Clinical Evaluation of Everoshine (Everolimus Eluting) Coronary Stent in Coronary Artery Lesions

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Disclosure

- I do not have any potential conflict of interest to declare

Background

- The new-generation drug-eluting stents (DES) represent the current standard of care in patients undergoing percutaneous coronary intervention (PCI).
- The last decade has seen significant growth in indigenous stent manufacturing in India that are widely used across the world.
- The Everoshine DES (Kamal Medtech, Faridabad, Haryana,India) is a novel thin-strut cobalt-chromium Everolimus-eluting stent with biodegradable polymer that features some of the latest developments in DES technology.
- Biodegradable polymer DES (BP-DES) was recently developed to overcome current limitations of newer-generation durable polymer DES (DP-DES) like delayed endothelial healing, Late and Very late Stent thrombosis and Neoatherosclerosis which were attributed to sustained inflammatory responses induced by permanent polymers.

STENT SPECIFICATION

Design:	Open Cell Stent Design
Material:	Cobalt Chromium (CoCr) L605
Length (mm):	8, 13, 16, 20, 24, 28, 32, 36, 40, 43 & 47
Diameter (mm):	2.00, 2.25, 2.50, 2.75, 3.00, 3.50, 4.00 & 4.50
Strut Dimensions:	Thickness 65 µm | Strut 70 µm | Connectors 50 µm
Nominal Pressure (NP):	9 atm
Rated Burst Pressure (RBP):	16 atm
Foreshortening:	Nearly Zero
Recoil:	≤ 5 %
Crossing Profile:	Nearly 1.00 mm
Min. Guidewire Diameter:	0.014"
Min. Guiding Catheter I.D.:	5 Fr Compatible
Radial Strength:	Excellent
Flexibility:	Excellent

KAMAL

Corporate Address:
5-B, Hansalaya Building, 15,
Barakhamba Road, New Delhi-110001
An ISO 13485 Certified Company.

Manufacturing site Address:
Plot No.: 917, Sector 68,
IMT Faridabad-121001, Haryana, INDIA

Phone: +91-11-23123158 | 23531369
Email: info@kamalmedtech.com

ORDERING INFORMATION

Dia(mm)	8	13	16	20	24	28	32	36	40	43	47
2.00	ER20008	ER20013	ER20016	ER20020	ER20024	ER20028	ER20032	ER20036	ER20040	ER20043	ER20047
2.25	ER22508	ER22513	ER22516	ER22520	ER22524	ER22528	ER22532	ER22536	ER22540	ER22543	ER22547
2.50	ER25008	ER25013	ER25016	ER25020	ER25024	ER25028	ER25032	ER25036	ER25040	ER25043	ER25047
2.75	ERF27508	ER27513	ER27516	ER27520	ER27524	ER27528	ER27532	ER27536	ER27540	ER27543	ER27547
3.00	ER30008	ER30013	ER30016	ER30020	ER30024	ER30028	ER30032	ER30036	ER30040	ER30043	ER30047
3.50	ER35008	ER35013	ER35016	ER35020	ER35024	ER35028	ER35032	ER35036	ER35040	ER35043	ER35047
4.00	ER40008	ER40013	ER40016	ER40020	ER40024	ER40028	ER40032	ER40036	ER40040	ER40043	ER40047
4.50	ER45008	ER45013	ER45016	ER45020	ER45024	ER45028	ER45032	ER45036	ER45040	ER45043	ER45047

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Established
Everolimus
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Superior Clinical Outcomes

- The safety and efficacy of Everoshine stents have been established in well-structured clinical trials. However, there is a scarcity of data in real world different clinical and Anatomical settings.
- In this study, we aimed to evaluate Everoshine stent’s real-world performance, safety and efficacy in different clinical and anatomical settings.
- This was a single-center, single-arm prospective observational study carried out at a tertiary care center.
- The study protocol and related procedures were approved by the institutional review board and ethical committee.

