

## Clinical Trials > NOVAFIM- Escorts Heart Institute Angiographic Study

Committed to conducting clinical trials, Vascular Concepts has completed various trials and registries with Pronova in 2078 patients both in India and Abroad.

Following are the details of the Clinical trials-

ProNOVA First In Man study in India was conducted at the Escorts Heart Institute and Research Centre. ProNOVA a drug eluting (Sirolimus) stent was used in the patients with coronary artery occlusions.

**Objective :** The study was conducted to establish the efficacy and safety profile of the ProNOVA stent system in patients undergoing angioplasty in India.

**Methodology :** The Inclusion criterias to include patients consisted of patients with de-novo lesions. Multi-vessel and multi-lesion CAD patients were also enrolled into the study. Patients with vessel diameter 2.5 to 3.5mm and a target lesion less than 30mm were included. Patients with overlapping stents with a maximum overlap length of upto 35mm were included. Patients with thrombotic lesions occupying upto 50% of artery diameter were also included into the study.

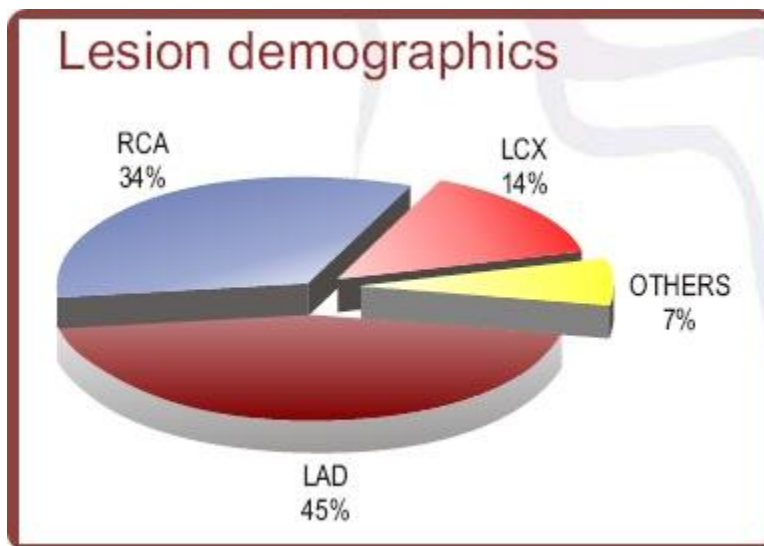
In exclusion criterias patients with ongoing AMI were excluded from study. Patients with severely calcified lesion were also excluded. Patients with ostial lesions were not enrolled. Unprotected left main coronary artery patients were excluded. Patients with total occlusions and those involving a side branch with more than 2mm diameter were also excluded. Post CABG patients were also excluded from the study.

### Results

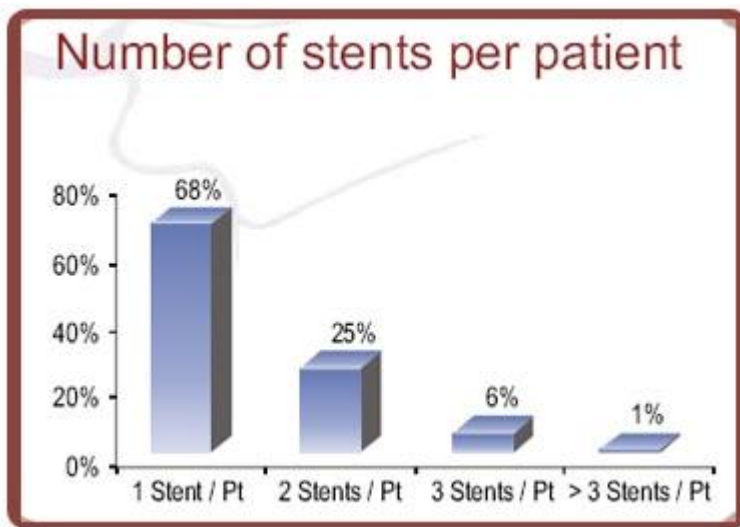
**Patient Demographics :** The number of patients enrolled in this study was 120. There were 83% males and 17% females. The mean age of the patients was 50.73 +/- 12.2 yrs. The mean LVEF of the selected patients was 50.9 +/- 6.8%. The total number of stents deployed in the study was 168 and on an average 1.40 stents were deployed per patient.

**Risk Profile :** The risk profile of patient population consisted of diabetes in 34% and hypertension in 60% patients. There were 32% smokers in the population subset. 33% patients had unstable angina and 47% patients had a history of prior MI.

