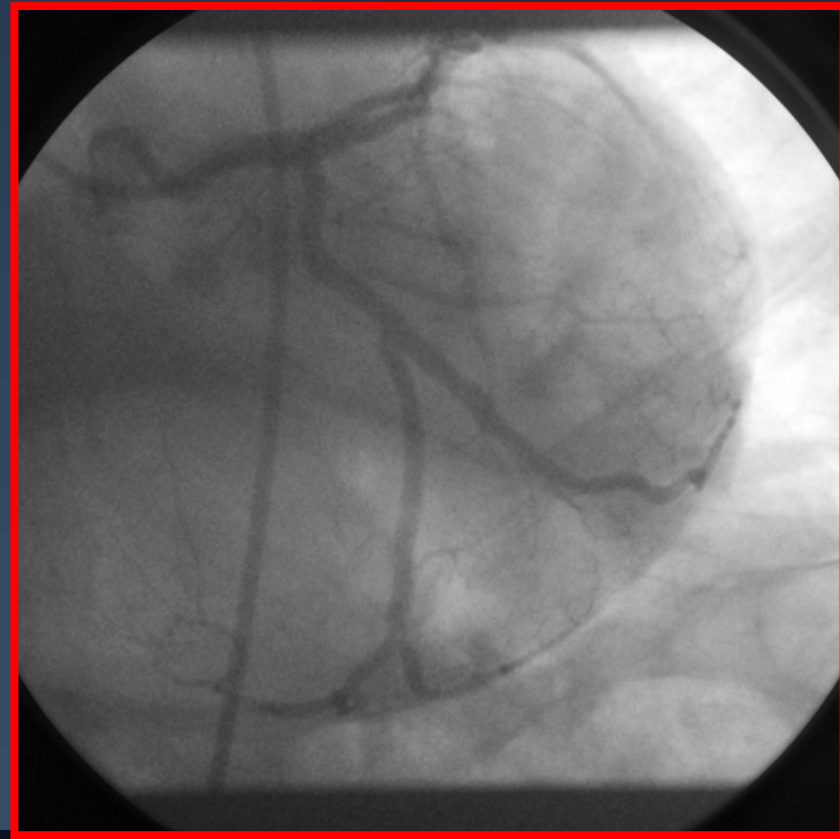
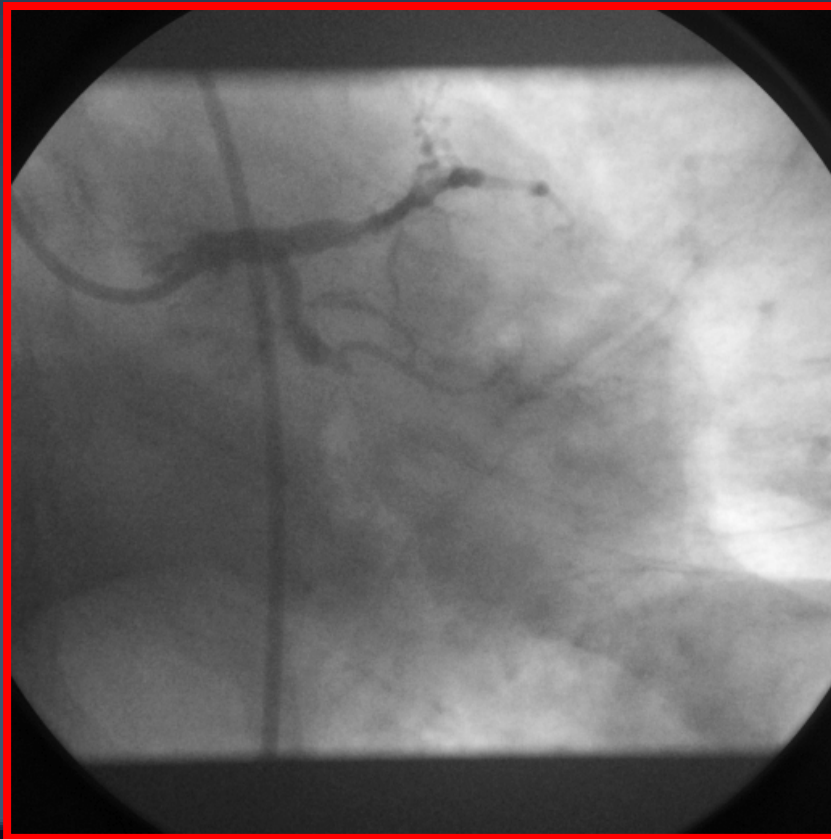
**DSG**

