Abbott

CORONARY | PERIPHERAL

CRT 2018 POSTER PRESENTATION

The use of Perclose ProGlide™ SMC System for Venous Access-Site Closure up to 24F Sheaths

SAIBAL KAR, MD; JAMES HERMILLER, MD; ET AL. CRT 2018

The Use of the Perclose ProGlide® Suture Mediated Closure (SMC) Device for Venous Access-Site Closure up to 24F Sheaths

Saibal Kar, MD[1]; James Hermiller, MD[2]; Kyler Conn[1]; Yu Shu, PhD[3]; and Kunal Sampat, MS[3]

[1]Cedars-Sinai Medical Center, Los Angeles, CA; [2]St. Vincent Heart Center of Indiana, Indianapolis, IN; [3]Abbott Vascular, Santa Clara, CA

ABSTRACT

Trial Name: Safety and Performance of Perclose ProGlide® Vascular Closure Device in Managing Large Hole Venous Access Site

Purpose: Evaluate the safety and performance of ProGlide in closure of venous access site in subjects with a large-caliber femoral vein sheath (24F).

Materials and Methods: This was a prospective analysis of retrospective data from the EVEREST II REALISM (REALISM) MitraClip study population who had received either ProGlide or manual compression (MC) as the intended method for venous access site closure. Seven (7) high frequency vessel closure device (VCD) usage sites from the REALISM study were selected as the study sites. The primary analysis cohort (ProGlide group) was defined as subjects who received at least one (1) ProGlide as the intended femoral vein access-site closure device. The primary analysis was the evaluation of ProGlide against an acceptance criterion of ≥90% for the rate of freedom from major femoral vein access-site related complications at 30-days post procedure.

Results: A total of 159 subjects from five (5) of the seven (7) high frequency VCD sites were included in this analysis. Two (2) high frequency VCD sites did not use any ProGlide for the femoral vein access site closure. The subjects enrolled were elderly with a mean age of 76 years, 53% were male, and presented with multiple comorbidities. The venous sheath for the MitraClip access site was 24 French (F). The primary endpoint of the rate of freedom from major femoral vein access-site related complication at 30-day was 98.1% (95% CI [94.6%, 99.6%]), meeting the predefined acceptance safety criterion of 90%. Of the 159 cases in which ProGlide was used, 144 received 2 ProGlides and 15 received 1 ProGlide. In the ProGlide cohort, 69.2% (110/159) of the subjects received ProGlide only as the intended hemostasis method, 17.6% (28/159) achieved hemostasis with ProGlide plus MC, in 12.6% (20/159) a secondary closure method (subcutaneous stitch) was used along with ProGlide, and in 0.6% (1/159) ProGlide plus MC and a secondary closure method other than subcutaneous stitch was used. Hemostasis at the time of the index procedure using ProGlide was achieved in an average time of 5.92 ± 6.19 minutes.

Conclusion: The study results have demonstrated that the safety assessment of ProGlide met the predefined acceptance safety criterion. The use of ProGlide in the closure of large bore venous access sites was associated with a low 30-day major complication rate.

INTRODUCTION

- Large-caliber femoral vein sheaths for transcatheter structural heart devices can increase venous access-site complications.
- Hemostasis for large-sized venous access sites is commonly achieved via manual compression (MC) or by a subcutaneous figure-of-eight stitch followed by prolonged application of a compression bandage (usually ≥12 hours). However, this combination leads to patient discomfort and extended immobilization, which in turn may lead to additional complications.
- The potential benefits of using a vascular closure device (VCD) are allowing closure of access site even in the heparinized condition and potentially early ambulation and discharge.
  - Currently, Perclose ProGlide® (ProGlide) is indicated for closing the common femoral artery access site of patients who have undergone diagnostic or interventional catheterization procedures using 5F to 21F sheaths.
  - However, studies have reported successful off-label use of ProGlide for the closure of venous access sites with up to 24F large-sized vascular sheaths.[1-6]

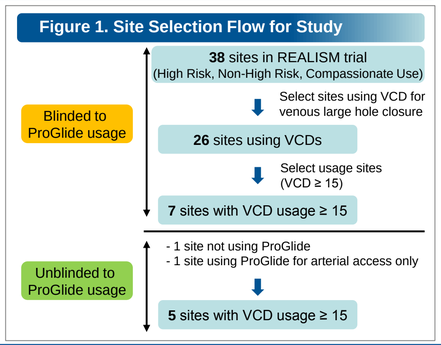
OBJECTIVE

The primary objective of this study was to evaluate the safety and performance of ProGlide in the closure of the venous access site in subjects treated with a large-caliber femoral vein sheath (24F).

