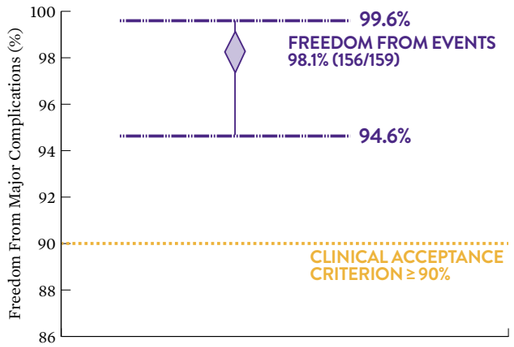
SAFETY AND COMPLICATIONS RESULTS

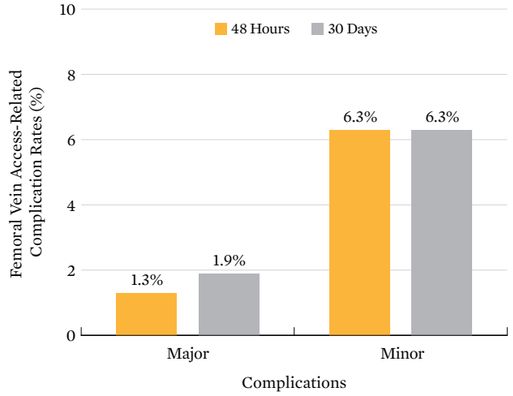
- The primary safety assessment met the pre-defined acceptance criterion
- Access-related major complication rates at 48 hours (1.3%) and 30 days were low (1.9%)
  - Most complications occurred within 48 hours

Freedom From Major Femoral Vein Access-Related Complications[4] Through 30 Days



Note: Primary analysis population used and included only each subject's first occurrence of each event. Purple dotted lines represent 95% confidence intervals.

Femoral Vein Access-Related Complication Rates



Note: Major complications were reported in 3 subjects and events included deep vein thrombosis in target limb (1), significant bleeding requiring transfusion or surgical intervention (1), hematoma not requiring transfusion or surgical intervention (1), access site re-bleeding requiring treatment or re-hospitalization (1), and pseudoaneurysm (1).

1. EVEREST II/REALISM Continued Access Registry Study.
2. The Use of the Perclose ProGlide Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths. Kar, Saibal; Hermiller, James; et al. CRT 2018.
3. Perclose ProGlide, MC, and secondary VCD (used in 1 subject [0.6%]; time to achieve hemostasis unknown).
4. Defined per Valve Academic Research Consortium (VARC)* definition as femoral vein access-related complication leading to death, life-threatening or major bleeding, requiring surgical interventions, hospitalizations, visceral ischemia or neurological impairment. The denominator excludes subjects who withdrew or lost to follow-up before the 30-day visit window (27 days post-procedure) without any femoral vein access-related complications.

*Kappetein et al. *J Am Coll Cardiol*. 2012;60(15):1438-1454.

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PERCLOSE PROGLIDE COHORT IN THE REALISM[1] CLINICAL TRIAL[2]

A prospective analysis was performed to evaluate the safety and effectiveness of Perclose ProGlide (Perclose) in closing large-sized venous access sites through a retrospective data collection. The prospective analysis included subjects in whom Perclose was used as the primary method for large-bore venous access site closure during the MitraClip index procedure with a 24F vascular sheath.

MATERIALS AND METHODS

- 5 sites with high VCD usage and using Perclose for venous closure were included
- Primary analysis cohort (Perclose group); subjects who received at least one Perclose as the intended femoral vein access site closure device

PRIMARY ANALYSIS POPULATION

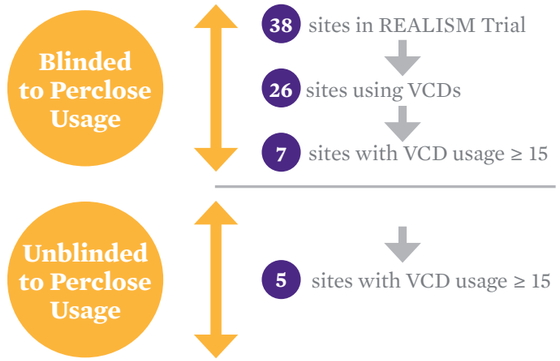
- Predefined subgroup analyses included:
  - + Perclose Alone (without any adjunctive methods other than brief [≤ 10 minutes] manual compression vs. Perclose plus secondary vessel closure method)
  - + One Perclose vs. Two Percloses

