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Prospective Evaluation of Factors Affecting the Safety and Efficacy of Perclose Proglide Vascular Closure Device in Neurovascular Interventions

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Abstract:

Background: Most of the neurointerventional procedures use various anticoagulants, antiplatelets, and fibrinolytic drugs, and it can predispose arterial access site complications. Safe and efficient closure arteriotomy site has extreme importance in reducing the morbidity. Percutaneous vascular closure devices (VCDs) enable us to close the arteriotomy sites. In this prospective study, we evaluated the factors affecting the safety and efficacy of Perclose ProGlide VCD in neurovascular interventions.

Materials and Methods: In this prospective study, we have evaluated the safety and efficacy of 327 Perclose ProGlide devices deployed in 217 patients who underwent various neurointerventions in our institute from October 2014 to October 2016. Time to achieve hemostasis (TAH) was calculated for various groups and the statistical significance of mean values between groups was estimated.

Results: Out of the 327 Perclose ProGlide deployed, complication rate was 0.91% and the mean TAH was 77.14 s. Assessment of TAH mean value showed statistically significant prolongation of TAH in obesity and those with larger arterial sheaths. Age, sex, post-heparin ACT, peri-procedure medications, and type of diseases had no significant role in increasing TAH. The evaluation also showed the presence of a learning curve in using this device.

Conclusion: Perclose ProGlide VCD is safe and effective in closing the arteriotomy after neurointerventions. Obesity and larger arterial sheaths are independent factors prolonging the TAH. Learning curve associated with this device mildly increases the hemostatic time and device-related complications.

Key Words:

Antiplatelets, neurointervention, obesity, time to achieve hemostasis, vascular closure device

Key Messages:

Complications related to the vascular access can be prevented effectively by using vascular closure devices. They have high safety profile with less complication rate.

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The common femoral artery is the preferred access artery in most of the neurointerventions and manual compression is the usual method to achieve hemostasis. Vascular access site complications, like local bleeding, hematoma, pseudo aneurysm, arteriovenous fistula, retroperitoneal hematoma, are reported up to 4.2%.[1] The complication rate in manual compression is directly related to the duration of compression and operator's experience.

Safe and efficient closure of the vascular access site has extreme importance in reducing the morbidity after neurointerventions. This is more important in those procedures which use postprocedure anticoagulants, antiplatelets, or both.

Neurointerventional procedures like stent-assisted aneurysm coiling, flow diverter placement, cranial, and spinal dual arteriovenous fistula embolization, acute stroke thrombectomy, and carotid stenting might require postprocedure antiplatelets, anticoagulants, or both. Delaying postprocedure medications for early sheath removal or delaying sheath removal for continuing medications can invite unnecessary complication and result in increased morbidity.

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Percutaneous vascular closure devices (VCDs) enable the operator to remove femoral arterial sheaths safely and immediately after any neurointerventional procedures. Compared to the manual compression, use of VCDs reduces patient discomfort, discharge time, and reduces total expense.[2,3] The commonly used VCDs in neurointerventions are Angio-Seal (St Jude Medical, USA), Mynx (Cordis, USA), Perclose ProGlide (Abbot Vascular, USA). Literature reports varied results regarding the safety and efficacy of VCDs in femoral arterial closure.[4]

Perclose ProGlide suture-mediated closure (SMC) device [Figure 1] is a VCD used for percutaneous deployment of suture for closing common femoral arteriotomy. The device is composed of a sheath, handle, plunger, and knot pusher/trimmer device. The Perclose ProGlide tracks over a 0.038 guidewire and it delivers a single monofilament polypropylene suture. In this prospective study, we evaluated the factors affecting the safety and efficacy of Perclose ProGlide VCD in neurovascular interventions.

