

# Registry head to head

(paclitaxel VS sirolimus)

Milan, 10.2020

## ***“Treatment of coronary artery disease with a new-generation drug-coated balloon: final results of the Italian Elutax SV rEgistry-DCB-RISE”***

Bernardo Cortese, Fabrizio D’Ascenzo, Raffaella Fetiveau

### ➤ **Primary Outcome**

Assessment of target-lesion revascularization (TLR) at the longest possible follow-up

### ➤ **Secondary Outcome**

Assessment of procedural success and any complications due to the device.  
DOCE index (device-oriented adverse cardiovascular events)

### **Objective:**

Italian retrospective study conducted in 9 centers between 2012 and 2015 to analyze a new generation of DCB with advanced technology for the delivery of the drug to the wall without dispersion of the same during navigation and handling

### **Material:**

Elutax SV DCB, Emperor DCB \*

\* today Emperor RX-C or ELUTAX «3» (AR Baltic Medical, Lithuania)

## ▪ *Demographic characteristics*

N° of patients	544
N° of lesions treated with DCB	583
Age	67.25 ± 10.7
Male	388 (71%)

## ▪ *Cardiovascular risk factors*

Hypertension	413 (76%)
Diabetes	177 (32%)
Smoking history	217 (40%)
Previous myocardial infarction	228 (42%)
Previous bypass surgery	70 (13%)

## Angiographic and procedural characteristics

Target Vessel	
Left anterior descending artery	<b>274 (47%)</b>
Left circumflex artery	<b>102 (17%)</b>
Right coronary artery	<b>190 (33%)</b>
Number of diseased vessels	
One-vessel	<b>281 (48%)</b>
Two-vessels	<b>169 (29%)</b>
Three-vessels	<b>124 (21%)</b>

ISR after BMS	<b>114 (19%)</b>
ISR after DES	<b>189 (32%)</b>
Native vessel disease	<b>280 (48%)</b>

## Qualitative Comparative Analysis (QCA)

Lesion length, mm $\pm$ SD	16.9 $\pm$ 7.2
Long lesions (>24 mm)	88 (15%)
RVD, mm $\pm$ SD	2.84 $\pm$ 1.18
Preprocedural MLD, mm $\pm$ SD	0.43 $\pm$ 0.31
Percentage diameter stenosis pre, % $\pm$ SD	85.0 $\pm$ 11.4

### ➤ 13-month follow-up of 507 patients (at the longest possible date)

	TOT	De novo lesions	ISR
Lesioni Trattate	507	238	269
TLR	30 (5.9%)	6 (2.6%)	24 (9%)
DOCE	36 (7.1%)	6 (2.6%)	30 (11%)
TVMI	3 (0.6%)	0%	3 (1.1%)
Cardiac Death	3 (0.6%)	0%	3 (1.1%)

# SIROLIMUS INVESTIGATION

## ***“Mid-term clinical outcomes from use of Sirolimus coated balloon in coronary intervention; data from real world population»***

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### ➤ **Primary Outcome**

Evaluation of target-lesion revascularization (TLR) at one year of follow-up

### ➤ **Secondary Outcome**

Assessment of procedural success and any complications due to the device.  
Target-vessel myocardial-infarction (TVMI), Major Adverse Cardiac Events (MACE)

### **Objective:**

British retrospective study conducted between 2019 and 2020 to analyze the efficacy and pharmacokinetics of a new generation of DCB coated with the drug Sirolimus

### **Material:**

Magic Touch-SCB (Concept Medical, India)

# SIROLIMUS INVESTIGATION

## ▪ *Demographic characteristics*

N° of patients	288
N° of lesions treated with DCB	373
Age	65.8 ± 11.6
Male	241 (84%)

## ▪ *Cardiovascular risk factors*

Hypertension	216 (84%)
Diabetes	110 (38%)
Smoking history	101 (35%)
Previous myocardial infarction	153 (53%)
Previous bypass surgery	47 (16%)

# SIROLIMUS INVESTIGATION

## Angiographic and procedural characteristics

Target Vessel	
Left anterior descending artery	<b>170 (46%)</b>
Left circumflex artery	<b>98 (26%)</b>
Right coronary artery	<b>93 (25%)</b>
Number of diseased vessels	
One-vessel	not reported
Two-vessels	not reported
Three-vessels	not reported

ISR	<b>140 (38%)</b>
De novo lesions	<b>233 (62%)</b>



# SIROLIMUS INVESTIGATION

## Qualitative Comparative Analysis (QCA)

Lesion length, mm $\pm$ SD	
Long lesions (>24 mm)	
RVD, mm $\pm$ SD	
Preprocedural MLD, mm $\pm$ SD	
Percentage diameter stenosis pre, % $\pm$ SD	

### ➤ Follow-up at 1 year (288 patients)

	TOT	De novo lesions	ISR
Treated Lesions	373	233	140
TLR	45 (12%)	21 (9%)	24 (17%)
MACE	29 (10%)	11 (6%)	18 (17.6%)
TVMI	10 (3.4%)	4 (2%)	6 (6%)
Cardiac Death	5 (1.7%)	5 (1.7%)	0

# CONFRONTO

- *Treatment of coronary artery disease with a new-generation drug-coated balloon: final results of the Italian Elutax SV rEgistry-DCB-RISE*

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Treated lesions	507	238	269
TLR	30 (5.9%)	6 (2.6%)	24 (9%)
DOCE	36 (7.1%)	6 (2.6%)	30 (11%)
TVMI Cardiac	3 (0.6%)	0%	3 (1.1%)
Death	3 (0.6%)	0%	3 (1.1%)

- *Mid-term clinical outcomes from use of Sirolimus coated balloon in coronary intervention; data from real world population*

	TOT	De novo lesions	ISR
Treated lesions	373	233	140
TLR	45 (12%)	21 (9%)	24 (17%)
MACE	29 (10%)	11 (6%)	18 (17.6%)
TVMI Cardiac	10 (3.4%)	4 (2%)	6 (6%)
Death	5 (1.7%)	5 (1.7%)	0

**thanks  
for the  
attention**

