**Clinical Trials > EURONOVA Study**

**Background :** A clinical study conducted in a real world fashion to evaluate the safety and efficacy of a Sirolimus Eluting stent (ProNOVA). The study aimed to assess the acute performance characteristics of the ProNOVA drug eluting coronary stent, which was confirmed through documentation of 30 day MACE and repeat angiography after 6 months in patients who have had a successful ProNova stent implantation.

**Methodology :** A total of 65 patients completed the study after giving written informed consent. 77 stents were implanted in 72 vessels. The study used standard angiographic parameters and clinical endpoints as surrogate endpoints for restenosis. All patients were followed up after hospital discharge, at 30 days and at 6 months post procedure. A repeat angiography was performed at 6 months along with other clinical follow-up for studying parameters including death, target vessel failure of the study lesion, documented MI, % stenosis within the length of stent implantation and upto 5mm from the edge of the stent.

**Results:** The primary success rate was 100% with 0% acute MACE. The primary QCA results showed that the % stenosis diameter decreased from 73.84% pre-procedure (reference diameter 2.79 mm) to 12.33% post-procedure (reference diameter 3.08 mm), the mean luminal diameter increased from 0.79 mm before procedure to 2.67 mm post-procedure.

**Table 1:** Procedural and Stent Details

| | |
|---|---|
| Total stents deployed | 77 |
| Total number of lesions | 72 |
| Avg. stent per patient | 1.11 |
| Avg. stent length (mm) | 18.25 |
| Avg. vessel size (mm) | 2.79 |
| Number of patients with overlapping stents | 5 |
| Number of patients with two or more ProNOVA | 6 |
| Number of patients with small stents (2.5mm) | 18 |

**Table 2:** Vessels Treated

| | |
|---|---|
| LAD | 29 |
| RCA | 30 |
| LCX | 13 |

**Table 3:** Primary Results

| | |
|---|---|
| Acute Technical Success (Stent Placement) | 77/77 (100%) |
| Acute patient success | 65/65 (100%) |
| Acute MACE | 0/65 (0%) |

**Table 4:** Primary and Secondary Endpoints

| **MACE** | **In Hospital** | **6 months(0-180 days)** |
|---|---|---|
| Thrombosis | 0 | 0 |
| Death | 0 | *1 |
| MI/ NQWMI | 0 | 0 |
| Re Cath | 1** | 6*** |
| Re PCI | 0 | 6 |
| CABG | 0 | 0 |

* Sudden death, multimorbid patient, 3 vessel disease

** Treated artery was patent, no stenosis, normal finding

*** 4 patients had PTCA of other vessel, 2 patients had recath for suspicion of angina with normal finding in treated artery and no stenosis.

**Table-5:** Angiographic Follow-up

| | |
|---|---|
| MLD Pre-PCI | 0.78 mm |
| MLD Post-PCI | 2.67 mm |
| MLD at FUP | 2.07 mm |
| Early gain | 1.89 mm |
| Late Loss | 0.60 mm |
| Angiographic In-segment Restenosis | 8% |

**Conclusions:** PRONOVA stent was found to be safe in EURONOVA trial, with no Cardiac Death, MI and Stent thrombosis reported at 30 days and 6 months. The stent design also exhibited some unique features like superior flexibility and low profile. Hence PRONOVA stent confirmed its superior performance features and its safety and efficacy in this trial.

**Key Take Aways:**

* A real world study to evaluate the efficacy of ProNOVA stent system

*100% primary success ratewith 0% MACE

*Superior efficacy and manouverability of ProNOVA was confirmed in this trial.