# INFINNium FOR THREE VESSEL STENTING

Pre

**LCx - CTO**

Post

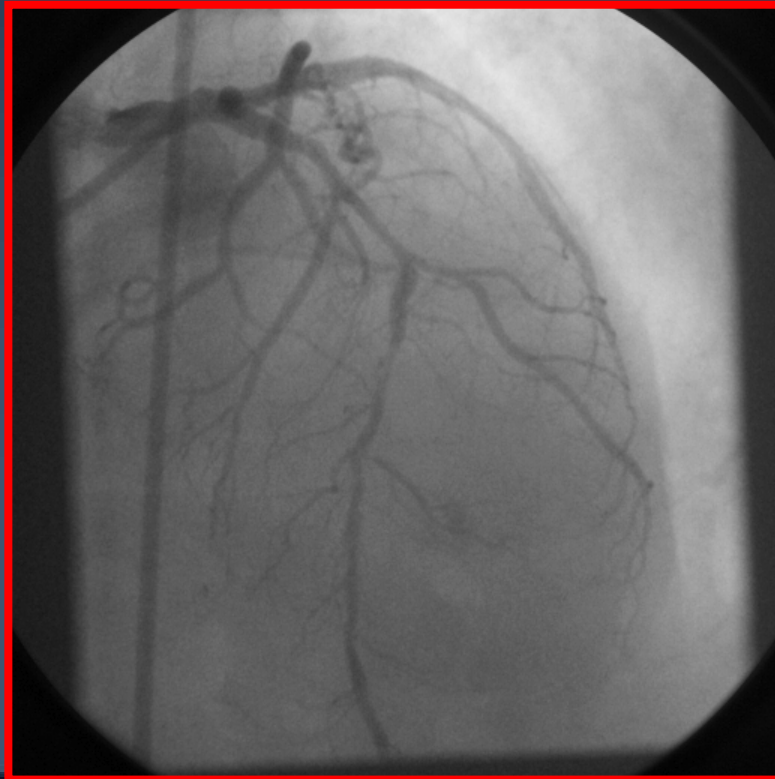


ZA

# INFINNIIUM FOR THREE VESSEL STENTING

**LAD - DIFFUSE AND