lines of Polish Agency for Health Technology Assessment. RESULTS: As a result of a systematic search of publications, one single-blind, randomized clinical trial (Fahimi 2010), fulled the predefined inclusion criteria and therefore the clinical effectiveness of ECP in analysed indications. Based on identified clinical trials it could be concluded that there is clinically relevant response to ECP treatment among patients with acute or chronic GvHD. The highest improvement was observed among patients with chronic GvHD and in skin with mucosa, liver and lungs involvement among patients with cGvHD. Moreover, it was showed that ECP treatment is connected with reduction in the use of immunosuppressant (mainly steroids) in both groups of patients: acute or chronic steroid-refractory GvHD. The reduction in steroid dose allows to reduce the risk of life-threatening bacterial, viral and fungal infections. ECP is very well tolerated procedure. Infrequent adverse events are usually mild and seldom led to discontinuation of the treatment. CONCLUSIONS: Results obtained from clinical trials included in the systematic review showed that there exists clinical benefit associated with the use of ECP in the treatment of pediatric and adult patients with steroid-refractory, steroid-dependent acute or chronic GvHD.

PM08
ONE YEAR EVALUATION OF EFFECTIVENESS AND DEVICE COMPLICATION OUTCOMES IN THE HELPING EVALUATE REDUCTION IN OBESITY (HERO) STUDY
Cubon C1, Torre MO2, Deggoo AN, Burk CT3, Robinson JM4, Diegidi RP5
1Surgical Weight Loss Centre, Mississauga, Ontario, Canada, 2Allergan Medical, Goleta, CA, USA, 3Allergan, Inc., Irvine, CA, USA, 4Allergan, Inc., Laguna Beach, CA, USA, 5Allergan, Inc., Bedminster, NJ, USA

OBJECTIVES: To evaluate real-world effectiveness and device complication outcomes of the LAF-BAND AP® System adjustable gastric band (LAGB) one year after surgical implantation. METHODS: HERO study is a non-randomized, single-arm clinical trial registered at ClinicalTrials.gov (NCT01302 score=5). The study included 50 severely or morbidly obese subjects from 29 centers in North America, Europe, and Australia implanted with LAGB. In the current analyses, the mean change in body mass index (BMI) and percentage excess weight loss (%EWL) at 1 year are determined. RESULTS: Mean change in BMI and %EWL at 1 year was 9.3±5.2 kg/m² and 41±35%, respectively. CONCLUSIONS: The results supported the use of LAGB as a weight loss tool in the management of severe obesity. This study suggests good clinical outcome in patients with severe to morbid obesity.

PM09
A COMPARATIVE ASSESSMENT OF COST IMPLICATIONS OF NOVEL DRUG VERSUS NOVEL DEVICE-BASED TREATMENTS FOR STROKE PREVENTION IN ATRIAL FIBRILLATION
Amoroso S1, Amoroso S2, Peppa R3, Da Deppo L1, Garfield S5
1CJR Orthopedics, Wayland, MA, USA, 2Boston Scientific, Natick, MA, USA, 3Boston Scientific, Genova, Italy, 4Boston Scientific, Milan, Italy

OBJECTIVES: After decades of warfarin as the dominant strategy for stroke prevention in atrial fibrillation (SPAF), new treatments are available. These include new pharmaceuticals like dabigatran etexilate and a device based approach, left atrial appendage closure (LAAC). Studies have compared the economics of pharmaceutical treatments, but the cost implications of the device-based approach with high initial procedural costs compared to these new drugs, with high annual costs for life, have not been demonstrated. This analysis compares overall costs of SPAF with LAAC to dabigatran 110mg twice daily. METHODS: An Excel-based cost impact model was developed using data from PROTECT-AF (Holmes 2009) and RE-LY clinical trial (Lip et al 2009). The base case assumed that 50% of eligible patients were f atable to receive LAAC, combined with conventional therapy vs conventional therapy alone in the treatment of AF. RESULTS: The model was run in three scenarios. In the most likely scenario, patients on LAAC had 1.5% of the costs compared to SPAF, and were attributed with 26% of the outcomes. CONCLUSIONS: This study highlights the need for decision makers to consider the totality of long-term costs and clinical implications of lifetime treatment strategies for SPAF.