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INTERVENTIONAL RADIOLOGY

ORIGINAL ARTICLE

Usefulness and safety of the "God's Hand" pneumatic compression device for hemostasis in femoral catheterization

Sungwon Kim
Jae Hyun Kwon
Yoon Hee Han
Jeung Sook Kim

PURPOSE
We aimed to assess the usefulness and safety of the God's Hand pneumatic compression device for hemostasis in patients undergoing percutaneous endovascular procedures via femoral artery.

METHODS
Two hundred thirty-seven patients in whom hemostasis of femoral catheterization was achieved using a God's Hand pneumatic compression device were enrolled. The patients were divided into group A, those in whom the device was applied for four hours, and group B, those in whom the device was applied for two hours, with an additional two hours of bed rest in both groups. Groups A and B were regrouped to groups A′ and B′ using the propensity score matching method (n=65, for both). Chi-squared test and logistic regression models were used to analyze the relationship between the complication rate and patient characteristics and procedure-related factors.

RESULTS
Clinical success was achieved in 216 of 237 patients (91.1%): 63 in group A (84%) and 153 in group B (94.4%); in propensity score matched groups, clinical success was seen in 47 patients in group A′ (81.5%) and 62 patients in group B′ (95.4%). Group B′ showed a higher clinical success rate than group A′ ($P = 0.028$). There were no major complications. In logistic regression models, a negative association was noted between the complication rate and the duration of God's Hand application; however, this association was not statistically significant.

CONCLUSION
The God's Hand pneumatic compression device is effective and safe for the hemostasis of femoral catheterization, and four hours of bed rest is sufficient for hemostasis in selected patients.

Percutaneous endovascular procedures are being performed increasingly as an alternative to surgery. The femoral artery is the most common site for arterial access. Manual compression of the puncture site has been used as a classical method for hemostasis. However, manual compression is associated with personnel demands and effort, fatigue of the operator's hand and arm, prolonged duration of bed rest, and patient discomfort (1–4). Therefore, several alternative devices for the support or replacement of manual compression have been developed, such as arterial closure devices (5, 6) and external compression devices (7, 8). Additionally, pneumatic compression devices have increased in use as an alternative to manual compression or arterial compression devices. A few studies have reported the feasibility and usefulness of pneumatic compression devices (8). The purpose of this study was to report the usefulness and safety of a pneumatic compression device for hemostasis in patients undergoing percutaneous endovascular procedures by femoral arterial access.

Methods

Patients

This research received a waiver of approval from the Institutional Review Board (IRB). Informed consent was waived by the IRB. This study included 237 consecutive patients in whom the hemostasis of femoral catheterization sites was achieved using the God's Hand Plus Pad pneumatic compression device (KoreaMCD) between October 2011 and July 2014. The inclusion criteria were prothrombin time international normalized ratio (PT INR) <1.5, platelet count >50,000/μL, arterial sheath ≤6 F, and no history of antiplatelet or anticoag-

From the Department of Radiology (J.H.K. ✉ *hkwon17@naver.com*), Dongguk University Graduate School of Medicine, Ilsan Hospital, Goyang, Korea.

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ulant use. The exclusion criteria for the application of the device included marked obesity and redundant overlying skin in the inguinal area. Patients were divided into groups A and B depending on the God's Hand application time. In group A, the patients underwent God's Hand application for 4 h. In group B, the patients underwent application of the device for 2 h. During the application of God's Hand, patients were expected to have absolute bed rest. After removal of the device, mobility was restricted in all patients in groups A and B for a further 2 h. All patient information and data were collected by a review of the electronic medical records. The baseline characteristics of the patients and interventional procedural details are summarized in Tables 1 and 2.

Device

The God's Hand Plus Pad is a single-use, disposable device that consists of a main body and several pieces of supplementary tape. The cruciform main body has self-adhesive peel backing and consists of a central semi-compliant inflatable bulb that is 4 cm in diameter, with a transparent plastic dome at the center of the body and four wings. The supplementary tape pieces also have self-adhesive peel backing (Figure).

