Apollo Endosurgery Announces DDW 2019 Clinical Highlights

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AUSTIN, Texas--(BUSINESS WIRE)--Apollo Endosurgery, Inc. ("Apollo") (Nasdaq:APEN), a leader in less invasive medical devices for gastrointestinal and bariatric procedures, today announced highlights from DDW 2019 which took place from May 18th to May 21st in San Diego.

During the 3-day conference, there were over 40 clinical presentations that described results from the use of Apollo's products in various clinical situations of which over 30 related to procedures that used the OverStitch endoscopic suturing system. Some of the noteworthy abstracts concerning OverStitch that were presented at DDW are highlighted below.

Endoscopic Sleeve Gastroplasty (ESG)

Long-Term Follow up and Outcomes After ESG for Treatment of Obesity (5 Year Data).

This abstract included the first 5-year patient data on the ESG procedure. Of those patients who had reached the 5 year follow-up mark, 69% of patients remained at least 10% below their initial total body weight with an average total body weight loss ("TBWL") of 14.5%.

Authors: Edward Villa, Christopher Grant Chapman, Center for Endoscopic Research and Therapeutics, University of Chicago, Chicago, Illinois, United States.

This meta-analysis evaluated the effectiveness of ESG in terms of TBWL, excess body weight loss ("EBWL"), and body mass index ("BMI"). Five studies with 550 patients showed pooled 6-month TBWL of 15.6% and five studies with 365 patients were used for pooled 12-month TBWL of 17.0%. For EBWL, six studies with 337 patients were used for pooled 6-month EBWL of 56.3% and four studies with 223 patients were used for pooled 12-month EBWL of 67.8%. Finally, five studies with 301 patients were used to derive pooled 6-month BMI decrease of 13.1% and five studies with 332 patients for pooled 12-month BMI decrease of 14.5%.

Evaluation of Weight Loss and Adverse Events Associated with ESG: A Pooled Analysis with Systematic Review.
Authors: Zohair Ahmed 1, Najib Nassani 1, Jean M. Chalhoub 2, Brian R. Boulay. 1
1Gastroenterology and Hepatology, University of Illinois at Chicago, Chicago, Illinois, United States; 2Gastroenterology and Hepatology, University of Massachusetts Medical Center, Springfield, Massachusetts, United States.

The pooled analysis included eleven studies (prospective and retrospective) of ESG published between January 2013 and October 2018 and included 477 patients. The pooled TBWL was 16.5% at 6 months. The review identified no serious adverse events or patient mortality.

ESG for Obesity: Improved Body Composition at 1-Year Follow-Up.
Authors: Adrian Sartoretto 2, George Marinos 2, Zhixian Sui. 1,2 The University of New South Wales, Randwick, New South Wales, Australia, 2The BMI Clinic, Double Bay, New South Wales, Australia.

This study analyzed 121 consecutive patients who underwent ESG in an outpatient setting from October 2016 to January 2018. At one year, the average TBWL was 17% and 80% of patients had lost more than 10%. Unique to this study was the evaluation of body composition. On average, there was a reduction in body fat mass of 15.7 kg, and an increase in lean body mass of 3.5 kg, and a reduction in visceral fat mass of 1.4 kg. The authors suggested that the increase in lean body mass and improved body composition lowers the risk of weight regain following an ESG.

The authors also reported that there were no major intra or post procedure complications.

Authors: Avik Sarkar 1, Augustine Tawadros 1, Iman Andalib 1, Haroon M. Shahid 1, Amy Tyberg 1, Resheed Alkhairi 1, Monica Gaidhane 1, Prashant Kedia 2, Keshav Kukreja 2, Elizabeth S. John 2, Bryce Bushe 2, Ma Gualuape Martinez 4, Felipe Zamarrica 4, Mine C. Carames 5, Juan C. Carames 5, Fernando Casasrovigdez 6, Vincenzo Bove 3, Guido Costamagna 3, Ivo Boskoski 3, Michel Kahaleh. 1Gastroenterology, Robert Wood Johnson, New Brunswick, New Jersey, United States; 2Gastroenterology, Methodist Hospital, Dallas, Texas, United States.
This was an international, multicenter, retrospective study reviewing the outcomes of ESG in centers starting an ESG program. The study reported technical success in 100% of the patients in all six centers, a mean procedure time of 89 minutes, and no significant adverse events. These results demonstrated equivalence in outcomes for new ESG centers as compared to previous studies by experienced ESG centers.

**Bariatric Surgery Revisions**

**Endoscopic Suturing for Weight Regain After Sleeve Gastrectomy: Multicenter Series.** Authors: Eric J. Vargas 1, Jose Nieto 2, Andrew C. Storm 4, Lea Fayad 3, Fateh Bazerbachi 1, Reem Matar 1, Vivek Kumbhari 3, Bahram K. Abu Dayyeh. 1 1Gastroenterology, Fondazione Policlinico A. Gemelli, Roma, Italy; 2Gastroenterology, Hospital Juarez de Mexico, Mexico City, Mexico; 3Gastroenterology, Santander Hospital, Reynosa, Mexico; 4Gastroenterology, Hospital Central de la Policía, Bogota, Colombia.

