Abbott Unveils Late-Breaking Data Showing Intravascular Imaging Via OCT Can Improve Stent Procedural Outcomes, Especially In Complex Cases

• Data from the landmark ILUMIEN IV trial, the first randomized imaging trial with global representation, has the potential to change clinical practice related to stent placement

• The study proved that intravascular imaging with OCT improves physicians' ability to place and expand a stent to maximize the open space within the blood vessel

• The ILUMIEN IV trial also found that OCT guidance is associated with a lower risk of adverse events related to safety

AMSTERDAM – Aug. 27, 2023 – Abbott today announced late-breaking data from the first-of-its-kind ILUMIEN IV OPTIMAL PCI (ILUMIEN IV) clinical study, a randomized global imaging trial. The study found that during percutaneous coronary interventions (PCI), guidance with optical coherence tomography (OCT) compared to angiography helps physicians achieve improved stent expansion for a greater minimal stent area (MSA). According to the study, OCT guidance during PCI is associated with a lower risk of stent thrombosis (ST), a potentially fatal complication of PCI procedures.

The results of ILUMIEN IV were presented as a late-breaking clinical trial at the European Society of Cardiology (ESC) Congress 2023 in Amsterdam, Netherlands (August 25-28, 2023) and simultaneously published in The New England Journal of Medicine.

Currently, coronary angiography (use of X-ray to assess blood vessels) is the standard of care for guidance when physicians implant stents to treat patients with coronary heart disease. OCT imaging provides doctors with additional high-definition images that improve visualization of vessel structure, giving actionable data that translate into patient benefits, according to the new ILUMIEN IV findings. These findings have the potential to shift physicians' approaches to treating patients with complex coronary disease.

"The ILUMIEN IV results should have a major impact on clinical practice," said Gregg W. Stone, M.D., the ILUMIEN IV study chairman, director of academic affairs for the Mount Sinai Health System and professor of medicine (cardiology) and population health science and policy at the Icahn Mount Sinai. "The demonstration that stent thrombosis is reduced by approximately two-thirds with OCT is especially important as most patients who develop stent thrombosis die or have a heart attack. OCT guidance also reduced angiographic complications and led to better stent implantation."

ILUMIEN IV included patients with medication-treated diabetes and or complex-artery disease exclusively. The study evaluated OCT-guided stent implantation compared to stenting using angiography alone in 2,487 patients from 18 countries at 80 sites across numerous regions of the world, from India to the U.S. and Japan to Europe.

The study showed:

Improved stent expansion. ILUMIEN IV data showed OCT guidance resulted in a statistically significant 7% increase in MSA compared to angiography guidance alone. A larger MSA has shown correlation with a reduction in future adverse events in previous studies. [1],[2]
Reduced risk of future blockages. OCT guidance was associated with a 64% reduction in ST rates, resulting in a statistically significant difference compared to angiographic guidance.
Additional safety benefits. OCT guided PCIs vs. angiography was associated with a 39% reduction in cardiac death and 24% reduction in target vessel myocardial infarction, respectively.

While the study met its primary imaging endpoint of improving MSA, it did not achieve superiority in reducing the primary clinical endpoint, target vessel failure (TVF), a composite of cardiac death, myocardial infarction (MI) and target vessel revascularization (TVR) at two years. Despite the numeric reductions in both cardiac death and target vessel MI when OCT was used, the lack of differentiation in TVR may have been impacted by the COVID-19 pandemic, regional variations in routine practice, and access to healthcare.

"The ILUMIEN IV data demonstrate the impact that OCT guidance can have when treating patients with complex coronary disease," said Nick West M.D., chief medical officer and divisional vice president of global medical affairs at Abbott's vascular business. "In these cases, angiography alone simply cannot match the precision afforded by OCT to determine a treatment plan."

Ultreon™ Software, the latest OCT offering from Abbott, is the only intracoronary imaging solution on the market powered by artificial intelligence, guiding stents to be placed with precision. This leading technology provides enhanced views of coronary anatomy and blockages to help support physicians' decision-making in real time.

About Abbott:
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[1] Prati F, Romagnoli E, La Manna A, et al. Long-term consequences of optical coherence tomography findings during percutaneous coronary intervention: the Centro Per La Lotta Contro L'infarto - Optimization Of Percutaneous Coronary Intervention (CLI-OPCI) LATE study. EuroIntervention 2018;14:e443-e51

[2] Katagiri Y, De Maria GL, Kogame N, et al. Impact of post-procedural minimal stent area on 2-year clinical outcomes in the SYNTAX II trial. Catheter Cardiovasc Interv 2019;93:E225-e34.