Hemostasis procedure

First, the main body was secured over the puncture site after removal of the self-adhesive backing, with the sheath in the femoral artery such that the center of the bulb was located 1 cm proximal to the skin entry site of the sheath. Supplementary tapes were applied over the wings of the main body to reinforce the skin attachment. Next, the central bulb was inflated using 150 mL room air, and the sheath was removed while maintaining manual compression over the bulb. The skin entry site was observed for the hemostatic and bleeding status via the transparent central bulb while compressing the central bulb manually for 2–3 min. If any signs of bleeding were present, the bulb was inflated with an additional 20–30 mL room air. In case of any signs or symptoms of leg ischemia during inflation of room air or manual compression of the central bulb, the bulb was gradually deflated until the ischemic signs disappeared. If hemostasis was successful, the puncture site was observed for 2–3 min for evaluation of the hemostatic status via the central transparent bulb. The patient was returned to the ward, keeping the God's Hand at the femoral puncture site. At the ward, the bleeding status, ischemic signs, and any other complications were assessed every 30 min for 2 h in group A and 4 h in group B, while keeping the God's Hand in position. The device was removed after 2 or 4 h of application. The femoral puncture site was observed to identify any complications, such as bleeding, hematoma formation, arteriovenous fistulas, or pseudoaneurysms until ambulation.

Main points

- The God's Hand Plus Pad is a single-use, disposable pneumatic compression device for hemostasis of femoral puncture site.
- The device is effective and safe for hemostasis of femoral artery puncture site in selected patients (PT INR <1.5, platelet count >50,000/μL, arterial sheath ≤6 F, and no use of antithrombotic or anticoagulant).
- The device could reduce bed rest time and increase patient's comfort compared with manual compression. Moreover, it has no major complications such as arterial stenosis or occlusion, which has been reported as the major complication of arterial closure devices.

Assessment

Electronic medical records for baseline medical characteristics, interventional procedural details, outcomes and complications of hemostasis were reviewed. The baseline medical characteristics included sex, age, body mass index, smoking history, and a medical history of hypertension, diabetes mellitus, dyslipidemia, chronic kidney disease, cerebrovascular disease, ischemic heart disease, chronic liver disease, or malignancy (Table 1). Interventional procedural details included the procedure type, sheath size, and time of previous common femoral artery access arterial sheath time (from the puncture to removal of the sheath) (Table 2). The clinical success of hemostasis was defined as the ability of ambulation after 4 or 6 h of bed rest without any complications related to hemostasis. The complications were classified as major or minor complications according to the Society of Interventional Radiology guidelines (9). Major complications were defined as those that necessitated additional interventional procedures, prolonged hospitalization, permanent adverse sequelae, or death. All other complications were classified as minor, including mild hemorrhage and mild hematoma, which needed no additional therapy, had no consequence, and was managed by close observation only (9). The baseline medical characteristics of patient factors showed a statistically significant difference between groups A and B. Sixty-five patients were selected in each group using the propensity score matching statistical method, which corrects differences between two groups. The patients in groups A and B selected by the propensity score matching method were reclassified to groups A′ and B′, respectively (n=65, for both). The baseline medical characteristics of the patients and interventional procedural factors showed no significant differences between groups A′ and B′ after regrouping using the propensity score matching method (Tables 1 and 2).

Statistical analysis

Propensity score matching by a nearest neighbor method was used to adjust for confounders between groups A and B showing statistically significant difference in baseline medical characteristics (10). Matched variables included all baseline medical characteristics of the patients (Table 1). The χ^2 test was used to compare the interventional procedure-related factors, clinical success rates and complication rates of the two groups before and after propensity score matching. Unadjusted and adjusted logistic regression models with covariates representing patient characteristics and procedure-related factors were performed to determine the association between the complication rates and patient characteristics and procedure-related factors in groups A′ and B′, with odds ratios (ORs) and 95% confidence intervals (CIs). A P value <0.05 was deemed to indicate statistical significance. Statistical analysis was performed using SAS software (ver. 9.3; SAS Institute Inc.).