Materials and Methods

This is a single-center prospective study that included 217 consecutive patients undergoing various neurointerventions, in which Perclose ProGlide was used as femoral arterial closure device from October 2014 to October 2016. The procedures were performed by two interventional neuroradiologists with 10 and 6 years of experience, respectively. Institutional Ethics Committee approval was obtained and informed consent was taken from all patients prior to the procedures. Patients were selected for the device mainly based on the use of peri-procedure anticoagulants, antiplatelet, and fibrinolytic usage in which the manual compression for achieving hemostasis was difficult. The other factors considered for the device usage were old age (above 50 years) and the presence of obesity with body mass index (BMI) more than 30 kg/m^2. Patients who did not meet these criteria were excluded from the study. Totally, 217 patients were selected and 327 devices were placed, including both right and left femoral arteries.

For all patients, the activated clotting time (ACT) was assessed before the administration of heparin (pre-ACT) and just before the device placement (post-ACT). All patients received 5000 units of heparin and 1000 units after every hour. Post-heparin ACT was kept 2–2.5 times than the baseline in all cases involving stent or flow diverter placement. After all neurointerventions, to assess the size and presence of arterial diseases, common femoral arterial angiogram was obtained through the arterial sheath.

Perclose ProGlide deployment steps

1. Passage of 0.035″ Radifocus (Terumo, Tokyo, Japan) guidewire through the arterial sheath up to the thoracic aorta;
2. Removal of the arterial sheath over the guidewire, keeping the guidewire *in situ*;
3. Passing the Perclose ProGlide up to the proximal skin marker of the device, followed by the removal of guidewire;
4. Suture deployment and removal of the device;
5. Pulling the suture thread (blue end) for knot application;
6. Suture approximation and tightening and trimming of suture using suture pusher/trimmer;
7. If no active bleeding, a light bandage will be applied, and in case of ongoing bleeding, manual compression is applied.

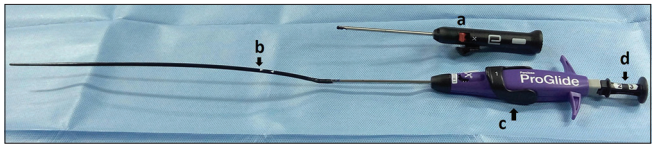

Figure 1: Perclose ProGlide device – (a) Knot pusher/trimmer, (b) sheath, (c) handle, (d) plunger

Time to achieve hemostasis (TAH) was calculated in seconds from Step 5 to complete cessation of bleeding.

Patients were clinically observed very closely for first 6 h for any puncture site complications. Femoral and distal arterial pulsations were assessed by palpation at 24 h, at the time of discharge, and during the follow-up at 6 weeks. All device and puncture site-related complications were documented during this period.

Statistical analysis

For statistical comparison of TAH between various groups, the data were presented as mean [standard deviation (SD)]. Since both left and right values are used in the analysis, to incorporate the correlated nature of the data, the statistical significance of mean values between groups was based on linear models using generalized estimating equations method. *P* values <0.05 were taken as the criteria for statistical significance. Microsoft Excel and IBM Statistical Package for the Social Sciences (SPSS) Statistics for Windows version 21 were used for data analysis.

Results

A total of 327 ProGlide devices were used in 217 patients, which indicated bilateral arterial sheaths were used in about 50% of patients (patient demographics, procedures performed, and mean TAH values are included in Table 1, while analysis of TAH is included in Table 2). Bilateral arterial access was taken mainly for cranial dural arteriovenous fistula embolization, flow diverter placement, and stent-assisted coiling. In all the procedures, left-side sheaths were of 6F size. Mean TAH for

Table 1: Patient's demographic data and TAH

Total number of patients: 217
Total number of devices: 327 (50% of patients had bilateral sheaths)
Mean age (SD): 49.82 (14.94)
Male:female ratio: 1.3:1
Distribution of ProGlide usage (total 327)
Aneurysm: 135
DAVF: 103
SVM: 30
Stroke: 28
BAVM: 10
Stenting: 21
Mean post-heparin ACT (SD) - 257.96 s (20.28)
TAH in seconds
Maximum: 600, Minimum: 20, Mean: 77.14