Weight regain is a common occurrence following sleeve gastrectomy weight loss surgery. This was a multicenter retrospective cohort study that reported on the use of endoscopic suturing to address patient weight regain following sleeve gastrectomy. Mean percentage TBWL at 1, 2, 3, 6, and 9 months was 5.8%, 9.9%, 10.2%, 12.7%, and 18.5%, respectively following the revision. The study showed that using OverStitch for revision of sleeve gastrectomy after weight regain was safe and an effective treatment as an adjunct to lifestyle and pharmacotherapy.

**Comparison of Endoscopic and Surgical Revisions in the Treatment of Weight Regain Following Roux-en Y Gastric Bypass.** Authors: Pichamon Jirapinyo, Ethan Dwane Maahs, Christopher C. Thompson, Brigham & Women's Hospital, Boston Massachusetts, United States; Medicine, Ann Arbor, Michigan, United States; Hitchcock Medical Center, Lebanon, New Hampshire, United States; Johns Hopkins Medicine, Baltimore, Maryland, United States; Yale University School of Medicine, New Haven, Connecticut, United States.

Weight regain is a common occurrence following Roux-en Y gastric bypass ("RYGB") surgery. Revision options for these patients include Transoral outlet reduction ("TORe"), an endoscopic procedure that uses endoscopic suturing, and surgical RYGB revision. The authors conducted a matched cohort study of patients who underwent either endoscopic or surgical revision of RYGB for treatment of weight regain. At six months the endoscopic and surgical groups had lost on average 11.2% and 10.3%, respectively, of their total body weight and at twelve months the endoscopic and surgical groups had lost on average 13.9% and 12.6% of their total body weight. The rates of serious adverse events were 5.6% and 38.9% for the endoscopic and surgical groups, respectively. Endoscopic revision using suturing offered greater safety and comparable weight loss to surgical revision.

**Non-bariatric intervention**

**Determining Appropriate Reimbursement for Innovative Endoscopic Devices Using Cost-Minimization Analysis: Endoscopic Suturing to Prevent Stent Migration for Benign Esophageal Strictures.** Authors: Eric Dinesh Shah 1, Amy E. Hosmer 2, Arpan H. Patel 1, Shannon Morales 1, Ryan Law. 1 1Gastroenterology, Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire, United States; 2The Ohio State University, Columbus, Ohio, United States; 3Division of Gastroenterology, Michigan Medicine, Ann Arbor, Michigan, United States.

The authors developed a decision analytic model comparing fully-covered metal stent placement with or without stent anchoring using an endoscopic suturing device for non-malignant conditions (fistula, leak, perforation or stricture) from a payer perspective. The model accounted for technical success rates of suture placement, clinically significant adverse events with suturing and stent migration rates with or without endoscopic suturing based on a recent systematic review. The authors concluded that a defined reimbursement pathway for endoscopic suturing is justified to prevent stent migration.

**Endoscopic Rectal Reconstruction After Removal of Large Rectal Lesions.** Authors: Sergey V. Kantsevoy, Shira Levihim, Alan Chen, Amit Raina, Paul J. Thuluvath. Mercy Medical Center, Baltimore, Maryland, United States.

The study evaluated the technical feasibility and effectiveness of endoscopic reconstruction of rectal mucosa using the OverStitch endoscopic suturing system to prevent immediate and delayed adverse events after the en bloc endoscopic removal of large rectal lesions. Reconstruction of the rectal mucosa in all patients was successful and all patients were discharged home with rectal reconstruction and none of the study patients had either immediate or delayed adverse events. The study concluded that endoscopic rectal reconstruction was effective in preventing immediate and delayed adverse events after the endoscopic removal of large rectal lesions.

**About Apollo Endosurgery, Inc.**

Apollo Endosurgery, Inc. is a medical technology company focused on less invasive therapies to treat various gastrointestinal conditions, ranging from gastrointestinal defect repairs to the interventional treatment of obesity. Apollo's device-based therapies are an alternative to invasive surgical procedures, thus lowering complication rates and reducing total healthcare costs. Apollo's products are offered in over 70 countries today and include the OverStitch™ Endoscopic Suturing System, the OverStitch Sx™ Endoscopic Suturing System, and the ORBERA® Intragastric Balloon.

Apollo's common stock is traded on Nasdaq Global Market under the symbol "APEN." For more information regarding Apollo Endosurgery, go to: [www.apolloendo.com](http://www.apolloendo.com) [5].

**Cautionary Note on Forward-Looking Statements**

Certain statements in this press release are forward-looking statements that are subject to risks and uncertainties that could cause results to be materially different than expectations. Important factors that could cause actual results to differ materially include: reports of adverse events related to our products, outcomes of clinical studies, developments in medical
technology, regulatory approvals and extensive regulatory oversight by the FDA or other regulatory bodies, unfavorable media coverage related to our products or related procedures, reimbursement decisions by private or government payors, physician adoption and recommendations of procedures utilizing our products and other factors detailed from time to time in the reports Apollo files with the Securities and Exchange Commission, or SEC, including its Form 10-K for the year ended December 31, 2018 and its Form 10-Q for the three months ended March, 31, 2019. Copies of reports filed with the SEC are posted on Apollo’s website and are available from Apollo without charge. These forward-looking statements are not guarantees of future performance and speak only as of the date hereof, and, except as required by law, Apollo disclaims any obligation to update these forward-looking statements to reflect future events or circumstances.

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