Rapstrom 3 year – 504 patient registry

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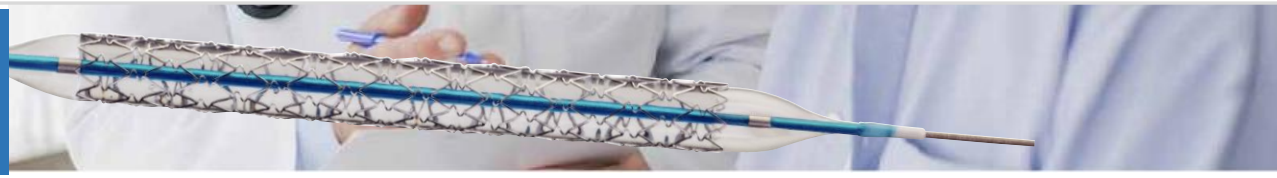
Rapstrom Stent Post Market Surveillance Registry

Long-term Outcome
(3 years follow-up)

Rapstrom Registry



Study Design

- Multicenter Registry to assess the safety and efficacy of Rapstrom Stent in 504 **patients** with de novo in single or double vessel disease patients (single lesion / vessel)
- Stent diameters – **2.50 to 4.00 mm**
- Stent lengths – **13 to 38 mm**
- Primary Safety and Efficacy End-points – MACE at long term FU (3 yrs)

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Rapstrom Registry

Baseline Clinical Characteristics

Patient (n) 504	
Male [n (%)]	374 (74%)
Age (years+SD)	54.± 11
BMI (kg/m2+SD)	24.6± 1.9
Cardiovascular risk:	
Diabetes mellitus [n (%)]	171 (34%)
Current smoker [n (%)]	165 (33%)
Hypercholesterolaemia [n (%)]	262 (52%)
Family history of CAD [n (%)]	241 (48%)
Hypertensive [n (%)]	254 (51%)
Previous MI [n (%)]	131 (26%)
Previous CABG [n (%)]	15 (3%)
Prior PCI [n (%)]	20 (4%)
Anginal status [n (%)]	
STEMI- NSTEMI	197 (39%)
Unstable angina	168 (33%)
Stable angina	111(22%)
Silent ischaemia	28 (6%)

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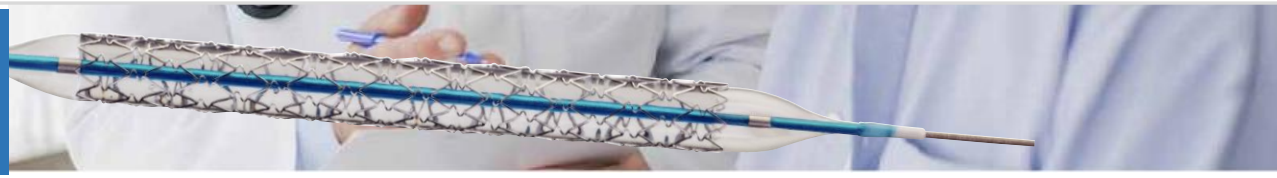
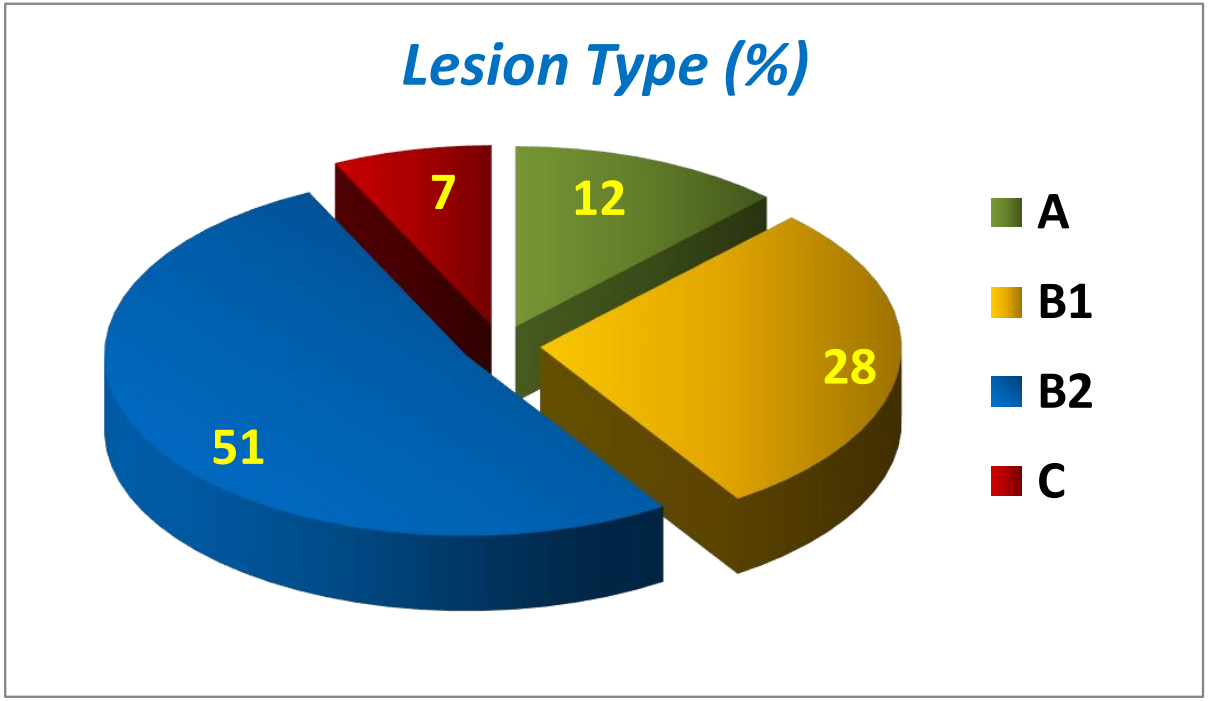
Rapstrom Registry