TAH: time to achieve hemostasis; DAVF: dural arteriovenous fistula; SVM: spinal vascular malformations; BAVM: brain arteriovenous malformation; ACT: activated clotting time; SD: standard deviation

Table 2: Analysis of TAH against various factors

Factors	TAH mean (SD)	*P*
Age		
<50 yrs	72.18 (78.890)	0.262
>50 yrs	81.64 (76.201)	
Sex		
Male	71.49 (78.416)	0.110
Female	85.36 (75.663)	
ACT Postintervention		
<250 s	89.69 (89.517)	0.087
>250 s	72.12 (71.230)	
Size of the sheath		
6F	59.00 (36.836)	0.060
7F	87.78 (91.984)	0.020
8F	84.75 (77.908)	0.285
9F	65.00 (07.908)	
Type of diseases treated		
Aneurysm	83.04 (81.945)	0.187
DAVF	77.33 (83.604)	0.348
SVM	77.00 (62.541)	0.414
Stroke	76.79 (67.333)	0.432
BAVM	45.50 (19.214)	0.295
Stenting	61.90 (62.958)	
Peri-procedure medications		
No antiplatelets and fibrinolytics	100.78 (99.816)	0.027
Clopidogrel+Aspirin	75.43 (70.642)	0.522
Prasugrel+Aspirin	60.59 (52.704)	0.713
Fibrinolytics	64.21 (61.942)	0.866
Anticoagulants	71.36 (74.254)	0.739
Antiplatelets + anticoagulants	67.13 (58.517)	
Presence of obesity		
Obesity present	110.19 (89.469)	0.031
Obesity absent	74.79 (75.438)	
Learning curve assessment		
First 50 devices	100.39 (73.676)	0.002
51 to 327 devices	70.30 (77.342)	

TAH: time to achieve hemostasis; DAVF: dural arteriovenous fistula; SVM: spinal vascular malformations; BAVM: brain arteriovenous malformation; ACT: activated clotting time; SD: standard deviation

6F sheath was 59 s compared to 87 s for 7F sheath, but this difference did not show statistical significance (*P*-value – 0.06). However, TAH of 7F showed a significant increase compared to other sheaths (*P*-value – 0.02). TAH of 8F and 9F sheaths was not significant due to their less number (7% of total) and also due to the use of Preclose technique in procedures with 9F sheath (3 patients).

TAH in various diseases did not show any significant increase. However, mean TAH of arteriovenous malformation (AVM) patients was low compared to other diseases and this low value is probably due to less aggressive intraprocedure anticoagulation during AVM embolization. Peri-procedure medication also failed to show any significant influence in the prolongation of TAH. Contrary to our expectation, significantly increased TAH was noted for procedures without any antiplatelets or fibrinolytics. A significant number of cases in this group were included during the initial phase of the study. During this initial period, TAH was significantly prolonged due to the learning curve. This was confirmed by high mean TAH (100.39 s) in first 50 patients compared to the remaining patients (70.30 s) with *P* value 0.002.

Obese patients showed significant prolongation of TAH; of this, significant number of patients were females. This reflected in the prolongation of mean TAH in females (71.49 s in males and 85.36 s in females).

Out of this 327 device deployment, clinical complication and device failure rate were 0.91% and 0.61%, respectively. During deployment, two devices failed due to rupture of the suture thread and the arteriotomy was closed with another Perclose ProGlide devices. One patient developed subacute femoral artery thrombotic occlusion, for which surgical thrombectomy and venous patching was done. Two patients developed mild puncture site hematoma 1–2 h after the suture placement, which was controlled with manual compression. Ten patients received manual compression after Perclose ProGlide to stop minor oozing.

All other patients showed good pulsation on palpation at 24 h and at the time of discharge. None of the patients showed any clinically significant change in femoral arterial pulsation at 6 weeks follow-up time. About 50% of the patient underwent re-puncture, and no significant difficulty was experienced during any of the re-puncture.

Discussion

Use of VCD is a great advantage in neurointervention procedures to reduce the access site complications, related morbidity, and help in early ambulation of the patients.

