IJC Heart & Vasculature 13 (2016) 6–13

Contents lists available at ScienceDirect

IJC Heart & Vasculature

journal homepage: http://www.journals.elsevier.com/ijc-heart-and-vasculature

Femoral arterial closure using ProGlide® is more efficacious and cost-effective when ambulating early following cardiac catheterization

Aravind Sekhar, M.D., Ph.D. [a,b], Brad S. Sutton, M.D., M.B.A. [a,b], Prafull Raheja, M.D. [a,b], Amr Mohsen, M.D. [a,b], Emily Anggelis, B.S. [a,b], Chris N. Anggelis, M.D. [a,b], Matthew C. Keith, M.D., Ph.D. [a,b], Buddhadeb Dawn, M.D. [c], Samantha Straton, R.N. [a,b], Michael P. Flaherty, M.D., Ph.D. [a,b,*]

[a] Division of Cardiovascular Medicine, University of Louisville, Louisville, KY, United States
[b] Jewish Hospital Heart and Lung Institute, Louisville, KY, United States
[c] Division of Cardiovascular Diseases, Kansas University Medical Center, Kansas City, KS, United States

ARTICLE INFO

Article history:
Received 22 July 2016
Received in revised form 8 September 2016
Accepted 24 September 2016
Available online 11 October 2016

Keywords:
ProGlide
Vascular closure
Cost
Cardiac catheterization

ABSTRACT

Objective: This was a prospective, single-center study evaluating the efficacy and cost-effectiveness of early ambulation (within 30 min) following femoral artery closure with the ProGlide® suture-mediated vascular closure device (PD) in patients undergoing diagnostic cardiac catheterization compared with manual compression.
Background: It is unclear whether early ambulation with ProGlide is safe or is associated with patient satisfaction and cost savings as compared with manual compression (MC).
Methods and results: Inclusion criteria were met in 170 patients (85 PD and 85 MC patients). Patients ambulated 20 ft. within 30 min (PD) or after the requisite 4 h recumbent time (MC) if feasible. Primary endpoint was time-to-ambulation (TTA) following device closure. We also directly compared the safety of closure, times-to-hemostasis (TTH), -ambulation (TTA) and -discharge (TTD) with MC and, using a fully allocated cost model, performed cost analysis for both strategies. Multivariate analysis was used to determine predictors of patient satisfaction. The primary endpoint of safe, early ambulation was achieved following closure (mean of 27.1 ± 14.9 min; 95% confidence interval [CI] 25.2–30.2). Predictors of patient satisfaction in the PD group were absence of pain during closure, decreased TTA, and drastic reductions in TTD; the latter contributed indirectly to significant cost savings in the PD group (1250.3 ± 146.4 vs. 2248.1 ± 910.2 dollars, respectively; $P < 0.001$) and incremental cost savings by strategy also favored closure over MC ($84,807).
Conclusions: ProGlide is safe and effective for femoral artery closure in patients who ambulate within 30 min after cardiac catheterization; translating into improved patient satisfaction and substantial cost savings.

1. Introduction

Femoral artery cannulation continues to be the predominant route for vascular access in coronary and structural heart interventions in the United States (US) despite the increasing use of radial artery access [1–3]. However, femoral artery access site bleeding complications carry an increased morbidity and mortality as compared to other access routes [4]. Therefore, proficiency with arterial puncture and closure (either manual or device-related) is crucial and plays a vital role in the safety of diagnostic cardiac catheterization (cath). Minimizing femoral artery access site complications remains the rationale for the introduction and widespread use of vascular closure devices (VCD). However, with the wide variety of devices available each with unique mechanisms for vessel closure, the safety and efficiency of access site management using VCDs remains controversial. Large meta-analyses, registry and single-center studies provide conflicting data regarding VCD-related vascular complication event rates as compared with manual compression (MC) [5–10]. Of the major advantages of VCDs, reduced time-to-ambulation (TTA), when associated with no increase in vascular complications [11], is among the most desirable in terms of patient satisfaction and cost-effectiveness [12,13]. A wide variety of closure devices are currently available for use, each classified based on their method of closure; either collagen or procoagulant-based (e.g., Angioseal®, St. Jude Medical, St. Paul, MN), clip/staple-based (e.g., Starclose®, Abbott Scientific, Abbott Park, IL) or suture-mediated (e.g., Perclose ProGlide® and ProStar®, Abbott Scientific, Abbott Park, IL) [14].

