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Efficacy and Safety of the Perclose Closer S Device After Neurointerventional Procedures: Prospective Study and Literature Review

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BACKGROUND AND PURPOSE: **The purpose of this study was to examine the efficacy and safety of the 6F Closer S device (Perclose; Redwood City, CA) versus manual compression to close arteriotomy sites after neurointerventional procedures in both virgin vessels and those previously treated with the device.**

METHODS: **This single-center, multiple-operator, controlled, prospective study included 475 procedures (337 patients) with the device and 79 procedures (79 patients) with manual compression. A substantial number of patients receiving anticoagulation and/or antiplatelet medications were included. Efficacy and safety were evaluated on the basis of the rate of hemostatic success and the incidence of clinically significant complications. The literature was reviewed by using MEDLINE.**

RESULTS: **Overall success rates were 95% in the device group versus 96% in the manual-compression group ($P = 0.78$), and clinically relevant complication rates were 0.6% versus 2.5%, respectively ($P = 0.15$). Success rates significantly declined in vessels previously treated with the device three or more times. However, complication rates did not significantly change. Literature review yielded 12 articles reporting complication rates of 3.2–35% for the device and 2.3%–33.3% for manual compression.**

CONCLUSION: **The device was safe and effective for closing arteriotomy sites in patients undergoing neurointerventional procedures, including those receiving anticoagulation/antiplatelet therapy or those previously treated with the device one or two times.**

Peripheral arterial access sites are used as entry points in an increasing number of invasive vascular procedures, including cardiac, peripheral, and neurologic interventions. The traditional approach to hemostasis after removal of the catheter sheath has been manual compression followed by a period of bed rest. Complications related to the peripheral arterial access site, such as bleeding, hematoma, pseudoaneurysm, intimal dissection, and arteriovenous fistula, are known to occur. The incidence of these complications is 3%–14% in studies of percutaneous coronary interventions of manual compression, and surgical repair is required in as many as 40% of patients with such complications (1, 2). The complication rate may depend on the type of intervention, the duration of manual compression, and the operator's experience (3). Access-site complications increase the length and cost of hospitalization lengths, as well as periprocedural mortality and morbidity rates (1, 2, 4–6).

A number of new devices have been developed to aid in closing the arteriotomy site to reduce complications and hospitalization duration. These devices include collagen plugs (AngioSeal, St. Jude Medical Center, St. Paul, MN; VasoSeal Datascope, Montvale, NJ), balloon-positioning catheters combined with collagen and thrombin (Duett Vascular Solutions, Minneapolis, MN), and a percutaneous suture-closure device (Perclose, Redwood City, CA) (4, 7). Studies of the efficacies of such devices have produced varying results (4, 7–17). Furthermore, the Perclose device has undergone several revisions in the past decade. Few studies have been performed to evaluate recent models (18, 19), and even fewer have be conducted to evaluate the efficacy and safety of repeated use of the device in the same vessel. Therefore, the purpose of this study was to compare use of this device with manual compression—in both virgin and previously treated vessels—in our neurointerventional laboratory. We also reviewed the literature to

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TABLE 1: Baseline characteristics

Characteristic	Device Group (n = 475)	Manual-Compression Group (n = 79)	P Value
Male/Female	197 (41)/278 (59)	30 (38)/49 (62)	>.05
Age (years)[a]	58.8 ± 14.4	50.1 ± 17.0	<.0001
Diabetes	108 (23)	3 (3.8)	<.0001
Coronary artery disease	84 (18)	10 (13)	>.05
TIA/CVA	184 (39)	8 (10)	<.0001
Preprocedural drug			
Heparin	104 (22)	5 (6.3)	.0013
Abciximab	14 (2.9)	0	>.05
Aspirin/clopidogrel	268 (56)	12 (15)	<.0001
Previous device procedures			
0	337 (71)	54 (68)	>.05
1	90 (19)	15 (19)	>.05
2	34 (7.2)	8 (10)	>.05
3	9 (1.9)	1 (1.3)	>.05
4	4 (0.8)	0	>.05
5	1 (0.2)	1 (1.3)	>.05

Note.—Data in parentheses are percentages.
[a] Mean ± standard deviation.

investigate the efficacy and safety of older and newer Perclose devices compared with manual compression.

Methods

This single-center, multiple-operator, controlled, prospective study included 559 consecutive percutaneous femoral neurointerventions performed in 416 patients between March 29, 2002, and April 1, 2004. Institutional review board approval was obtained, informed consent was obtained from all patients. Patients were nonrandomly assigned to one of two groups on the basis of the method used to achieve hemostasis: group A included 337 patients who received the 6F device (Closer S; Perclose) in 475 procedures, and group B included 79 patients who received manual compression in 79 procedures. Patients were preferentially selected for the use of the device according to qualitative criteria, such as obesity, that made manual compression technically difficult, older age (generally >40 years), few or no previous uses of the device in the same vessel, and an absence of vessel calcifications on fluoroscopy. Patients who did not meet these criteria were generally selected for manual compression.