Older generation SMCs are associated with more vascular complications due to the complex steps involved in needle deployment, knot formation, and its approximation. Needle deployment from outside the vessel, improvement in knot formation, suture approximation, and its trimming make the newer SMCs more safe and effective. Perclose ProGlide is a new generation SMC used for femoral arterial closure.

This prospective study evaluated the TAH and various related factors in a large sample of patients undergoing various neurointervention procedures. Our cohort represents the first and the largest prospective study evaluating the factors affecting the efficacy of Perclose ProGlide device in neurovascular interventions. The efficacy of the device was assessed by calculating the TAH after applying the suture knot over the arteriotomy. Our study results showed faster arteriotomy closure and cessation of puncture site bleeding (mean TAH was 77.14 s) with a relatively low rate of complication (0.91%). Previously reported study with an older generation of ProGlide showed greater than 96% success rate and 1% significant complications.[5,6]

One previous study comparing mean time to hemostasis of Angio-Seal and Perclose device showed 5.3 and 46.8 min, which was significantly higher compared to our observation (77.14 s).[7]

The influence of various factors on TAH and their significance of association were assessed. Evaluation of our data failed to show any significant influence of patient's age in prolonging

the TAH. A study by Shah *et al*.[8] also showed age was not a significant factor in arterial closure compared to manual compression. However, Jovin *et al*.[9] showed that older age was associated with significant puncture site complications.

High BMI and increasing size of the arterial sheath has a positive relationship in increasing puncture site complications.[10] Our series also confirmed these observations. Significant increase in TAH was observed in 6F and 7F sheaths. But this association is not seen with larger size sheaths (8F and 9F) probably due to low sample size and use of the Preclose technique with two devices in the case of 9F sheaths. It is recommended to use two devices with Preclose technique if sheath size is more than 7F.[9,11]

Most of the obese patients in our cohort were females and this reflected in the prolongation of TAH in females. The main causes of TAH prolongation in obesity are premature tightening of the suture knot, interposition of soft tissues between the knot and artery, and also the difficulty in knot approximation with the knot pusher.

Postprocedure ACT measured just before the deployment of Perclose ProGlide and types of diseases treated did not show any significant role in prolonging TAH. Studies have shown that only high values of ACT are associated with puncture site bleeding complication after the placement of VCDs.[12]

Evaluation of peri-procedure medications and TAH showed high mean values in patients who did not receive any antiplatelets and fibrinolytics. On further evaluation, it was found that most of these procedures were performed during the initial phase of Perclose ProGlide usage. Because of this, first 50 Perclose ProGlide deployment were taken and evaluated separately. This showed a high mean TAH value in the first 50 patients (mean 100.39 s; *P* value 0.002). This was mainly due to the learning curve associated with this device and the learning curve is significant in SMC devices.[13] Our study did not show any significant association with TAH prolongation and peri-procedure medications. However, few studies showed an increase in puncture site bleeding complications due to antiplatelets and antifibrinolytics.[14,15]

In this cohort, two device failures and two puncture site complications were observed, out of which only one patient developed clinically significant arterial occlusion. Other two were mild puncture site bleeding without any clinical significance. All these device failures and puncture site complications happened during the learning curve period and no significant complications were observed in the later period. Because of this learning curve associated with suture-mediated VCDs, supervised deployment of the least first 25 devices is essential to avoid device failures, vascular injury and related complications.[16]

The main limitation of the study is that this was a single-center study, which gave insights into our experience with Perclose ProGlide VCD. We did not select a comparison group from manual compression and from other devices. Even though it is large sample prospective study, more data and comparison with other devices will definitely provide additional insights into the factors related to the device failure and complications.

Conclusion

Perclose ProGlide VCD is safe and effective in closing the femoral arteriotomy after neurointerventions. Obesity and larger arterial sheaths are independent factors prolonging the TAH. Learning curve associated with this device increases the hemostatic time and device-related complications.

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Conflicts of interest
There are no conflicts of interest.

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