METHODS

- This study was a prospective analysis of retrospectively collected data from the EVEREST II and REALISM continued access registry for the continued data collection on the use of Abbott Vascular's MitraClip System in "real world" conditions (NCT01940120).
  - In the REALISM study, ProGlide was used off-label, at the physician's discretion, for closure of large hole venous access sites.
- Clinical trial sites with high VCD usage (≥ 15 VCD cases during study period) and using ProGlide for venous closure were included (**Figure 1**)

Figure 1. Site Selection Flow for Study



METHODS cont'd

- Primary analysis population: subjects who received at least one ProGlide as primary intended femoral vein access-site closure device during the MitraClip index procedure (VCD usage per study site, see **Figure 5**; Baseline characteristics, see **Table 1**). Predefined subgroup analyses included:
  - ProGlide Alone (without any adjunctive methods other than brief [≤ 10 minutes] MC) vs ProGlide Plus (ProGlide plus secondary vessel closure method)
  - One ProGlide vs Two ProGlides
- 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%)
- Data were collected at baseline, during or immediately post procedure, at hospital discharge, and at 30-days post procedure

Table 1. Key Baseline Demographics and Risk Factors

Baseline Characteristics, % (n/N)	ProGlide (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% (134/158)
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 Class III IV	 59.7% (95/159) 24.5% (39/159)

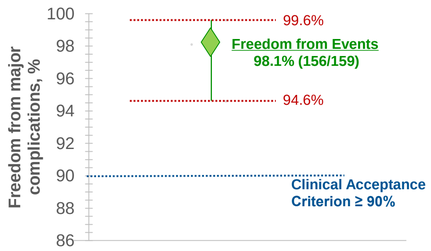
NYHA = New York Heart Association;
REALISM = Real World Expanded Multicenter Study of the MitraClip® System study;
VCD = vascular closure device

RESULTS

- The study cohort consisted of older men and women with a high rate of co-morbidities (**Table 1**)
- Most subjects were treated with two ProGlides (90.6% [144/159] versus one ProGlide, 9.4% [15/159])
- The primary safety assessment met the pre-defined acceptance criterion (**Figure 2**)
- Access-related major complication rates at 48 hours (1.3%) and 30 days were low (1.9%) (**Figure 3**)
  - Most of the complications occurred within 48 hours (**Figure 3**)
- The majority of subjects (110/159 [69.2%]) were treated with ProGlide alone (**Figure 4A**)
- In the "ProGlide Alone" group, mean time to achieve hemostasis was 5.15±6.05 min (**Figure 4B**)
- The annual ProGlide usage varied widely among the 5 clinical trial sites, ranging from 3.2 to 21.9 cases per enrollment year. Despite the low level of usage and experience, complication rates were low (**Figure 5**).

Primary Assessment Met Pre-Defined Acceptance Criterion

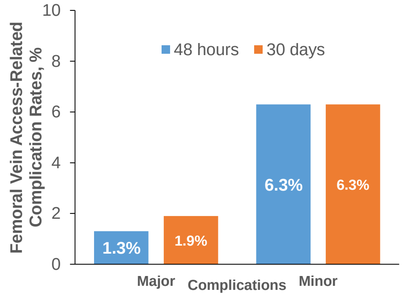
Figure 2. Freedom from Major Femoral Vein Access-Related Complications* Through 30 Days



* Defined per Valve Academic Research Consortium (VARC)[7] 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.
Note: Primary analysis population used and included only each subject's first occurrence of each event. Red dotted lines represent 95% confidence intervals.