Abbreviations: VCD, vascular closure devices; MC, manual compression; PD, Perclose ProGlide device; TTH, time-to-hemostasis; TTA, time-to-ambulation; TTD, time-to-discharge.

* Corresponding author at: Physiology & Biophysics, Division of Cardiovascular Medicine, University of Louisville School of Medicine, Rudd Heart and Lung Center, 201 Abraham FlexnerWay, Suite 800, Louisville, KY 40202, United States.
E-mail address: mpflah01@louisville.edu (M.P. Flaherty).

http://dx.doi.org/10.1016/j.ijcha.2016.09.002

Although data are available for the use of older versions of the suture-mediated VCDs in the setting of percutaneous coronary intervention, there are no data directly comparing femoral vessel closure using ProGlide (PD; the most recent generation in the Perclose device series) with manual compression, specifically following diagnostic cardiac cath. Moreover, whether patients can be safely ambulated and discharged early following femoral artery closure has only been demonstrated once with the StarClose VCD [12]. To date, this has not been prospectively evaluated with the Perclose devices. Here, we assessed prospectively, the safety and efficacy of early ambulation following use of ProGlide in patients undergoing diagnostic cardiac catheterization as compared to MC. We further assessed patient satisfaction and the cost-effectiveness of ProGlide-mediated vessel closure versus MC.

2. Methods

2.1. Patient population and study design

This study was a prospective study approved by the institutional review board at the University of Louisville School of Medicine (Louisville, Kentucky) and conducted at a single, high-volume quaternary-care center in Louisville Kentucky. Baseline patient characteristics are shown in Table 1. Two hundred and twelve consecutive patients presenting from April to June (2012) for elective diagnostic cardiac cath using either the right or left femoral arterial approach signed an informed consent. One hundred and seventy of these patients met entry criteria (Table 2) and were enrolled. Screen failures were excluded based on clinical and/or angiographic criteria. Catheterizations were performed under conscious sedation, using 5 or 6 French AvantiPlus® (Cordis, Bridgewater, NJ) or Pinnacle® (Terumo, Somerset, NJ) sheaths. We compared manual compression (85 patients) to vessel closure using the ProGlide suture-mediated VCD (PD) (85 patients). Of the six board-certified interventional cardiologists deploying the PD in the study, all had greater than three years (range 3.2–9 years) of experience using Perclose devices.

Table 1
Baseline characteristics of 170 patients enrolled.

Demographic characteristics			
	ProGlide	Manual compression	*P*
	$n = 85$	$n = 85$	
Age — year			
Mean	60 ± 12	59 ± 10	NS
Male sex — no. (%)	73 (86)	76 (89)	NS
Race — no. (%)			
White	64 (75)	66 (78)	NS
Black	20 (24)	17 (20)	NS
Asian	0 (0)	2 (2)	NS
Other	1 (1)	0 (0)	NS
Body mass index (BMI)[a]			
Mean	27 ± 3.0	25 ± 4.0	NS
Hypertension — no. (%)	70 (82)	64 (75)	NS
Diabetes — no. (%)	36 (42)	37 (44)	NS
Dyslipidemia — no. (%)	54 (63)	61 (72)	NS
Smoking — no. (%)	66 (78)	65 (77)	NS
Current	34 (52)	39 (60)	NS
Previous	32 (48)	26 (40)	NS
Family history CAD — no. (%)	30 (35)	21 (25)	<0.05
Procedure characteristics			
Pre-procedural angiography — no. (%)	85 (100)	85 (100)	NS
Retrograde puncture — no. (%)	85 (100)	85 (100)	NS
Right groin approach — no. (%)	78 (92)	83 (98)	NS
Vessel diameter ≥5.0 mm — no. (%)	85 (100)	85 (100)	NS

