

### Safety and Accuracy of a Novel Bioimpedance System for Real-Time Detection and Monitoring of Endovascular Procedure-Related Bleeding in a Porcine Models

*Généreux P, Bueche K, Vondran J, Chuang A, Razavi M. J Invasive Cardiol. 2020;32(7):249-254. Epub 2020 June 8.*

#### PURPOSE

- To determine the safety and accuracy of a novel bleed detection system, the Early Bird Bleed Monitoring System (EBBMS), for the detection of simulated internal bleeding and the monitoring of bleed progression associated with endovascular procedures.

#### METHODS

- Prospective, self-controlled, acute animal study including 20 Yorkshire cross swine undergoing endovascular procedures involving cannulation of both femoral artery and vein
- Extravascular bleeding was simulated by a continuous and controlled subcutaneous injection of a blood solution proximal to the access site.
- The capacity of the EBBMS to detect bleed occurrence and to characterize its progression in three levels of severity (level 1, level 2, level 3) was assessed.

#### RESULTS

- Forty EBBMS devices were inserted in 20 animals (40 procedures).
  - Bleeding was appropriately detected in all of them.
- EBBMS achieved a **sensitivity of 100% and specificity of 100%** in detection of bleeding.
- Detected volume of blood significantly increased through each EBBMS level ( $P < .001$ ).
  - **Level 1:**  $31.5 \pm 12.7$  mL
  - **Level 2:**  $77.8 \pm 53.5$  mL
  - **Level 3:**  $145.5 \pm 100.5$  mL
- No significant difference in bleed detection was seen when the EBBMS was inserted in the femoral vein or artery.
- No device-related complications were reported.

#### AUTHOR CONCLUSIONS

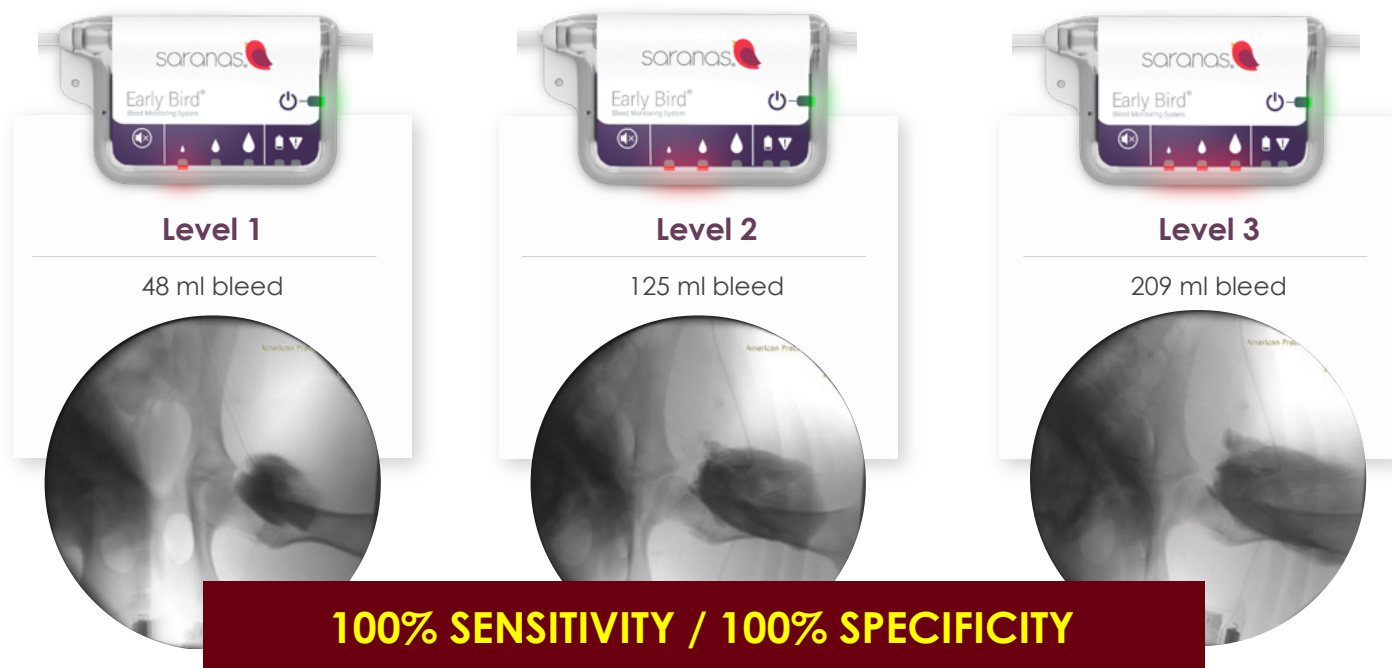
- The EBBMS accurately detected access-related bleeding onset and progression during a simulated endovascular procedure.

**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.

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#### SIGNAL PROGRESSION DRIVEN BY VOLUME



#### 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 accurately detect bleeding early and 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.

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