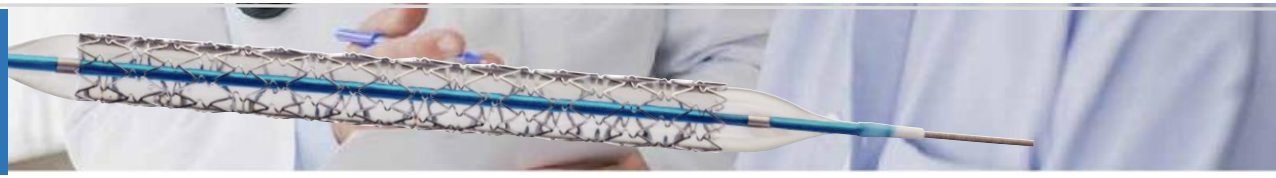
Treated Lesions (654 Lesions)



Reference vessel Diameter (mm+SD)	**=**	**2.76±0.41**
Lesion length (mm+SD)	**=**	**21.8 ± 8.7**

Rapstrom Post market surveillance Registry (3 Year FU, 504 patients)

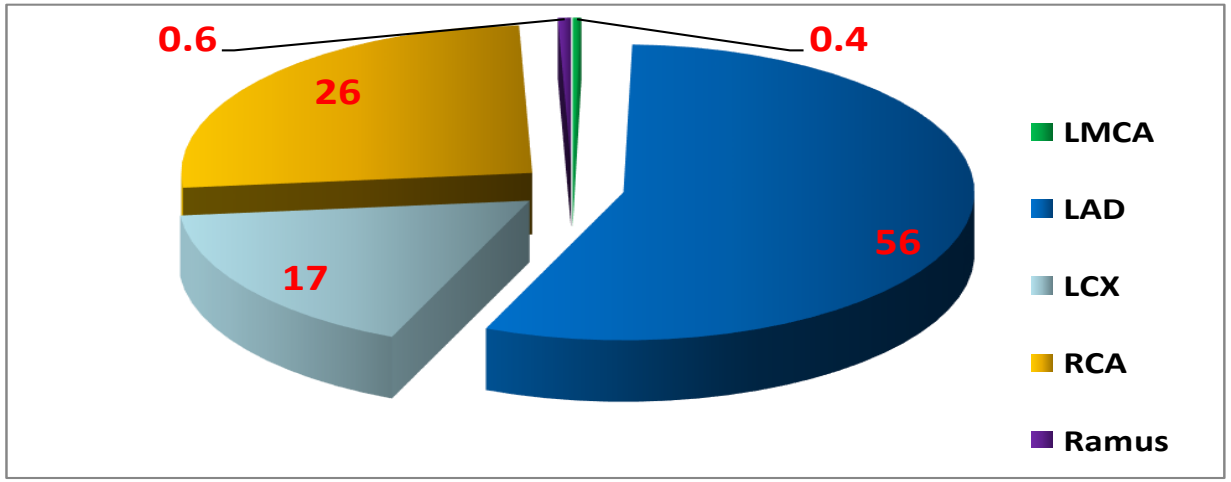
Rapstrom Registry



Procedure Data

- Patients 504
- Total treated vessels [n] 635 vessels
- Totale treated lesions [n] 654 lesions

- Total no of vessel/ patient 634/504 (1,3)
- Total no of treated lesions / vessels 654/634 (1,02)
- Total number of stents used 662
- Stent / vessel ratio 1,01
- Stent / patient ratio 1,3