Continuous data are presented as means ± SD; categorical data are presented as counts (percentages).
[a] Body mass index is the weight in kilograms divided by the square of the height in meters.

Table 2
Major inclusion and exclusion criteria.

Major inclusion criteria
Candidates for elective cardiac diagnostic catheterization performed percutaneously via the right or left femoral arterial approach
Vessel size >5 mm by visual estimate
Access using 5F or 6F introducer sheath
Confirmed angiographic absence of current or previously treated significant (≥50% stenosis) femoral artery atherosclerosis
Lack of obvious fluoroscopic evidence of significant femoral vessel calcification
Confirmed post-procedural puncture site between the common femoral artery bifurcation and inferior border of the inferior epigastric artery
Major exclusion criteria
Vessel size <5 mm by visual estimate (or plaque burden resulting in lumen <5 mm)
Inability to control post-procedural hypertension in the cath lab (systolic ≥180 mm Hg, diastolic ≥100 mm Hg)
Inability to ambulate 20 ft due to co-morbidity or functional limitation
Access site complications prior to ProGlide deployment

2.2. Study device description

The ProGlide is the fifth generation of the single-use 6F disposable suture-mediated Perclose devices that delivers two needles and a single suture through the arterial wall (adventitia to lumen) for closure of the femoral arteriotomy following percutaneous diagnostic or interventional cath or peripheral procedures that utilize 5–21F sheaths. The ProGlide single device delivery system is for use with any 0.035 in. guidewire and contains a "knot-pusher". Further details of its use have been previously reported [14].

2.3. Procedural definitions and study variables

All patients underwent pre-procedural fluoroscopy-guided identification of the mid-femoral head to determine the puncture site. Post-cardiac cath femoral angiography was performed on all patients. In patients who met inclusion criteria (Table 2), hemostasis was achieved either by (i) placement of the PD with a check for hemostasis made and time recorded, or (ii) following transfer to holding for manual compression. If immediate hemostasis was not achieved manual compression was performed for 3 min and additional adjunctive compression followed as necessary; not to exceed 5 min (min) or device success was not achieved. If additional time for manual compression was required, this time was recorded. In the MC group, manual compression was performed by experienced cath lab nurses with the application of a Neptune® hemostasis Pad(s) (TZ Medical Inc., Portland, OR) and the holding time was determined by the French size of the sheath used; with 3 min of compression per French size being the standard. If after 15 (5F) or 18 (6F) min, hemostasis was not achieved, manual pressure was held for additional 5 min increments until hemostasis was achieved. The time in min from removal of sheath to when no compression was required to control bleeding at the access site was defined as time-to-hemostasis (TTH). Mechanical compression devices were not used as an adjunct to achieve hemostasis in any patient.

Once hemostasis was achieved, patients were ambulated. Prior to ambulation, the access site was assessed for bleeding and/or complications. The primary endpoint for the study was mean TTA following PD artery closure. Early ambulation was defined as TTA ≤30 min in the PD patients and the requisite recumbent time for MC patients was 4 h from TTH. The 4 h limit for the MC group is an institutional policy and consistent with previous reports [15,16] and was followed to ensure congruence between groups when assessing complication rates. Patients in the device group underwent a 'challenge test' consisting of simultaneous head and leg lifts to assess the adequacy of hemostasis. Those in the PD group who did not achieve hemostasis within 5 min of device deployment or who converted to manual compression were ambulated at the discretion of the interventionalist to ensure patient