Results

Clinical success was achieved in 216 of 237 patients (91.1%): 63 of 75 in group A (84%) and 153 of 162 in group B (94.4%). In propensity score matched groups, clinical success was seen in 53 of 65 in group A′ (81.5%) and 62 of 65 in group B′ (95.4%). Group B′ showed a higher clinical success rate than group A′ (P = 0.028; Table 3). Minor complications occurred in 21 of 237 patients (8.8%): 12 of 75 in group A (16%) and 9 of 162 in group B (5.6%). After propensity score matching, group A′ showed a higher

Table 1. Baseline medical characteristics of patients before and after propensity score matching

	Before matching			After matching		
	Group A n=75	Group B n=162	Standardized mean difference	Group A′ n=65	Group B′ n=65	Standardized mean difference
Propensity score	0.867 (0.342)	0.401 (0.492)	1.241	0.455 (0.194)	0.415 (0.175)	0.189
Gender, n (%)						
Male	36 (48.00)	104 (64.20)	0.322	33 (50.77)	28 (43.08)	-0,153
Female	39 (52.00)	58 (35.80)		32 (49.23)	37 (56.92)	
Age (years), mean±SD	64.31 (12.71)	58.49 (12.20)	0.458	62.31 (12.36)	60.51 (11.53)	0.142
BMI, n(%)						
Low weight (<18.5 kg/m^2)	2 (2.67)	11 (6.79)	0.179	2 (3.08)	4 (6.15)	-0,049
Normal (18.5–24.9 kg/m^2)	50 (66.67)	110 (67.9)		44 (67.69)	39 (60)	
Obese (25.0–29.9 kg/m^2)	19 (25.33)	35 (21.6)		16 (24.62)	18 (27.69)	
Extremly obese (≥30 kg/m^2)	4 (5.33)	6 (3.7)		3 (4.62)	4 (6.15)	
Smoking, n (%)	16 (21.33)	61 (37.65)	0.396	16 (24.62)	15 (23.08)	-0,037
Hypertention, n (%)	37 (49.33)	66 (40.74)	-0.171	32 (49.23)	30 (46.15)	-0,0610
Diabetes mellitus, n (%)	19 (25.33)	27 (16.67)	-0.198	12 (18.46)	7 (10.77)	-0,1760
Dyslipidemia, n (%)	7 (9.33)	7 (4.32)	-0,171	4 (6.15)	5 (7.69)	0.053
Chronic kidney disease, n (%)	2 (2.67)	5 (3.09)	0.026	2 (3.08)	2 (3.08)	0.000
Cerebrovascular or ischemic heart disease, n (%)	39 (52.00)	43 (26.54)	-0,506	32 (49.23)	29 (44.62)	-0,092
Chronic liver disease, n (%)	8 (10.67)	80 (49.38)	1.246	8 (12.31)	9 (13.85)	0.050
Malignancy, n (%)	11 (14.67)	91 (56.17)	1.165	10 (15.38)	10 (15.38)	0.000
Platelet count, mean±SD	223067 (178849)	80467 (80539)	0.55	221154 (216577)	82952 (80951)	0.057
PT INR, mean±SD	1.06 (1.23)	0.17 (1.02)	-0,981	1.08 (1.05)	0.14 (0.11)	0.195

SD, standard deviation; BMI, body mass index; PT INR, prothrombin time international normalized ratio.