CALCIFIC DISEASE**

**Pre**



**Post**



ZA



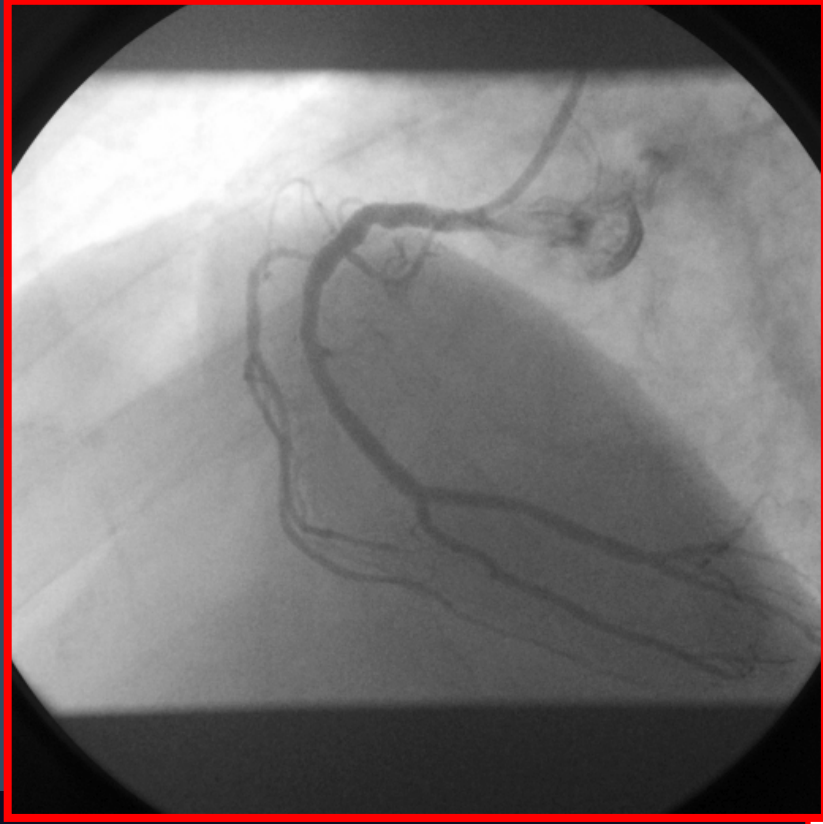
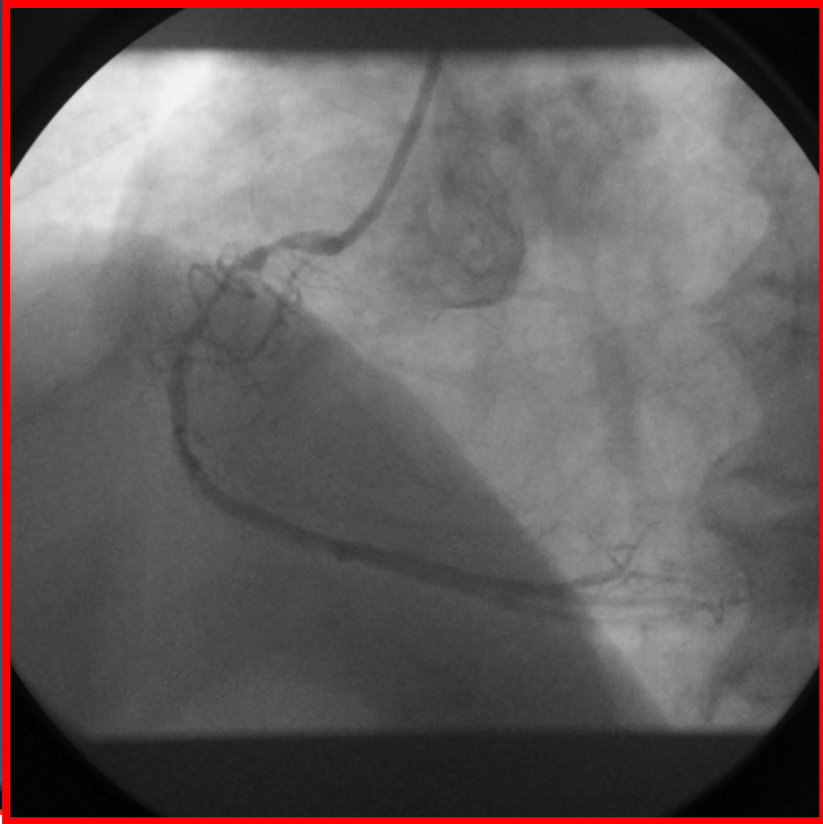
# INFINNium FOR MV STENTING (RCA+OM+LAD)