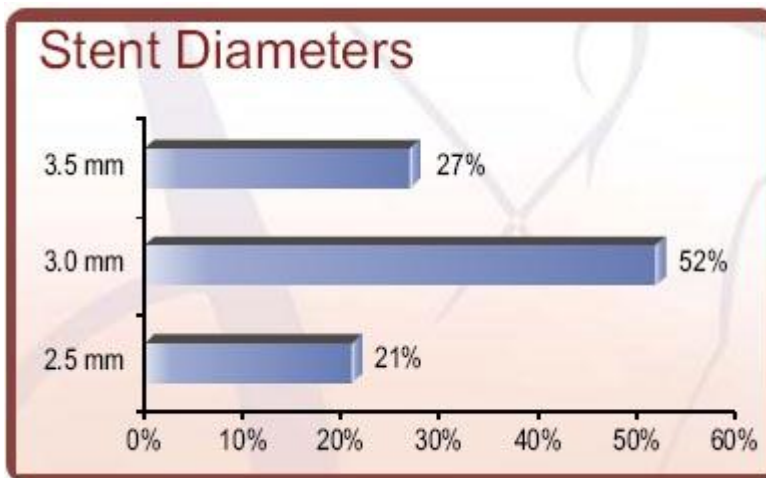
### Lesion Demographics :



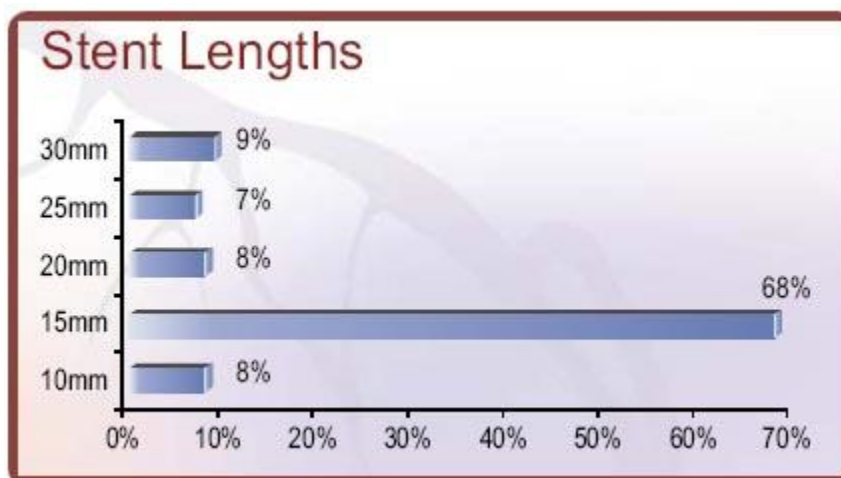
**Number of Stents Per Patient :** In 68% of the patients only 1 stent was deployed. In 25% patients 2 stents were used. In 6% patients 3 stents were used and in 1% patients 4 stents were used.



**Stent Diameters :** In 27% patients stents of 3.5mm diameter were used. In 52% patients 3.0mm diameter stents were used. In 21% patients 2.5mm stents were used.

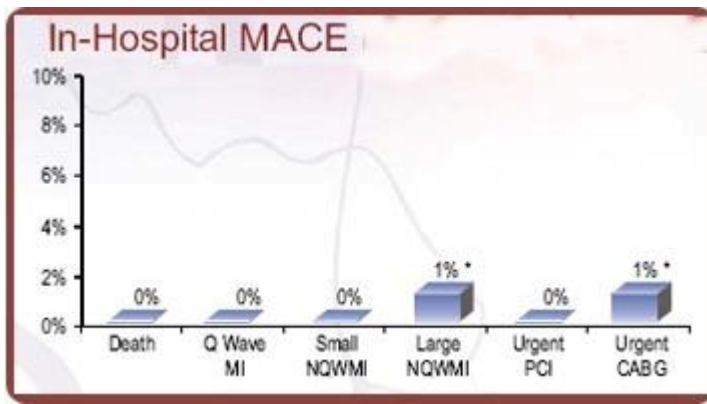


**Stent Length :** In 9% of the patients 30mm of stent length was used. Whereas in 7% patients 25mm of stent length was used. 8% patients had 20mm of stent length, 68% patients had 15mm of stent length and 8% patients had 10mm of stent length.

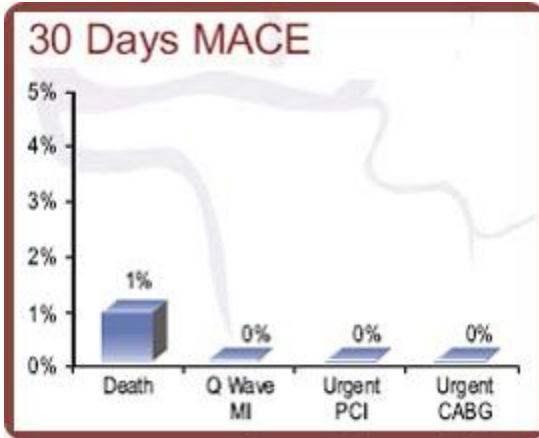


**Procedural results :** Deployment success was found out to be 100%. Residual stenosis (<20% post PCI) was also 100%. All patients had a TIMI-III flow post PCI.

In-Hospital MACE (Major Acute Coronary Events) : Death (0%), Q wave MI (0%), Small NQWMI (0%), Large NQWMI (1%), Urgent PCI(0%) and Urgent CABG in (1%) patients.