PRIMARY ENDPOINT

- Rate of freedom from major femoral vein access site-related complication at 30 days post-procedure, compared to pre-defined clinical acceptance criteria (≥ 90%)

  Note: Data collected at baseline, during or immediately post-procedure, at hospital discharge and at 30 days post-procedure

SITE SELECTION FLOW FOR STUDY



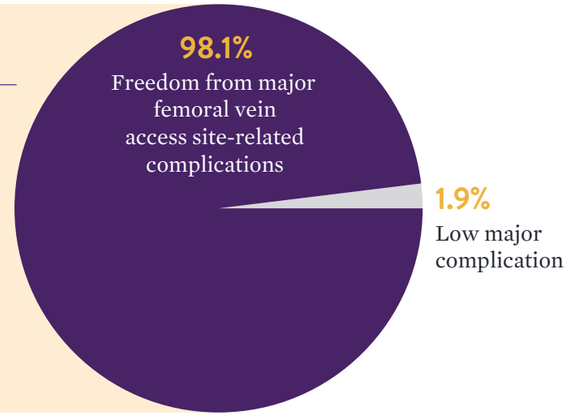
Of the 7 sites with high VCD usage, 1 did not use Perclose and 1 used Perclose for arterial access only.

BASELINE CHARACTERISTICS % (n/N)	PERCLOSE (N=159)
Age at procedure, years (range)	76 (28/98)
Male	52.8% (84/159)
Congestive heart failure	89.2% (141/158)
Hypertension	84.8% (143/158)
Atrial fibrillation	64.7% (99/153)
Coronary artery disease	67.7% (107/158)
Diabetes	26.4% (42/159)
Moderate to severe renal disease	24.5% (39/159)
Chronic pulmonary disease	23.3% (37/159)
NYHA Functional Classification III IV	 59.7% (95/159) 24.5% (39/159)
NYHA = New York Heart Association	

RESULTS

KEY STUDY FINDINGS[2]

- Major complication was low at 1.9%
- Freedom from major femoral vein access site-related complications was 98.1% at 30 days
- Perclose is safe and effective in the closure of venous access site with up to 24F sheath

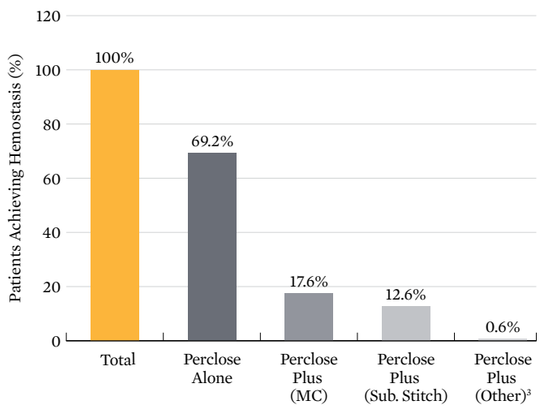


Low major complications at 30 days

SUBJECT RESULTS

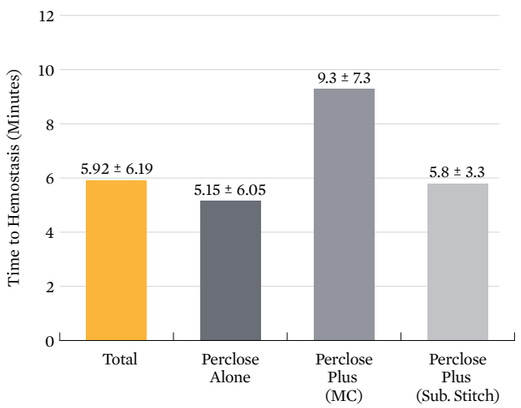
- Patients treated with two Percloses 90.6% [144/159] vs. one Perclose 9.4% [15/159]
- Majority of subjects 69.2% [110/159] were treated with Perclose alone
- "Perclose Alone" group mean time to achieve hemostasis was 5.15 ± 6.05 minutes

Achievement of Hemostasis With Perclose Alone vs. Perclose Plus Adjunctive Methods



MC = manual compression, Sub. = subcutaneous.

Mean Time to Achieve Hemostasis



Data shows mean ± standard deviation.