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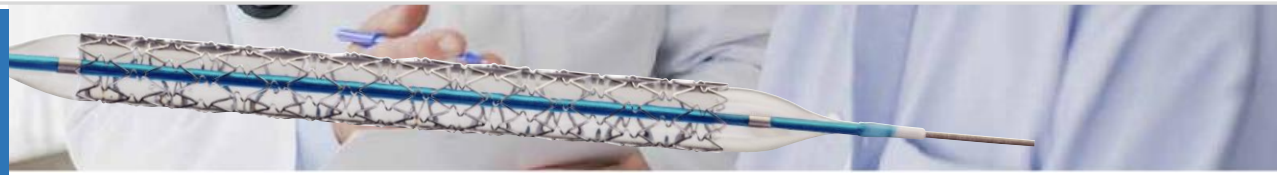

3- Year Clinical Follow up

Variables	3-Year FU (504 pts)
Cardiac Death	2 (0,4%)
Non Cardiac death	4 (0,8%)
Myocardial infarction	NSTE= 12 (2,3 %) STE =8 (1,6%)
i TLR	29 (5,7 %)
TLR / TVR	35 (6,9%)
Subacute Thrombosis	0
AnyARCStent Thrombosis	4 (0,8%)
Possible	1
Probable	2
Definite	1
MACCE	47 (9,3%)

Rapstrom Post market surveillance Registry (3 Year FU, 504 patients)

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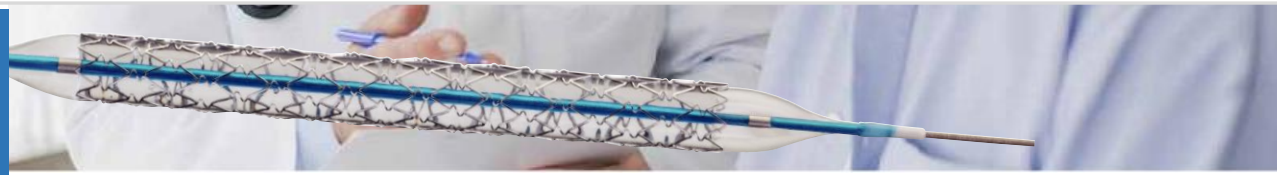
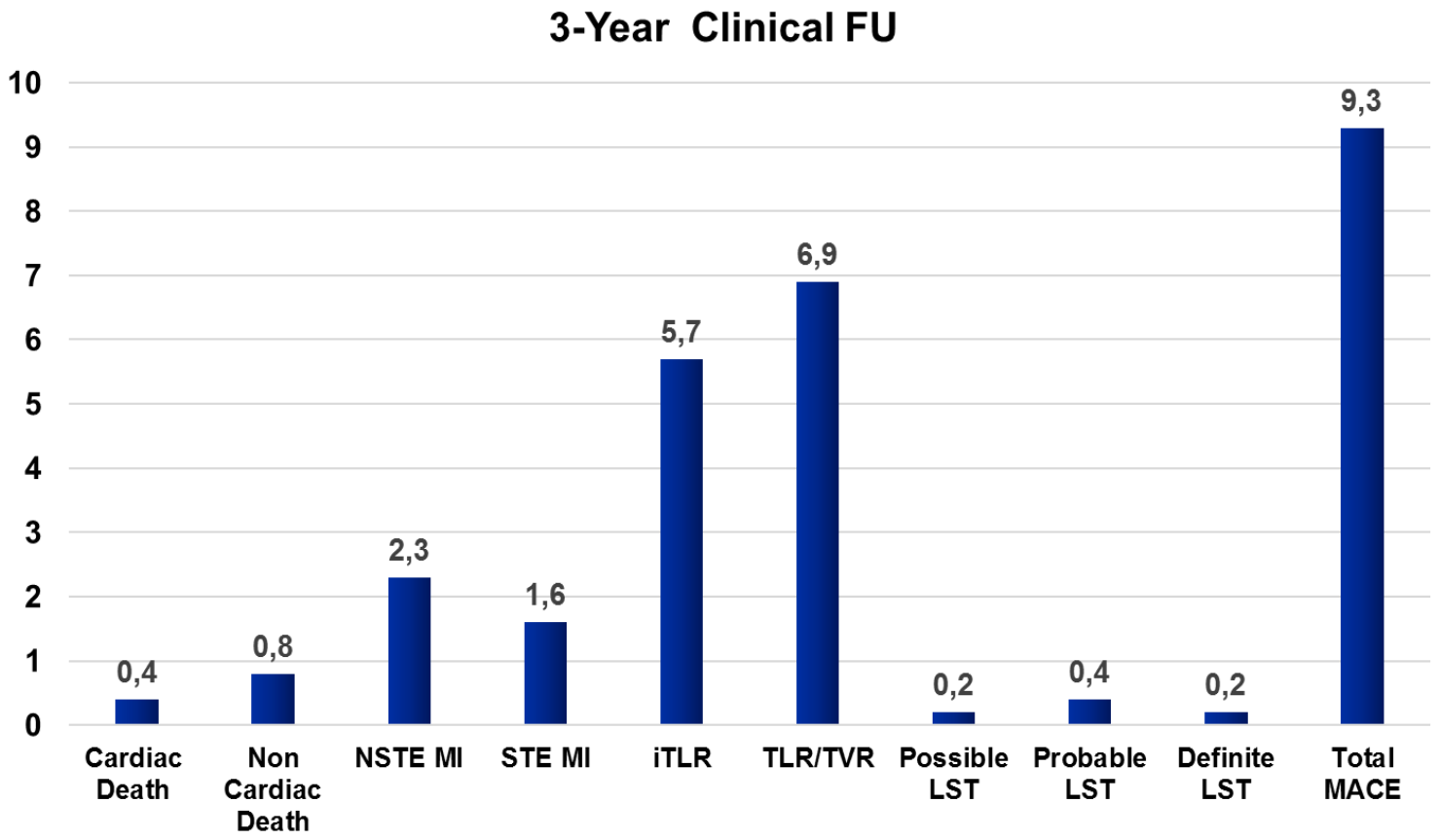
Rapstrom Registry