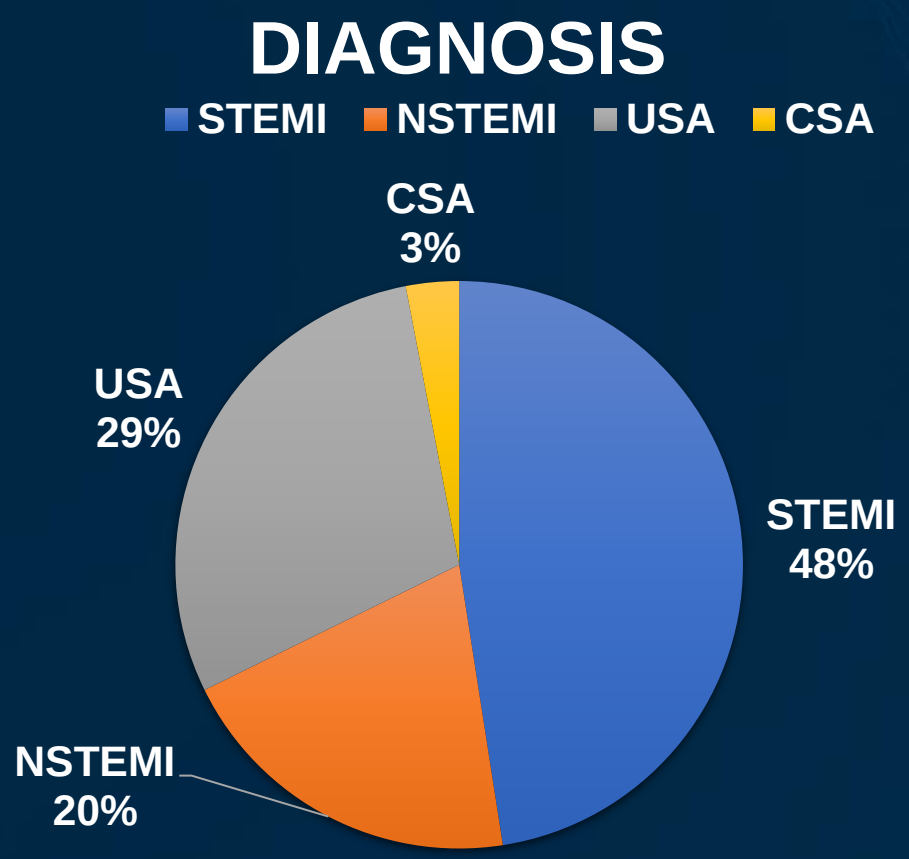
Methods

- The study population included of 200 patients who underwent single or multi vessel revascularization with clinical presentations such as Stable Angina and Acute Coronary Syndrome(ACS) in period between October 2020 and August 2021 who completes one-year follow-up period.
- All the patients enrolled were implanted with at least one Everoshine DES and responded to follow-up.
- The endpoint of the study was the incidence of Major adverse cardiac events (MACE) defined as Cardiac death, Target vessel MI, TVR and stent thrombosis.
- Clinical, Telephonic follow-up was performed and MACE was analyzed at 30 days, and 12 months.

