

## IP121.

**Is It a Warning Beacon? Insight From the Manufacturer and User Facility Device Experience Database About the Beacon Tip Catheter Recall**

Andrew Schwieder,<sup>1</sup> Michael Amendola<sup>2</sup>, <sup>1</sup>Virginia Commonwealth University School of Medicine, Richmond, Virg; <sup>2</sup>Virginia Commonwealth University Medical Center, Richmond, Virg

**Objectives:** Beacon Tip (Cook Medical, Bloomington, Ind) catheter is a common type of angiographic catheter. On April 15, 2016, the U.S. Food and Drug Administration (FDA) issued an unclassified recall owing to complaints of tip splitting and/or fracture. The Manufacturer and User Facility Device Experience (MAUDE) Database was established by the FDA to allow for voluntarily reporting of adverse outcomes with medical devices. We set forth to examine how reports to the MAUDE changed before and after this catheter recall.

**Methods:** The MAUDE database was accessed in December 2018 for all MAUDE entries for the Beacon Tip 2 years before and after the recall. The database was searched for days to report from index date, catheter French size, delayed in presentation, if additional procedure was undertaken, and if material was left in the patient. The threshold for an additional procedure was defined as any intervention requiring a new site of entry for removal of foreign material.

**Results:** A total of 144 entries were examined: 64 before the recall (44.4%) and 80 after the recall (55.6%; Table).

**Conclusions:** In examining the MAUDE database, we have found there were more entries after the FDA recall. There were fewer delayed presentations and material left in the patient in the postrecall period. There was no statistically significant change in the French size, days to report or additional procedures in comparing the time periods. These data are encouraging in terms practitioners' responsible behavior after an endovascular catheter recall as captured by this national complication database.

**Table.** Manufacturer and user facility device experience (MAUDE) database entries

	Prerecall (n = 64)	Postrecall (n = 80)	P value
Mean days to reporting	43.7 ± 65.5	54.7 ± 88.2	.41 <sup>b</sup>
Injury	84.4	80	.52 <sup>a</sup>
Mean French size	4.4 ± 0.47	4.5 ± 0.52	.05 <sup>b</sup>
Delayed presentation	21.9	3.8	.001 <sup>a</sup>
Additional procedure	18.8	20	1.0 <sup>a</sup>
Material left in the patient	29.7	12.5	.01 <sup>a</sup>

<sup>a</sup>Fisher's exact test.

<sup>b</sup>Two-tailed t-test. Values are mean ± standard deviation or percent.

**Author Disclosures:** M. Amendola: Nothing to disclose; A. Schwieder: Nothing to disclose.

## IP123.

**Vascular Interventions in Gynecologic Surgery Are Uncommon But Are Associated With Major Morbidity and Mortality**

Scott R. Levin, Susanna W. de Geus, Nyia L. Noel, Alik Farber, Michael K. Paasche-Orlow, Jeffrey J. Siracuse. Boston University School of Medicine, Boston, Mass

**Objectives:** Vascular repairs during gynecologic operations are uncommon and have been poorly characterized. Our goal was to determine

contemporary incidence, associations, and outcomes of vascular repairs in gynecologic operations across multiple centers.

**Methods:** The National Surgical Quality Improvement Program database (2005-2017) was queried for patients undergoing elective gynecologic operations with vascular repairs performed concurrently or perioperatively. Multivariable analyses evaluated associations with vascular repairs and 30-day postoperative major morbidity (deep wound infection, cardiopulmonary and renal complications, cerebrovascular accident, nerve injury, sepsis, reoperation) and mortality.

**Results:** We identified 201,226 gynecologic operations: hysterectomy (88.3%), myomectomy (5.9%), adnexal (3.5%), vulvovaginectomy (1.1%), nonadnexal tumor/cyst/endometrioma excision (0.5%), ectopic pregnancy treatment (0.4%), and pelvic lymphadenectomy (0.3%). Median age was 46 years and 65.7% of patients were white (65.7%). There were 189 vascular repairs performed in 178 (0.08%) patients and the majority were concurrent (89%). The most common repairs were open intra-abdominal blood vessel repair (51.9%), major intra-abdominal artery ligation (22.2%), vena cava reconstruction/ligation (5.3%), common iliac vein ligation (3.7%), and aorta or great vessel suture repair (3.7%). Most repairs were performed during any hysterectomy (85%) and during operations employing an open surgical approach (71.2%;  $P < .001$ ). In multivariable analysis, vascular repair was seen more often with any hysterectomy (odds ratio [OR], 8.9; 95% confidence interval [CI], 2.62-30.25;  $P < .001$ ), open operations (OR, 5.24; 95% CI, 2.64-10.42;  $P < .001$ ), malignancy (OR, 2.84; 95% CI, 1.78-4.53;  $P < .001$ ), bleeding disorders/chronic anticoagulation (OR, 2.33; 95% CI, 1.02-5.32;  $P = .046$ ), American Society of Anesthesiologists class III to IV (OR, 1.69; 95% CI, 1.22-2.35;  $P = .002$ ), and nonobesity (OR, 1.4; 95% CI, 1.02-1.91;  $P = .035$ ). Vascular repair independently predicted major morbidity/mortality (OR, 7.47; 95% CI, 5.35-10.44;  $P < .001$ ) as did open approach (OR, 1.98; 95% CI, 1.88-2.07;  $P < .001$ ), American Society of Anesthesiologists class III to V (OR, 1.84; 95% CI, 1.75-1.93;  $P < .001$ ), and any hysterectomy (OR, 1.33; 95% CI, 1.23-1.43;  $P < .001$ ).

**Conclusions:** Vascular repairs in gynecologic operations independently predict postoperative morbidity and mortality. We provide contemporary baseline rates and identify patients at higher risk of needing vascular repair.

**Author Disclosures:** S. W. de Geus: Nothing to disclose; A. Farber: Nothing to disclose; S. R. Levin: Nothing to disclose; N. L. Noel: Nothing to disclose; M. K. Paasche-Orlow: Nothing to disclose; J. J. Siracuse: Nothing to disclose.

## IP125.

**Moraxella Catarrhalis Bacteremia Associated With Lower Extremity Bypass Graft Infection: Case Report and Review of Literature**

Travis Sullivan,<sup>1</sup> Leroy Vaughan,<sup>2</sup> Michael Amendola<sup>3</sup>, <sup>1</sup>Virginia Commonwealth University Health System, Richmond, Virg; <sup>2</sup>VA Medical Center, Richmond, Virg; <sup>3</sup>Virginia Commonwealth University Medical Center, Richmond, Virg

**Objectives:** *Moraxella catarrhalis* bacteremia is a relatively rare, possibly underreported, cause of bacteremia in immunocompetent patients. This is a common gram-negative diplococci bacterium of the human upper respiratory flora in which greater than 95% of species produce beta-lactamase. A recent review resulted in only 63 published articles with 66 patients with a common cause owing to respiratory focus. Only 12 more newly published cases were accessible with the vast majority in the pediatric immunocompromised population, none of which involved a lower extremity bypass prosthetic graft.

**Methods:** We present a case of a 64-year-old Caucasian man who underwent a redo right common femoral to below knee popliteal bypass with Gore Propaten graft (W. L. Gore & Associates, Flagstaff, Ariz) as well as proximal superficial femoral and profundus femorus endarterectomies with XenoSure Biologic Vascular Patch (LeMaitre Vascular, Burlington, Mass).