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Translumina first to present 10-year safety data of DES

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The data presented shows numerically lower rates of stent thrombosis with Indian drug eluting stent (DES) Yukon Choice PC compared to American stents at a follow-up of 10 years.

Proving to be a major boost for the Indian medical device manufacturing industry, which is majorly dominated by US multinationals, a leading Indian producer Translumina Therapeutics LLP achieves a special feat of becoming the first company in the world to demonstrate a 10-year patient safety and efficacy data of its drug eluting stent (DES) Yukon Choice PC.

This is for the first time that a decade long research data has been presented for the efficacy and safety of DES since its launch in 2001, as no other research has published data of more than 5 years.

The research findings of a randomized control trial called ISAR-TEST 4 were presented by leading cardiac expert from Germany, **Dr. Sebastian Kufner** at the prestigious **2018 American Heart Association Scientific Sessions at Chicago, Illinois, United States,** today in the presence of leading cardiologists from all over the world.

“It was a privilege for me to present the first long-term data of Yukon Choice PC DES of 10 years efficacy and safety. This will not only prove the efficacy and safety of DES for long term, but also gives boost for the long-term success of the procedure of angioplasty after the launch of DES”, **said Dr Sebastian Kufner, Associate Professor of Cardiology, German Heart Centre, Munich, Germany.**

The data demonstrated that at 10 years, both Indian made ‘Yukon Choice PC’ and much used USFDA approved ‘Xience’ stents showed significantly better results than the Cypher stent regarding major adverse cardiac events, with a risk reduction of 18% and 21% and mortality risk reduction of 18% and 22%, respectively. There were no significant differences between Yukon Choice PC and Xience stents regarding these outcomes.

However, Yukon Choice PC showed the lowest rate of definite or probable stent thrombosis with a significant risk reduction than the ‘Cypher’ stent (50% reduction) and even a numerically lower rate as than the ‘Xience’ stent (29% reduction).

The significance of this data has been further acknowledged by one of the most respected journals of cardiology, ***‘Circulation’*** that published it in its exclusive ahead-of-print online edition simultaneously.

Gurmit Singh Chugh, Managing Director, Translumina Therapeutics, who was present during the data presentation, was very excited with results and its presentation at this prestigious forum. He stated “We are excited with this first long term data which is a new milestone and a benchmark for efficacy and safety of DES Worldwide. Yukon Choice PC showing the lowest Stent thrombosis rates compared to Xience and Cypher at 10 years creates a strong testimony that this technology is truly next generation in terms of safety.

Prof Adnan Kastrati, Principal Investigator of ISAR Test 4 and the **Director of Cardiac Cath Lab** at **German Heart Centre**, Munich stated “The 10-year results achieved in this trial with new-generation DES provide a strong argument against still existing concerns about the long-term safety of DES”.

He elaborated that Yukon Choice PC uses a unique technology consisting in the combination of special surface modification and low polymeric load for controlled and optimal release kinetics of an anti-proliferative drug. The excellent results are a confirmation of the great and durable performance of this device.

Yukon Choice PC stents are manufactured at the Dehradun facility of Translumina Therapeutics, which holds around 15 per cent share of the Rs 1,500 crore stents market in India. The trial ISAR-TEST 4 compared Yukon Choice PC against Xience (manufactured by Abbott Vascular, USA) in 2603 patients in Germany for a follow-up period of 10 years.

It is interesting to note that National Pharmaceutical Pricing Authority (NPPA) had put an upper ceiling of MRP in Feb 2017 by slashing the MRP of DES by over 70%. This move proved to be extremely beneficial for domestic manufacturers to make their high end technologies available to the hospitals at a time when multinational players were withdrawing their DES citing unaffordability. **Translumina Therapeutics** emerged a stronger player post price ceiling as it offered high quality and proven DES at the ceiling prices.

“I wish to dedicate this success to our Prime Minister Shri Narendra Modi who created a belief about the possibility of manufacturing high-end medical devices in India. He has provided an encouraging and conducive ecosystem for the manufacturing of complex technologies in India,” **said Punita Sharma, Co-Founder, Translumina Therapeutics.**

The DES market in the World was dominated by US multinationals for more than 15 years since the launch of DES. Most of the pivotal randomized trials of DES had a maximum follow-up for up to 5 years. With more young patients getting CAD, cardiologists from all over the world were anxious to get some insights on the long-term performance of the new generation DES in terms of efficacy and safety.

“The long-term data from the ISAR-TEST 4 trial shall not only increase the confidence of Cardiologists on these new generation DES but shall also reassure patients who have received these DES for the treatment of coronary artery disease. I am pleased that one of these technologies is coming from India which shall create immense positivity and high acceptance for Indian manufactured DES world over” **said Dr. Robert Byrne**, **Deputy Director of Cardiology** at **German Heart Center** and **Senior Author** of the presented study.