Table 2. Procedure-related factors of groups A′ and B′

	After matching		
	Group A′ n=65	Group B′ n=65	*P*
Procedure type, n (%)			
TFCA	52 (80)	46 (70.77)	0.222
TACE	7 (10.77)	10 (15.38)	0.435
Embolization	6 (9.23)	9 (13.85)	0.410
Sheath size, n (%)			
5 F	63 (96.92)	62 (95.38)	1.000
6 F	2 (3.08)	3 (4.62)	1.000
Previous CFA access time, mean±SD	1.32±0.83	1.31±1.2	0.932
Duration of cateterization, mean±SD	37.77±16.54	36.85±21	0.781

TFCA, transfemoral cerebral angiography; TACE, transcatheter arterial chemoembolization; F, french; CFA, common femoral access; SD, standard deviation.

complication rate (n=12; 18.5%) than group B′ (A′, n=12, 18.5%; B′, n=3, 4.6%; *P* = 0.028; Table 3).

No major complications occurred in either group A or B. Minor complications included seven cases of mild bleeding and five cases of small hematoma in group A and nine cases of mild bleeding in group B (Table 4). In three of seven patients in group A with mild bleeding, the complication occurred during application of the God's Hand device to the femoral puncture site during the early period of use. Redundant skin in the inguinal and pelvic regions was the cause of bleeding in these three patients. When bleeding was noted, the God's Hand device was removed immediately, and manual compression was performed. Two patients in group B showed mild bleeding during application of the device. In these two patients, manual compression was performed over the bulb, while the God's Hand device remained installed at the femoral puncture site. Other minor complications—13 cases of mild bleeding and five cases of small hematoma—occurred at the ward. Almost all complication cases at the ward were found at the time of removal of the God's Hand device. Mild bleeding could be recognized as a trace amount of dark brown-colored old blood. Cases of hematoma did not exceed an area of 5×5 cm. Therefore, an approximately 30 min application of a sand bag or observation was sufficient to control the complications, and no additional interventional procedure or surgical treatment was required.

Table 3. Clinical success and complication rate before and after propensity score matching

		Before matching			After matching		
	Total patients	Group A n=75	Group B n=162	*P*	Group A' n=65	Group B' n=65	*P*
Clinical success, n (%)							
Yes	216 (91.1)	63 (84)	153 (94.4)	0.017	53 (81.5)	62 (95.4)	0.028
No	21 (8.9)	12 (16)	9 (5.6)		12 (18.5)	3 (4.6)	
Complications, n (%)							
Yes	21 (8.9)	12 (16)	9 (5.6)	0.017	12 (18.5)	3 (4.2)	0.028
No	216 (91.1)	63 (84)	153 (94.4)		53 (81.5)	62 (95.4)	

Table 4. Complications of groups A and B

	Total patients	Group A	Group B
Major complication	0	0	0
Minor complication			
Bleeding	16	7	9
Hematoma	5	5	0

Table 5. Complication rate associated with patient- and procedure-related factors in groups A' and B'

	Model 1		Model 2		Model 3	
Group	OR	95% CI	OR	95% CI	OR	95% CI
B'	0.261	(0.068–1.005)	0.279	(0.06–1.291)	0.242	(0.042–1.381)
A' (ref.)	1	-	1	-	1	-

Model 1: Estimated using an unadjusted logistic regression model.
Model 2: Estimated using an adjusted logistic regression model with covariates (group, sex, age, body mass index, hypertension, diabetes mellitus, dyslipidemia, chronic kidney disease, cardiovascular or ischemic heart disease, chronic liver disease, malignancy, platelet count, prothrombin time international normalized ratio).
Model 3: Estimated using an adjusted logistic regression model with covariates (group, sex, age, body mass index, hypertension, diabetes mellitus, dyslipidemia, chronic kidney disease, cardiovascular or ischemic heart disease, chronic liver disease, malignancy, platelet count, prothrombin time international normalized ratio, procedure type, sheath size, time of common femoral access, duration of femoral catheterization).
OR, odds ratio; CI, confidence interval; ref., reference.