Long term clinical Follow up



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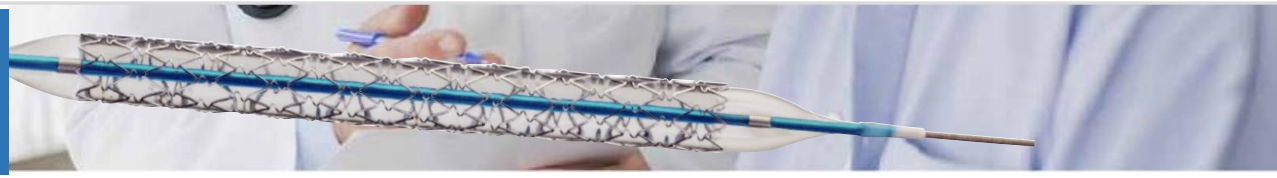


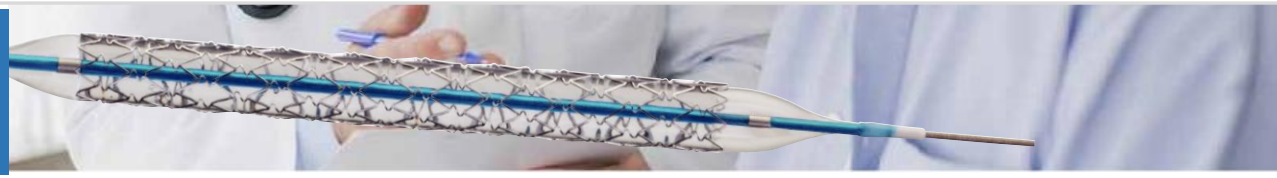
Result of QCA in Matched pairs

Angiographic FU in 103 coronary patients with 123 stents at 11,4 ±3,1 months

Variables	In-stent	In-segment
Reference vessel diameter (mm)		
After procedure	2.92±0.41	2.84±0.28
At 12 months	2.85±0.27	2.82±0.31
Minimal luminal diameter (mm)		
After procedure	2.76±0.31	2.,79±0.22
At 12 months	2.60±0.33	.2,61±0.29
P-value	0.75 (ns)	0.78(ns)
Late loss (mm)	0.16±0.07	0.18± 0.08
Diameter stenosis (%)		
After procedure	4,5 ± 3,7	5,8 ± 4,6
At 12 months	7,8 ±.4,8	9,4 ± 5,9
P-value	0.79 (ns)	0.83 (ns)
Binary restenosis rate at 6-12 months (≥ 50%)	5 (6,8 %)	

(Binary restenosis was calculated based on the unmatched data).

Rapstrom Registry



Final Remarks

- **II Generation DES with biodegradable polymer provide higher safety and efficacy profile ,and paricularly recommended in complex procedures**

- **Rapstrom** (II Generation Sirolimus Eluting, Biodegradable Polymer in Thin Strut Cobalt Chromium Stent**) Post Market Survielance Registry confirms a high level of safety and efficacy on long term clinical follow up with very low TLR and negligiable Late stent thrombosis at 3 yrs Follow-up**