In patients receiving the device, it was used immediately if their activated clotting time was <200 seconds, according to manufacturers' guidelines. Four operators trained in the use of the device (one physician [F.A.] and three registered radiology technicians [T.S.]) performed all procedures. If no ongoing bleeding was present, a light bandage was applied, and the procedure was considered successful. If bleeding from the puncture site continued after the device was deployed, manual compression was allowed for 1 minute. If bleeding persisted after 1 minute, the procedure was considered unsuccessful, and further manual compression was allowed as necessary. Patients were allowed to ambulate 2 hours later if no complications occurred.

Conventional manual-compression therapy consisted of compression at the site if the patient's activated clotting time was <200 seconds. Compression was maintained until hemostasis occurred and was followed by 6 hours of bedrest.

Patients were clinically examined for access-site complications at discharge, and all were contacted by telephone after 24 hours and asked about any possible delayed complications. If the patient had no complaints, follow-up was discontinued. If he or she had complaints, telephone follow-up or office visits were arranged until complications were identified or the symptoms resolved.

Procedural success for the device group was defined as the achievement of hemostasis within 1 minute, with ambulation and discharge within 2 hours. Procedural success for the manual-compression group was the achievement of hemostasis within 30 minutes, with ambulation and discharge within 6 hours. Safety was assessed on the basis of complications such as local infection, need for surgical intervention, need for transfusion, and pseudoaneurysm at time of the procedure or on follow-up.

Statistical Analysis

We compared manual compression and use of the device according to the following variables: type of closure; patient's sex and age; history of diabetes mellitus, coronary artery disease, transient ischemic attack (TIA), or cerebrovascular accident (CVA); anticoagulation, antiplatelet, and thrombolytic therapy; and number of previous device procedures performed on the vessel. Success and complication rates were compared between the device and manual-compression groups and between multiple-procedure groups. Analyses were done by using Fisher exact, χ^2, and Student t tests. All calculations were performed by using SAS (version 8.2; SAS, Cary, NC) with a 5% level of significance.

Results

Baseline characteristics for the two groups appear in Table 1. The device group had significantly more older patients, patients receiving anticoagulants, and patients with diabetes or a history of TIA or CVA than the manual-compression group. Safety and efficacy results overall and for virgin vessels appear in Table 2. Overall success or complication rates did not significantly differ between the device and manual-compression groups. Safety and efficacy results delineated by previous device procedures appear in Table 3. Differences between the groups were significant only for the types of complications in virgin vessels: subintimal dissection and infection in the device group and pseudoaneurysms in the manual-compres-

TABLE 2: Safety and efficacy results overall and in virgin vessels

Result	Overall[a]		Virgin Vessels		
	Device (n = 475)	Manual Compression (n = 79)	Device (n = 337)	Manual Compression (n = 54)	P Value
Success	450 (95)	76 (96)	320 (95)	53 (98)	>.05
Complication	3 (0.6)	2 (2.5)	2 (0.6)	2 (3.7)	>.05
Pseudoaneurysm	1 (0.2)	2 (2.5)	0	2 (3.7)	.0201
Infection	1 (0.2)	0	1 (0.3)	0	>.05
Subintimal dissection	1 (0.2)	0	1 (0.3)	0	>.05
Surgical intervention	3 (0.6)	2 (2.5)	2 (0.6)	2 (3.7)	>.05
Transfusion	0	0	0	0	NA

Note.—Data in parentheses are percentages. NA = not applicable.
[a] All $P > .05$.

TABLE 3: Safety and efficacy results no. of previous device procedures

Result	One Procedure[a]		Two Procedures[a]		Three or More Procedures[a]	
	Device (n = 90)	Manual Compression (n = 15)	Device (n = 34)	Manual Compression (n = 8)	Device (n = 14)	Manual Compression (n = 2)
Success	88 (98)	13 (87)	31 (91)	8 (100)	11 (79)	2 (100)
Complication	0	0	1 (2.9)	0	0	0
Pseudoaneurysm	0	0	1 (2.9)	0	0	0
Infection	0	0	0	0	0	0
Subintimal dissection	0	0	0	0	0	0
Surgical intervention	0	0	1 (2.9)	0	0	0
Transfusion	0	0	0	0	0	0

Note.—Data in parentheses are percentages.
[a] All $P > .05$, when applicable.