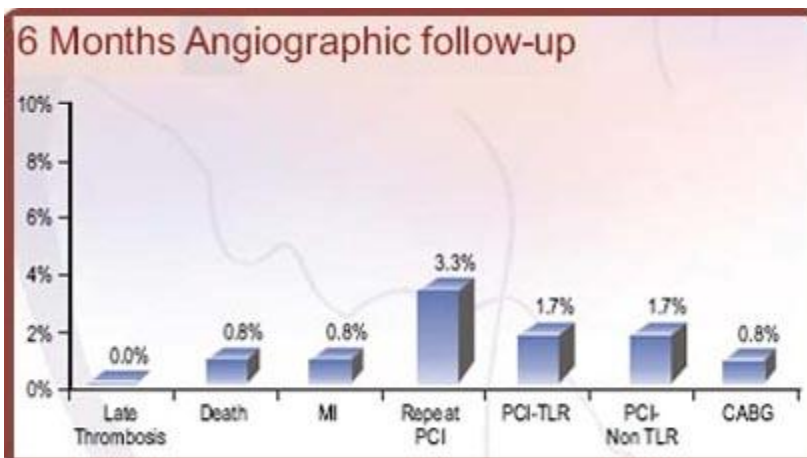


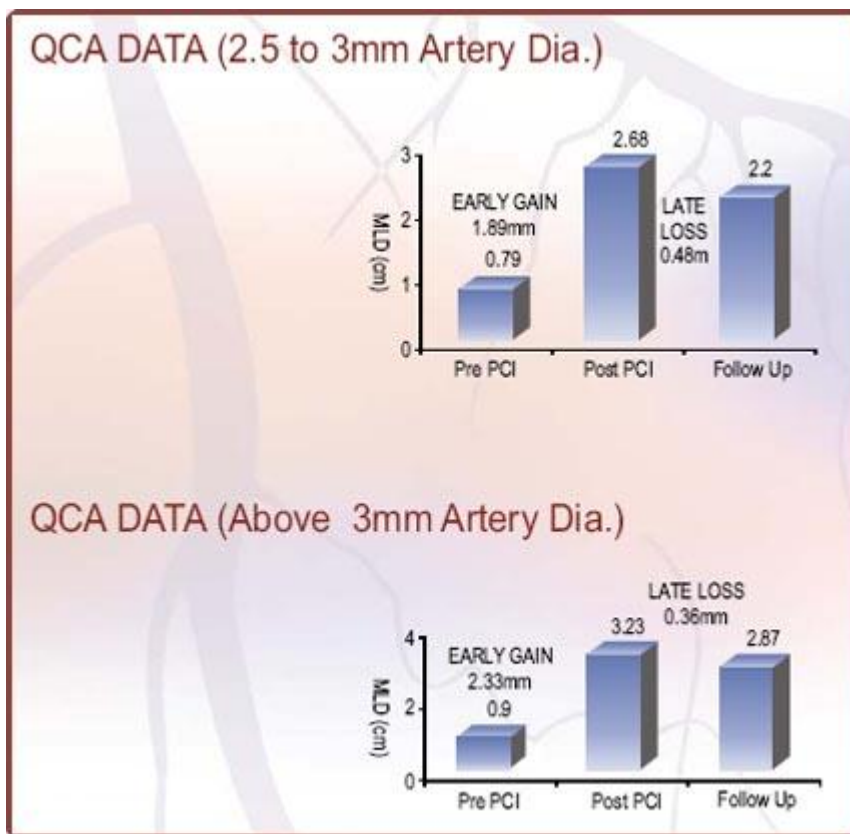
**30days MACE :** Death (1%), QWave MI (0%), Urgent PCI (0%) and Urgent CABG (0%).



The 6 months QCA (Quantitative Coronary Angiography) data showed that out of 120 patients enrolled, the total number of angiographic follow-up was done on 97 patients. Check angiograms were done in 80.8% patients. The total number of lesions checked at 6mths were 113. QCA was done on validated PIE-Medical software.

During 6 months angiographic followup late thrombosis was observed in 0.0% patients, death in 0.6%, MI in 0.8%, repeat PCI in 3.3%, PCI-TLR in 1.7%, PCI-NonTLR in 1.7% and CABG in 0.8%.





Insegment angiographic restenosis was found out to be 9.7% which is much better than previously done studies on other stents.

- \* 6months clinical follow up (patients not angiogrammed at 6 months)
- \* Patients without check anginas: 23
- \* Number of patients followed clinically (not willing for a CABG): 21
- \* Symptomatic status: All symptomatic

**Conclusions :** When looking at the primary endpoints 100% successful deployment was obtained. During inhospital MACE 1 Patient had to undergo CABG due to MI (wire perforation). In 30 day MACE 1 patient died. In secondary endpoints, 6 months angiographic insegment restenosis was 9.7% which is comparably much better. The TLR was 1.66% with death of 1 patient and 1 MI (which occurred within 30 days).

**Key Take Aways :**

- \* Successful deployment of the stents was obtained
- \* 6 months angiographic restenosis was 9.7% which is better than obtained in other available studies