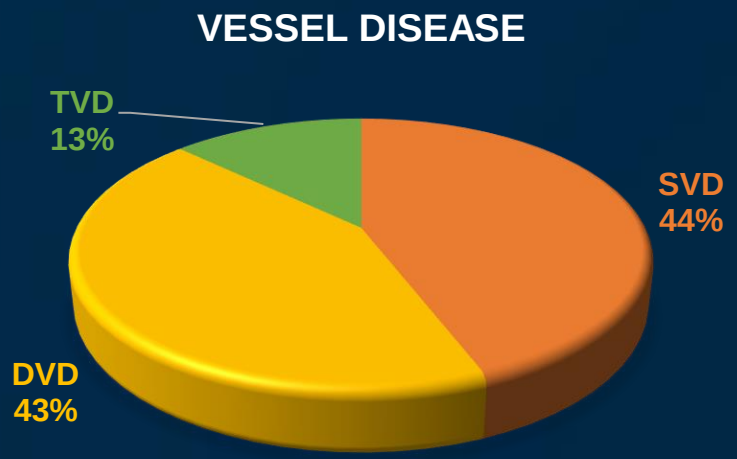
Results

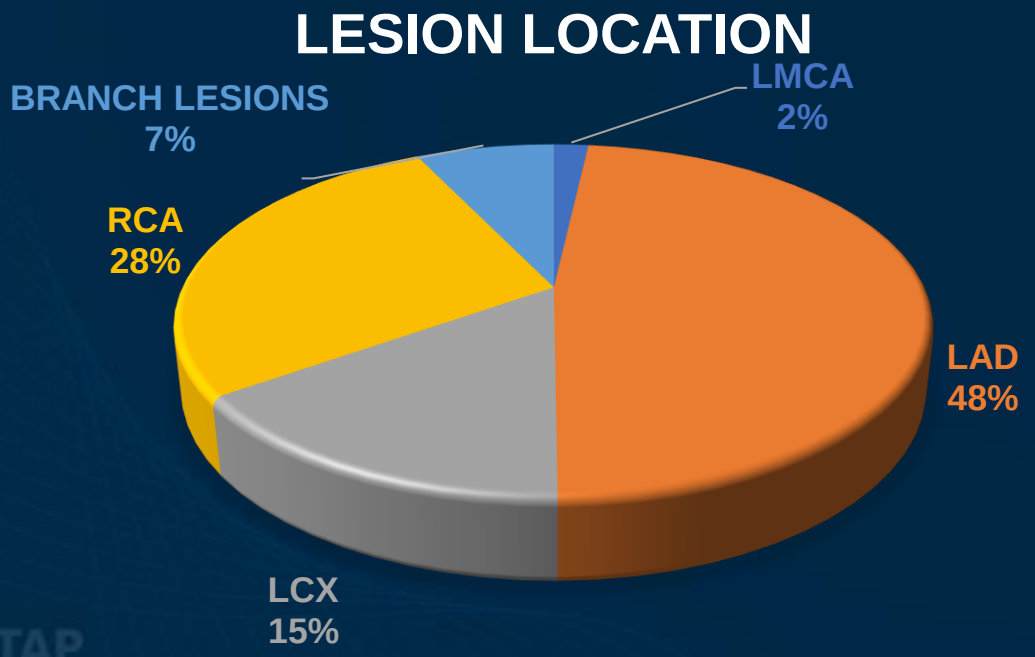
Out of 200, 193 patients were responded. Total 310 lesions were treated with 260 Everoshine stents in the study

Clinical Characteristics	
Age(years)	57.8±11.01
Male	142 (73.6)
Hypertension	90 (47.4)
Diabetes	68 (35.2)
Smoke	20 (10.4)
Family history of CAD	22 (11.4)
Renal Impairment	12 (6.2)
Good LV function	90 (47.4)
Mild LV dysfunction	38 (19.7)
Moderate LV dysfunction	58 (30.05)
Severe LV dysfunction	**3 (1.5)**



