

### Comparison of a Pure Plug-Based versus a Primary Suture-Based Vascular Closure Device Strategy for Transfemoral Transcatheter Aortic Valve Replacement: The CHOICE-CLOSURE Randomized Clinical Trial

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#### PURPOSE

- To evaluate the clinical efficacy of 2 different vascular closure device (VCD) strategies during transfemoral transcatheter aortic valve replacement (TAVR).
  - Pure plug-based technique (MANTA®, Teleflex®, Wayne, Pennsylvania) with no additional VCDs
  - Primary suture-based technique (ProGlide™, Abbott Vascular, Abbott Park, Illinois) potentially complemented by a small-plug

#### METHODS

- Investigator-initiated, open-label, multicenter, randomized controlled trial
- Patients undergoing transfemoral TAVR were randomly assigned to vascular access site closure using one of the following:
  - MANTA: N = 258 (50%)
  - ProGlide: N = 258 (50%)
- Primary endpoint
  - Rate of in-hospital access-site or access-related major and minor vascular complications according to the Valve Academic Research Consortium (VARC)-2 criteria
- Assessed clinically significant access-site hematomas associated with a bleeding event of at least BARC (Bleeding Academic Research Consortium) type 2 severity

#### RESULTS

- In-hospital access-site or access-related major and minor vascular complications
  - MANTA: 19.4% (50/258)
  - ProGlide: 12.0% (31/258)
  - RR: 1.61, 95% CI: 1.07- 2.44
  - p=0.029
- Access-site or access-related bleeding
  - MANTA: 11.6%
  - ProGlide: 7.4%
  - RR: 1.58, 95%CI: 0.91-2.73
  - p=0.133
- Device failure
  - MANTA: 4.7%
  - ProGlide: 5.4%
  - RR: 0.86, 95% CI: 0.40- 1.82
  - p=0.841
- Time to hemostasis
  - MANTA: 80 s [32, 180]
  - ProGlide: 240 s [174, 316]
  - p<0.001

#### AUTHOR CONCLUSIONS

- Among patients treated with transfemoral TAVR, a pure plug-based vascular closure technique using the MANTA VCD is associated with
  - Higher rate of access-site or access-related vascular complications
  - Shorter time to hemostasis compared to a primary suture-based technique using the ProGlide VCD

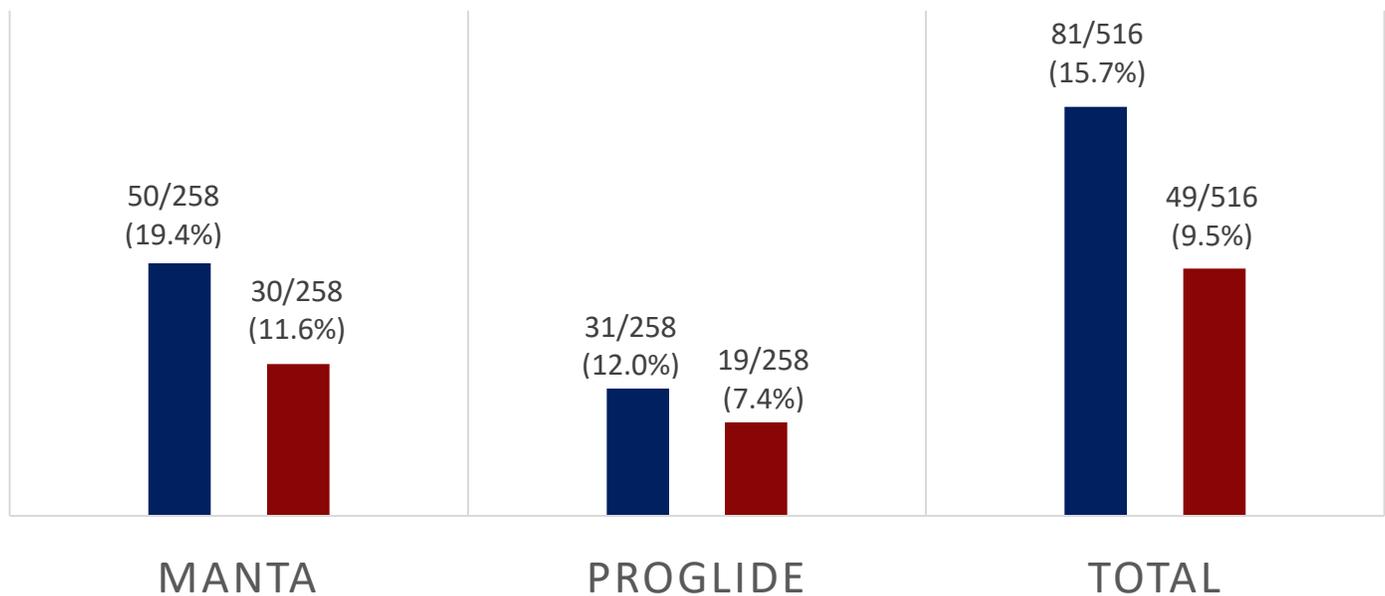
**Indications for Use.** The Early Bird is indicated for the introduction of catheters, catheter balloons, and other diagnostic and interventional devices into the femoral artery or femoral vein while maintaining hemostasis during diagnostic and interventional endovascular procedures.

**Contraindications.** There are no known contraindications for Early Bird.

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## IN-HOSPITAL TAVR OUTCOMES

■ Vascular Complications    ■ Access Site Related Bleeding



### KEY POINTS

- Although there was no significant difference between ProGlide and MANTA, bleeding complications after transfemoral TAVR occurred frequently in patients with either VCDs (**overall 9.5% access-site related bleeding**).
- Preventative and bleeding avoidance strategies, such as the early detection of bleeding events, can reduce the risk of bleeding in a TAVR patient population.

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