**RCA**

Pre

**RCA**

Post



PCP

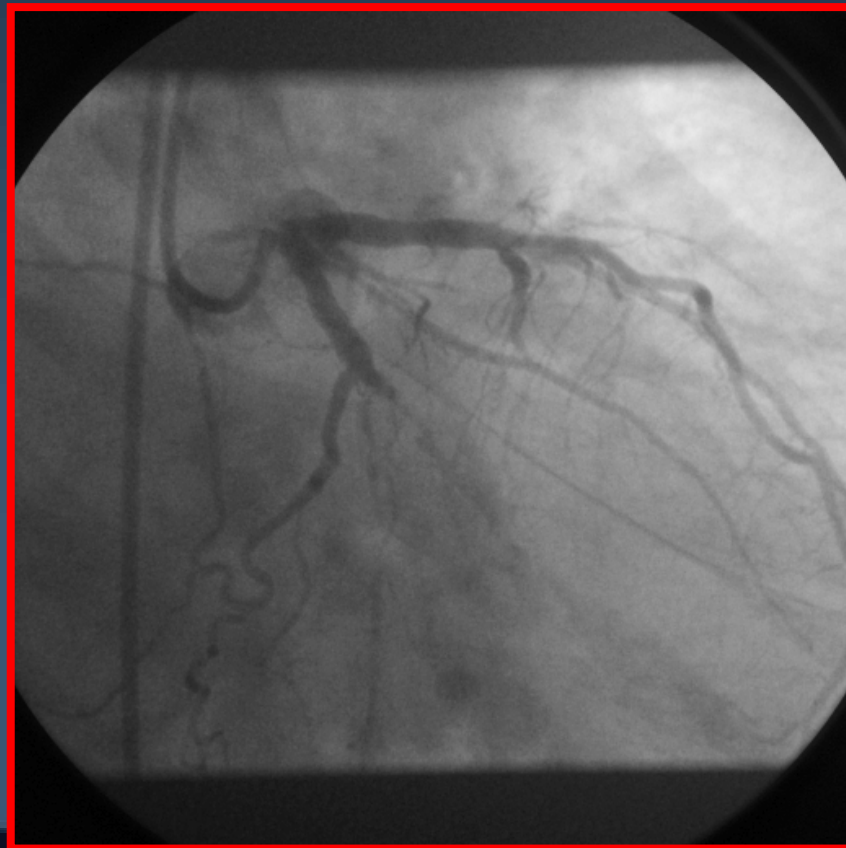
# INFINNIIUM FOR MV STENTING IN CAD

**LCx**

Pre

**LCx**

Post



PCP

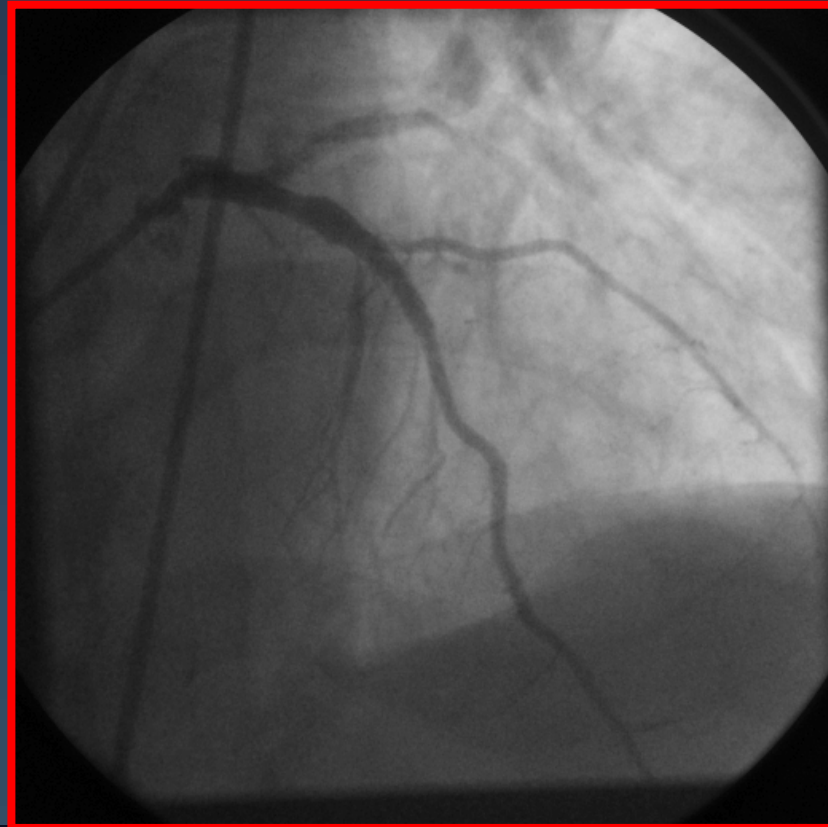
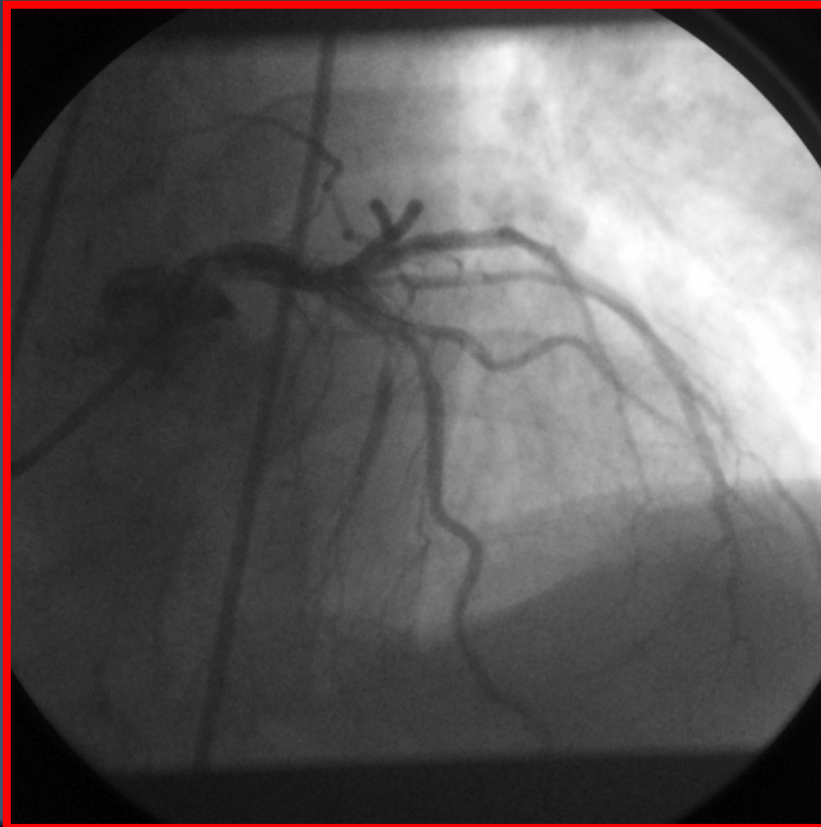
# INFINNium FOR MV STENTING IN CAD

**LAD**

Pre

**LAD**

Post



PCP

## **INFINNIUM FOR MV STENTING IN CAD** **CONCLUSION (1)**

- Bioabsorbable Polymer-Based Paclitaxel-Eluting **INFINNIUM** Stent can be **Deployed Successfully** in Almost All Patients with Multivessel CAD Having Complex Lesions (B<sub>2</sub>&C)
- **Multivessel Stenting** Using **INFINNIUM** Stent with / without Other DES in Highly Complex Lesions is **Safe** with < 1% Risk of Acute / Subacute Stent Thrombosis and **No Late Stent Thrombosis** upto One Year of FU
- The Stent is Highly Effective in **Preventing Repeat Revascularization** - Re-PTCA / CABG

## **INFINNIUM FOR MV STENTING IN CAD CONCLUSION (2)**

- Despite Using Multiple Stents Per Patient, the **Cost** of Treatment May be **Comparable to CABG**, Because of Relatively Lower Cost and Layered Pricing
- Prospective Multicentric Randomized Trial Needed to Assess its **Cost-Effectiveness in Comparison to CABG** in MVD