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R&D Roundup, October 2019: TCT Brings More Transcatheter Valve Results, New Product Launches, Reassuring Data On Paclitaxel Risk

by Reed Miller

An overview of October's ten most-read *Medtech Insight* articles on topics related to research and development of new medical technology.

Highlights of *Medtech Insight*'s coverage of research and development news in October include presentations of new clinical trial data at the Transcatheter Therapeutics Conference in San Francisco, several new product announcements, and the release of new data from Germany that may reassure physicians about the safety of paclitaxel-coated vascular devices.

Boston Scientific Corp.'s Acurate neo self-expanding transcatheter aortic valve replacement (TAVR) system performed worse than Edwards Lifesciences Corp.'s Sapien 3 TAVR in the SCOPE I trial. Jonas Lanz of Bern University Hospital in Switzerland presented the 30-day outcomes from SCOPE I at the Transcatheter Cardiovascular Therapeutics (TCT) conference, held in San Francisco at the end of September. Boston Scientific expects the next generation of Acurate neo, Acurate neo2, to yield better results than Acurate neo. The company expects to launch Acurate neo2 in 2020.

Also at TCT, Michael Mack of the Baylor Health Care System in Plano, TX, presented the three-year results from the <u>COAPT</u> trial <u>which confirmed Abbott Laboratories Inc.</u>s' MitraClip transcatheter mitral valve replacement device can improve the prognosis of functional heart failure patients. Suzanne Baron from the Lahey Hospital and Medical Center in Burlington, MA, <u>presented a cost-effectiveness analysis of the COAPT results</u> showing that MitraClip was cost-effective compared to medical therapy.

As cardiovascular interventionists were meeting at TCT, the North American Spine Society

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convened its annual meeting in Chicago, where <u>robotic spine-surgery technologies were a major topic of discussion</u>. At the meeting, <u>NuVasive Inc.</u> unveiled its new Pulse robotic spine surgery system and <u>Globus Medical Inc.</u> showcased a new imaging platform and interbody module.

On 8 October, the *European Heart Journal <u>published a review of German insurance data from 65,000 patients showing no long-term increase in mortality* associated with paclitaxel-coated devices used to treat peripheral artery disease. Interventionalists and regulatory agencies have been carefully examining real-world data on paclitaxel-coated devices since a meta-analysis published in December 2018 showed a 90% higher five-year mortality rate in patients treated with drug-coated devices used to treat peripheral artery disease.</u>

Among the major trial announcements in October was <u>Medtronic PLC</u>'s <u>launch of a pivotal trial of its EV ICD</u>, <u>an implantable cardioverter defibrillator without a transvenous lead</u>. The company expects EV ICD will prove to be more cost-effective than standard implantable cardioverter defibrillators (ICD) because its substernal lead will create fewer complications than traditional transvenous ICD leads.

<u>Exact Sciences Corp.</u> and the Mayo Clinic <u>announced their collaboration on a 150,000-patient</u> <u>clinical trial of Exact's Cologuard colon cancer test</u>. The <u>Voyage</u> trial will track outcomes of patients tested with Cologuard for at least seven years.

<u>Medtronic PLC launched its artificial intelligence endoscopy system, GI Genius, during United European Gastroenterology Week in Barcelona</u>. Medtronic will market it through a distribution agreement with Dublin-based Cosmo Pharmaceuticals. In a recent study comparing GI Genius to white-light endoscopy, GI Genius achieved 99.7% sensitivity per lesion, with a false-positive rate of less than 1%.

<u>Abbott Laboratories announced an update to its Merlin patient care network</u>, which works with the CardioMEMS HF sensor for heart failure patients. The new version allows physicians to send patients and their caregivers custom messages through a mobile app rather than just prescripted messages. The company expects it will promote more constructive interactions between heart failure patients and their doctors.

Tom O'Brien, worldwide president of <u>Ethicon Inc.</u>'s endomechanical division, <u>talked to Medtech Insight about his company's launch of the new Echelon circular powered stapler</u>. The <u>Johnson & Johnson</u> subsidiary believes this technology will overcome the limitations of current circular staplers and reduce the number of significant complications in the complex surgeries for colorectal, gastric or esophageal cancers.

In a Start-Up Spotlight, <u>Medtech Insight provided an update on Miach Orthopaedics Inc.</u>, the developer of the Bridge-Enhanced ACL Repair (BEAR) technology as an alternative to

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conventional anterior cruciate ligament reconstruction surgery. Trials have shown BEAR can restore torn ligaments to normal strength and function and the Boston-based company expects it to earn de novo clearance from the US Food and Drug Administration soon.

The table below lists the 10 most-read research and development articles in *Medtech Insight* in October, ranked in the order of popularity.

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