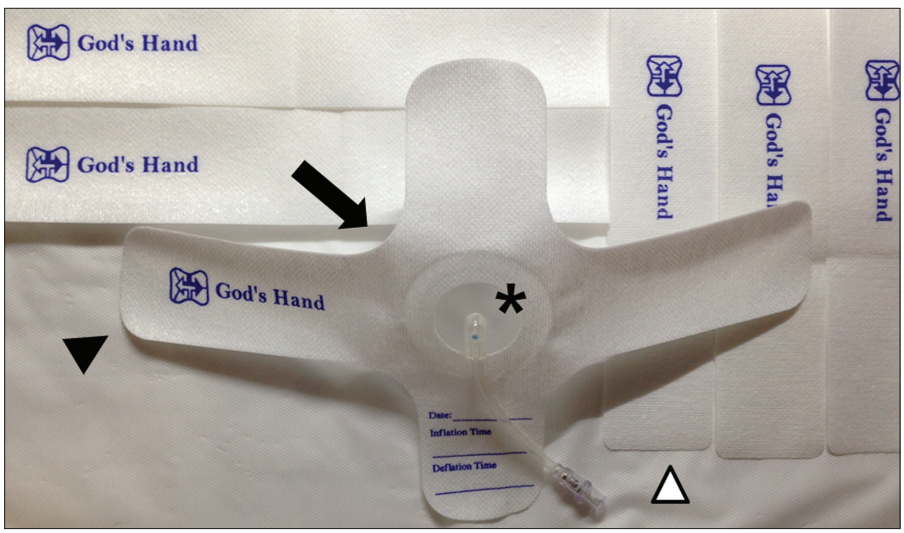

Figure. The image shows God's Hand Plus Pad. The main body *(black arrow)* has a self-adhesive peel backing and a semi-compliant inflatable bulb *(asterisk)* under a transparent dome at the center of the body. The supplementary tape *(white arrowhead)* has self-adhesive peel backing and a support wing at the main body *(black arrowhead)*.

Comparison of complications between groups A' and B' using the unadjusted logistic regression model revealed no association between complication rates and the duration of God's Hand application (Model 1, OR=0.261, 95% CI=0.068–1.005). Moreover, in multivariable-adjusted models with covariates representing patients characteristics and procedure-related factors, the complication rate did not show any association with the duration of God's Hand application (Model 2, OR=0.279, 95% CI=0.06–1.291; Model 3, OR=0.242, 95% CI=0.042–1.381; Table 5).

Discussion

The God's Hand Plus Pad is a single-use, disposable pneumatic compression device for hemostasis of femoral puncture site. In this study, the device was effective and safe for hemostasis of femoral artery puncture site in selected patients regardless of patient- and procedure-related factors. The device reduced bed rest time to four hours and increased patient's comfort compared with manual compression. Moreover, the device did not develop major complications such as arterial stenosis or occlusion, which had been reported as a complication of arterial closure devices.

Manual compression has been the gold standard approach for hemostasis at the puncture site of the common femoral artery for arterial access in cardiac and vascular diagnosis and intervention. Manual compression usually requires sustained partially occlusive pressure over the puncture site for approximately 15–20 min to achieve hemostasis (5, 11). After successful hemostasis by manual compression, 4–6 h of bed rest is required for complete hemostasis prior to ambulation, depending on the size of the sheath or catheter used, or the use of antiplatelets or anticoagulants during the procedure (5). Manual compression has dis-

advantages such as being highly time consuming, causing fatigue of the hand and arm, and requiring nursing assistance to monitor the patient (12, 13). To overcome the disadvantages of manual compression, other hemostatic methods, such as arterial closure devices (ACDs) and mechanical compression devices, have been developed (5, 6, 12, 13).