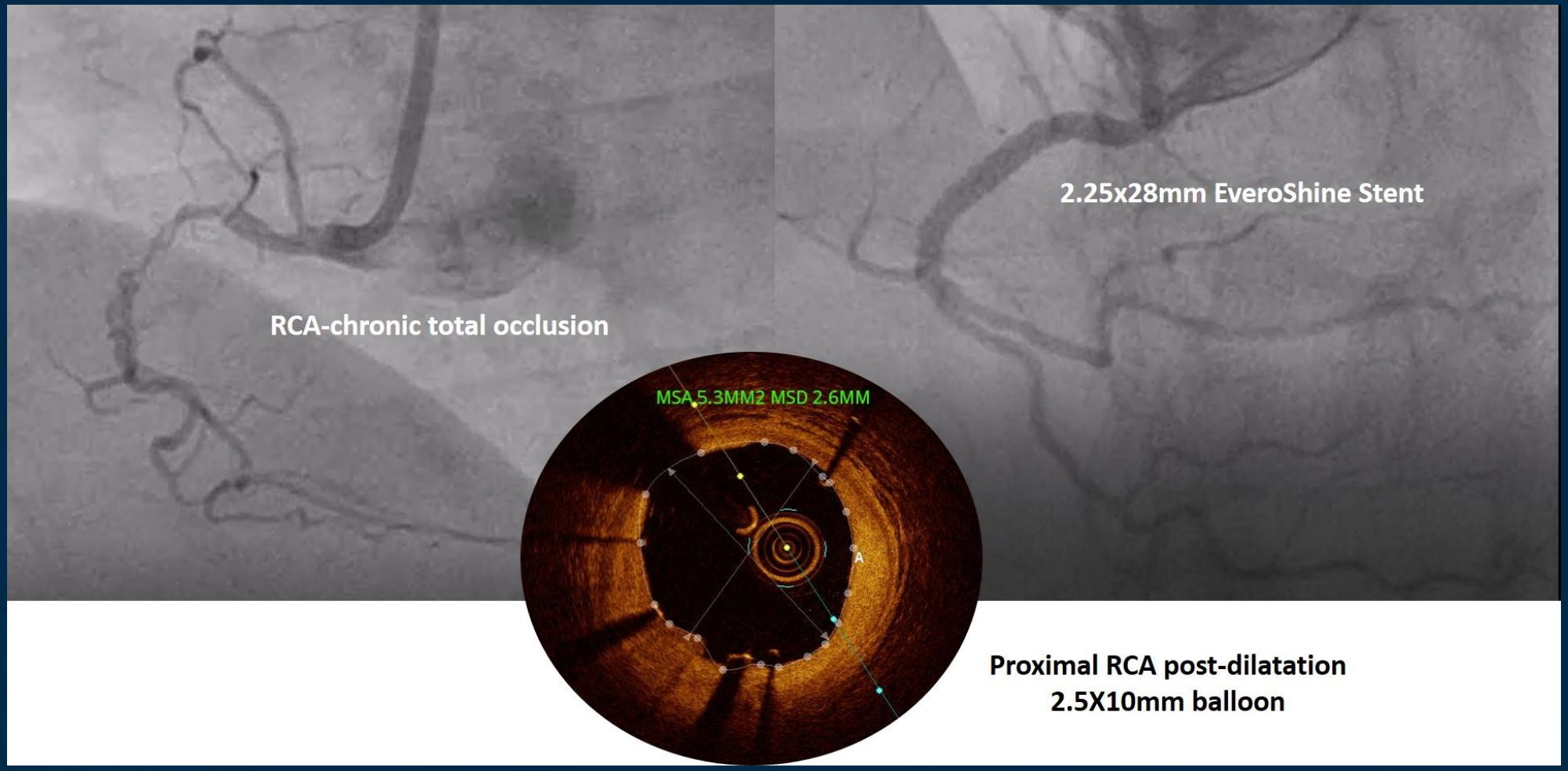
Results





Stent characteristics	
Stent diameter, mm	2.91 ± 0.39
≤2.5 mm, n (%)	65 (25)
>2.5 to <3.5 mm, n (%)	140 (53.8)
≥3.5 mm, n (%)	54 (20.8)
Stent length, mm	26.77 ± 9.78
< 15 mm, n (%)	20 (7)
15 to <20 mm, n (%)	43 (16.5)
20 to <26 mm, n (%)	68 (26.1)
≥26 mm, n (%)	128 (49.2)
No. of Stents (pts n=193)	
1	131 (50)
2	56 (21.5)
3	**6 (2.3)**

Case Example



Results

Death	1 month	12 months
All cause	4 (2.07)	5 (2.6)
Cardiac	2 (1.03)	3 (1.5)
MI	2 (1.03)	2 (1.03)
TLR	2 (1.03)	2 (1.03)
Stent Thrombosis	2 (1.03)	2 (1.03)
MACE	4 (2.07)	5 (2.6)

DISCUSSION

- ACS - 97%
- STEMI – 48%
- Diabetes – 35.2%
- Renal Impairement- 6.2%
- Moderate LVD- 30.05%
- LM / CTO / Ostial / Small vessel / Branch vessels
- Stent Diameter <2.5 mm in 25%
- Stent Length > 26 mm in 49.2%
- Stent Overlapping of ≥2 in 23.8%
- This highlights the safety and efficacy of Everoshine stents in complex clinical settings.

CONCLUSION

- The newer biodegradable polymer stents have good short-term clinical outcomes and can overcome the shortcomings of durable polymers.
- The study has shown that in the real-world scenario, Everoshine, the indigenous biodegradable polymer DES are both safe and effective.
- Further prospective randomized studies involving different complex anatomies are warranted to validate our findings on the safety and efficacy.

Thank you for paying attention

Presentor

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