

First-in-Human Study of the Saranas Early Bird Bleed Monitoring System for the Detection of Endovascular Procedure-Related Bleeding Events

[Généreux P, Nazif TM, George JK, Barker CM, Klodell CT, Slater JP, Razavi M, Bueche K, Patel MR, Kaki A, Kirtane AJ, Syed ZA, Muhs BE, Karpaliotis D. J Invasive Cardiol. 2020 Jul;32\(7\):255-261. Epub 2020 Jun 8.](#)

PURPOSE

- To evaluate the safety and accuracy of the Early Bird® Bleed Monitoring System (EBBMS) for the detection of access-site related bleeds in humans undergoing endovascular procedures.

METHODS

- The EBBMS was used during and after endovascular procedures, either as a venous or arterial access sheath.
- The primary endpoint was the level of agreement in bleed detection between the EBBMS and postprocedural computed tomography (CT) as reviewed by an independent core laboratory.

RESULTS

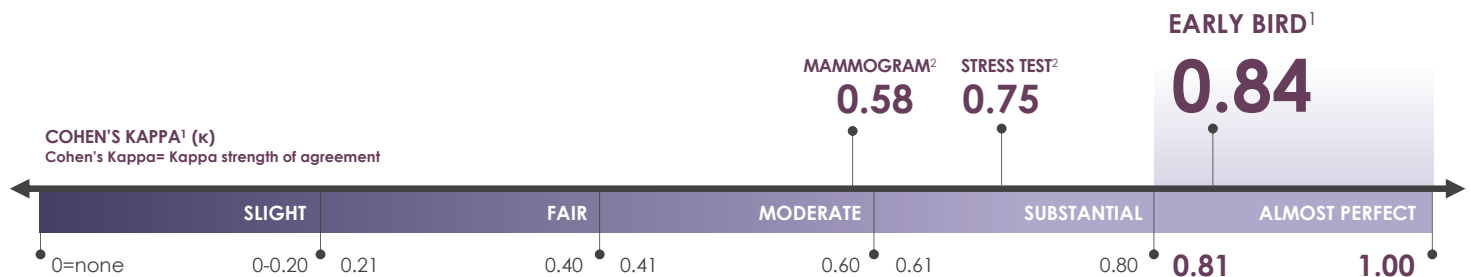
- 60 patients from 5 sites in the U.S. were enrolled and underwent elective endovascular procedures
 - TAVR (67%)
 - PCI (13%)
 - PVAD (8%)
 - BAV (7%)
 - TMVR (4%)
 - EVAR (2%)
- EBBMS detected no bleeds in 21 patients (35%) and bleeds in 39 patients (65%)
 - **Level 1:** 20 patients (33%)
 - **Level 2:** 15 patients (25%)
 - **Level 3:** 4 patients (7%)
- Bleeding detection occurred during the procedure in 31% of patients and post procedure in 69% of patients.
- **The level of agreement between the EBBMS and computed tomography scan was high (Cohen's kappa=0.84).**
- No device-related complications were reported.

AUTHOR CONCLUSIONS





- The EBBMS was safe across a variety of endovascular procedures and detected bleeding events with a high level of agreement with postprocedural CT scan.

First-in-Human Study of the Saranas Early Bird Bleed Monitoring System for the Detection of Endovascular Procedure-Related Bleeding Events (Continued)

EARLY BIRD DETECTS BLEEDS WITH 100% SENSITIVITY AND AS ACCURATELY AS CT SCAN (GOLD STANDARD)



MAJORITY OF BLEEDS DETECTED POST-PROCEDURE

Early Bird Bleed Detection	Total	Intra-Procedure (31%)	Post-Procedure (69%)
No Bleed Detected 	35% (n=21)	-	-
Level 1 	33% (n=20)	25.6% (n=10)	25.6% (n=10)
Level 2 	25% (n=15)	2.6% (n=1)	35.9% (n=14)
Level 3 	7% (n=4)	2.6% (n=1)	7.7% (n=3)

KEY POINTS

- Bleeding events after endovascular procedures are frequent and associated with increased mortality, morbidity, length of stay, and cost.
- The Early Bird is a novel technology designed to detect bleeding early with high accuracy and to monitor its progression.
- Early bleeding detection, during its presymptomatic stage, allows physicians to stay in control by taking preemptive action to impede the progression of bleeding and potentially mitigate its deleterious consequences.

Indications for Use. The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures.

Contraindications. There are no known contraindications for Early Bird.