Low Incidence of Access-Related Complications

Figure 3. Femoral Vein Access-Related Complication Rates

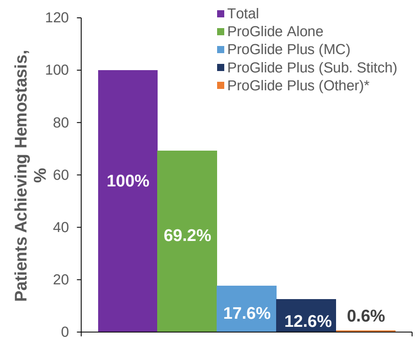


Note: Major complications were reported in 3 subjects and events included deep vein thrombosis in target limb (1), significant bleeding requiring transfusion or surgical intervention (1), hematoma not requiring transfusion or surgical intervention (1), access-site re-bleeding requiring treatment or re-hospitalization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

RESULTS cont'd

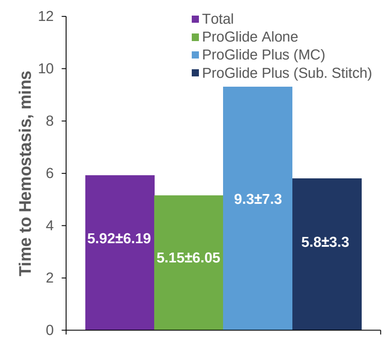
Figure 4. Achievement of Effective Hemostasis

A. Achievement of Hemostasis with ProGlide Alone vs ProGlide Plus Adjunctive Methods



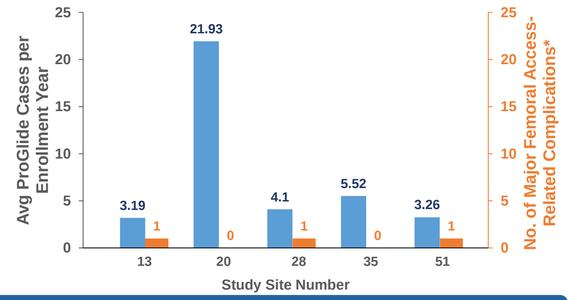
MC = manual compression, Sub. = subcutaneous;
* ProGlide, MC, and secondary VCD (used in 1 subject [0.6%]; time to achieve hemostasis unknown).

B. Mean Time to Achieve Hemostasis



Data shows Mean ± standard deviation

Figure 5. Annual VCD Use and No. of Major Femoral Access-Related Complications by Study Site



VCD = vascular closure device
Note: Average number of VCD cases per enrollment year for 19 sites with <15 VCD usage was 1.36.
* Defined as femoral vein access-related complication leading to death, life-threatening or major bleeding, requiring surgical interventions, hospitalizations, visceral ischemia or neurological impairment.

STUDY LIMITATIONS

- Prospective analysis on retrospective data set
- Not a randomized trial
- No comparator group

CONCLUSIONS

The use of ProGlide in venous closure following the insertion of a 24F sheath was associated with a low 30-day major complication rate (98.1% freedom from major complications). All patients achieved hemostasis with ProGlide with or without nonsurgical methods. Additionally, 69.2% of patients achieved hemostasis with one ProGlide alone in 5.15 mins. This analysis has demonstrated the safety and efficacy of the use of ProGlide in the closure of large bore venous access sites.

REFERENCES

1 Geis et al. EuroIntervention. 2015;10(11):1346-1353.
2 Ruter et al. J Invasive Cardiol. 2013;25(10):508-510.
3 Hamid et al. Catheter C ardiovasc Interv. 2013;81(4):586-590.
4 Kong. JACC Cardiovasc Interv. 2014;64:B247.
5 Yeo et al. J Invasive Cardiol. 2016;28(2):40-43.
6 Yap et al. EuroIntervention. 2014; Lond14A-eAbstract18.
7 Kappetein et al. J Am Coll Cardiol. 2012;60(15):1438-1454.

FINANCIAL DISCLOSURES

Saibal Kar: Research support and consulting honoraria from Abbott Vascular
James Hermiller: Consultant and proctor for Abbott; Consultant for Medtronic and Edwards
Kyler Conn: None
Yu Shu and Kunal Sampat: Abbott Vascular employees

This study was funded by Abbott Vascular.

CAUTION: This product is intended for use by or under the direction of a physician. Prior to use, reference the Instructions for Use, inside the product carton (when available) or at *eifu.abbottvascular.com* or at *medical.abbott/manuals* for more detailed information on Indications, Contraindications, Warnings, Precautions and Adverse Events.

Information contained herein for DISTRIBUTION outside the U.S. only. Check the regulatory status of the device in areas where CE marking is not the regulation in force.

Illustrations are artist's representations only and should not be considered as engineering drawings or photographs. Photos on file at Abbott.

Abbott International BVBA
Park Lane, Culliganlaan 2B, 1831 Diegem, Belgium, Tel: 32.2.714.14.11

www.cardiovascular.abbott


Abbott