TABLE 4: Comparison of safety and efficacy results

Previous Device Procedure	Success		Complications	
	No.	P Value[a]	No.	P Value[a]
0 (n = 337)	320 (95)	NA	2 (0.6)	NA
1 (n = 90)	88 (98)	>.05	0	>.05
2 (n = 34)	31 (91)	>.05	1 (2.9)	>.05
3 (n = 9)	7 (78)	.0256[b]	0	>.05[c]
4 (n = 4)	3 (75)	>.05[b]	0	>.05[c]
5 (n = 1)	1 (100)	>.05[b]	0	>.05[c]

Note.—Data in parentheses are percentages. NA = not applicable.
[a] Compared with results for 0 previous procedures.
[b] Groups with three to five procedures pooled, $P = .0096$.
[c] Groups with three to five procedures pooled, $P > .05$.

sion group. Overall success or complication rates between the device and manual-compression groups did not significantly differ in any of the vessel subgroups. Safety and efficacy results with repeated use of the device in the same vessel appear in Table 4. Complication rates among the groups were not significantly different. Success rates significantly declined only in vessels with a history of three or more previous device procedures.

Discussion

Review of the literature revealed a range in the incidence of peripheral arterial access-site complications after the use of older-generation Techstar (in 1997; Perclose) and Prostar (in 1996; Perclose) devices, with rates of 3.2%–15.2% compared with 2.3%–33.3% for manual compression (4, 9–17). To increase ease of use and reduce complication rates, a newer-generation device (Closer 6F; Perclose) with a number of technical changes was introduced in 2001. The most significant changes were an external rather than an internal needle-deployment system, a simplified knot-management system, and a smaller device size. A MEDLINE search revealed only three studies of the efficacy and safety of the device. Two of these involved human subjects and demonstrated complication rates of 9.1%–35% (18, 19). Table 5 shows summary results of our literature review. Total complications and the incidence of hematomas, arteriovenous fistulas, and pseudoaneurysms are reported for device and manual-compression groups. Infection was infrequently encountered in most series, and therefore not independently considered in this review. However, it was represented under total complications when applicable.

Our data compare favorably with those of previous studies, with overall complication rates of 0.6% in the device group and 2.5% in the manual-compression group ($P = 0.15$). Our data also revealed no significant difference in the success rates between the two groups. All patients successfully treated with the device were able to ambulate and be discharged 4 hours sooner than those in the manual-compression group, reducing hospitalization costs.

As noted earlier, a number of factors have been associated with access-site complications in patients

TABLE 5: Review of the literature

Reference	Device	Total Complications		Hematomas		Arteriovenous Fistulas		Pseudoaneurysms	
		Device	Control	Device	Control	Device	Control	Device	Control
9 (Tron et al, 1998)	Perclose Techstar	5/82 (6.1)	2/67 (3.0)	5/82 (6.1)	2/67 (3.0)	0/82 (0)	0/67 (0)	0/82 (0)	0/67 (0)
10 (Gerckens et al, 1999)	Perclose Techstar	12/298 (4.0)	22/292 (7.5)	11/298 (3.7)	21/292 (7.2)	0/298 (0)	0/292 (0)	1/298 (0.3)	1/292 (0.3)
11 (El Amine et al, 1999)	Perclose Techstar	6/50 (12.0)	4/50 (8.0)	5/50 (10.0)	4/50 (8.0)	0/50 (0)	0/50 (0)	1/50 (2.0)	0/50 (0)
12 (Baim et al, 2000)	Perclose Techstar	8/251 (3.2)	6/264 (2.3)	6/251 (2.4)	3/264 (1.1)	0/251 (0)	0/264 (0)	2/251 (0.8)	3/264 (1.1)
13 (Noguchi et al, 2000)	Perclose Techstar	4/30 (13.3)	10/30 (33.3)	4/30 (13.3)	10/30 (33.3)	0/30 (0)	0/30 (0)	0/30 (0)	0/30 (0)
14 (Rindner et al, 2001)	Perclose Techstar	134/880 (15.2)	215/874 (24.6)	40/880 (4.5)	55/874 (6.3)	2/880 (0.2)	6/874 (0.7)	7/880 (0.8)	16/874 (1.8)
15 (Duffin et al, 2001)	Perclose Techstar, Angioseal	31/280 (11.1)	12/197 (6.1)	25/280 (8.9)	7/197 (3.6)	0/280 (0)	0/197 (0)	0/280 (0)	0/197 (0)
18 (Hahn et al, 2001)	Perclose Closer S	2/22 (9.1)	NA	2/22 (9.1)	NA	0/22 (0)	NA	0/22 (0)	NA
16 (Kahn et al, 2002)	Perclose Closer Plus	145/1420 (10.2)	356/8581 (4.1)	73/1420 (5.1)	255/8581 (3.0)	0/1420 (0)	0/8581 (0)	26/1420 (1.8)	25/8581 (0.3)
17 (Rickli et al, 2002)	Perclose Techstar	8/96 (8.3)	6/97 (6.2)	7/96 (7.3)	5/97 (5.2)	0/96 (0)	0/97 (0)	1/96 (1.0)	1/97 (1.0)
4 (Assali et al, 2003)	Perclose Techstar, Angioseal	18/123 (14.6)	13/123 (10.6)	15/123 (12.2)	12/123 (9.8)	0/123 (0)	0/123 (0)	1/123 (0.8)	0/123 (0)
19 (Henk et al, 2003)	Perclose Closer S	41/117 (32.0)	NA	19/117 (16.2)	NA	0/117 (0)	NA	1/117 (0.8)	NA
Present study	Perclose Closer S	3/475 (0.6)	2/79 (2.5)	NA	NA	0/475 (0)	0/79	1/475 (0.2)	2/79 (2.5)

Note.—Data in parentheses are percentages. NA = not applicable.

undergoing percutaneous procedures. These factors include patient characteristics, the type of intervention, operator experience, and the use of thrombolytic or anticoagulation therapy (3). The use of thrombolytics and anticoagulants has received particular attention. Assali et al (4) reported a complication rate of 14.6% after device procedures in patients treated with glycoprotein IIb/IIIa inhibitors, and Zorger et al (20) reported a complication rate of 11.1% in patients treated with clopidogrel. Therefore, it is notable that the device group had a complication rate lower than that of the manual-compression group despite its increased proportion of obese or older patients; patients with a history of diabetes, TIA, or CVA; patients receiving aspirin/clopidogrel bisulfate (Plavix; Bristol-Myers Squibb/Sanofi Pharmaceuticals Partnership, New York, NY), anticoagulants (e.g., heparin), or thrombolytics (abciximab, ReoPro; Eli Lilly, Indianapolis, IN). Operator experience was comparable between the groups, with the same four operators performing both device and manual compression methods.

Another factor implicated in access-site complications is a history of previous device procedures in the vessel. Razminia et al (21) reported an overall complication rate of 0%–6% in patients undergoing multiple device procedures in the same vessel. Our data device-group patients with a history of previous device procedures in the same vessel suggest that this factor may be less critical than previously thought. One or two previous procedures had no significant effect on the success or complication rate. In patients with a history of three or more procedures, we observed no significant increase in the complication rate, but the success rate significantly decreased. This finding most likely reflects the increased technical difficulty of applying the device in previously treated vessels. In vessels undergoing multiple device procedures, we routinely encountered fibrosis not previously seen at the access site, which made deployment of the device more difficult than it would have been otherwise.

Of note, two of three device complications were identified on follow-up after discharge examination showed normal findings. One complication (an infection) was identified at 72-hour follow-up, and the other (a pseudoaneurysm) was identified at 48-hour follow-up. These observations emphasize the importance of strict follow-up for all patients until they are asymptomatic. In contrast, the third device complication was recognized immediately because of an inability to retract the device from the vessel. During surgical intervention, the device was visualized as being trapped under a calcified plaque.

Study Limitations

This study was a prospective but nonrandomized study; therefore, selection bias was possible. Indeed, several baseline characteristics were significantly different between the study groups. However, in all such discrepancies, the device group had more individuals

with baseline characteristics associated with higher failure and complication rates than did the manual-compression group. Therefore, the differences in baseline characteristics did not seem to improve the safety and efficacy results of the device group.

Our study of the efficacy and safety of repeated use of the Perclose device in the same vessel was limited in power because of the small samples of the high-use groups. Nevertheless, its power was sufficient to return statistically significant findings in several groups, especially when the data were pooled. Research of large samples of vessels with a history of multiple device uses is needed.

In addition, we did not evaluate the incidence of clinically insignificant groin hematomas. Because hematomas accounted for a substantial proportion of overall complications in other studies, this difference may account for our significantly lower complication rates. Adjusting the complication rates of previous studies by removing hematoma-related complications, we found an overall adjusted complication rate of 0%–15.8%. Several groups reported an adjusted complication rate of <1%, which is more comparable to our findings than other reported rates.

Conclusion

The Closer S device was a safe and effective means of closing femoral access sites in patients undergoing neurointerventional procedures. Safety and efficacy of the procedure was maintained in patients with unfavorable baseline characteristics, such as advanced age, history of diabetes, coronary artery disease, TIA, CVA, and anticoagulation/antiplatelet or thrombolytic therapy. Safety and efficacy were also maintained in vessels previously treated with the device one or two times. Use of the device is associated with a low rate of complications and a shortened time to ambulation, making it a useful tool for closing arterial access sites.

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