Among the mechanical compression devices using a pneumatic system, Femostop is one of the most widely evaluated (13, 14). Femostop, which can substitute for manual compression, is constructed with a compression plastic arch bar with a translucent dome that is supplied to the puncture site and a belt that is located under the hip and fixed to the plastic arch bar. Compression of the femoral artery site occurs via the pressure exerted by the inflated dome (13, 15, 16). Femostop requires about 20 min for initial hemostasis, and a time of 70 min has been reported depending on the coagulation status and sheath replacement time (13, 14). Safeguard has a similar structure to that of God's Hand and is a single-use, disposable external compression assist device that has a polyurethane window and pneumatic bladder that is inflated over the arteriotomy and secured via a sterile adhesive backing. However, Safeguard cannot be substituted for manual compression but only assist it (11). In our study, about 5–6 min were required to achieve initial hemostasis by God's Hand application. This is a relatively shorter time than mechanical compression devices or other pneumatic compression devices. In our study, the narrower inclusion criteria of the patients than those previously reported in the literature may have influenced the shorter time to achieve initial hemostasis. Exact application of the God's Hand device at the femoral puncture site and continuous pressure by the air-inflated bulb maintain stable compression at the femoral puncture site. This may influence the amount of time needed to achieve initial successful hemostasis. In addition, the ease of use of the God's Hand device may have affected the time duration for initial hemostasis.

ACDs include collagen plug/sponge devices, suture-mediated devices, staple/clip devices, and patch/pad technology. A systematic review indicated no significant differences in groin hematoma, bleeding, development of an arteriovenous fistula, or development of a pseudoaneurysm compared with standard manual compression, and the time to hemostasis was shorter than that of manual compression by 10–15 min (6). Consequently, ACDs allow earlier ambulation compared with manual compression. However, ACDs increase the rates of groin infection and severe complications such as arterial obstruction (17–20). Additionally, ACDs are largely operator-dependent and require a relatively long learning curve for effective use (21). In our study, there were no major complications that necessitated additional interventional procedures or prolonged hospitalization related to the use of ACDs. Furthermore, the God's Hand pneumatic compression device is relatively easy to use for hemostasis of the femoral artery puncture site without a prolonged learning curve. According to the literature, successful hemostasis of manual compression is achieved in approximately 90% of patients (13), and the successful deployment rate of ACD is >95% (5). The success rate (91.1%) of hemostasis in our study is comparable to that of previous reports. Groin hematoma was reported in 5%–23% of patients after manual compression; after ACD application, pseudoaneurysms were reported in 0.5%–9% of patients, and arteriovenous fistula in 0.2%–2% of patients (6, 13, 22). After Femostop application, hematoma occurred in 3.1%–10% of patients, and pseudoaneurysms in 3.1% of patients (13, 23). In our study, the overall complication rate was 8.8% in patients with hemostasis treated using the God's Hand device. Most complications were mild bleeding or small hematoma, which were managed conservatively. Moreover, no major complication—such as arteriovenous fistula, pseudoaneurysms, or arterial obstruction—was identified. It is considered that the God's Hand device applied at the femoral puncture site providing continued compression during immobilization may increase the success rate of hemostasis preventing hemorrhage or hematoma formation during bed rest after successful initial hemostasis. Additionally, direct visualization of the puncture site through the transparent bulb may make it possible to identify hemorrhagic complications instantly and to manage the complications promptly.

During the early period of the use of God's Hand for hemostasis, the device was applied at the puncture site for 4 h after initial hemostasis according to our protocol for manual compression. The application time was reduced from 4 h to 2 h, because no major complications were noted during the application of the God's Hand device at the puncture site for 4 h and bed rest for an additional 2 h in Group A. The clinical success rate of Group B′ was significantly higher than that of Group A′. However, the complication rate did not show a significant association with the duration of the God's Hand application in unadjusted and multivariable-adjusted logistic regression models. Although this result could be considered to indicate that a 2 h application of the God's Hand device was superior to a 4 h application for successful hemostasis, we interpret this result as indicating that a 2 h application was as effective and safe for successful hemostasis as a 4 h application of the God's Hand device. The higher complication rate in Group A′ may be due to the operator not being accustomed to appropriate use of the device in the early period of this study. While the use of the God's Hand device is much easier than ACDs, there is still a learning curve for the appropriate use of the device. Thus, in this study, a 2 h application of the God's Hand device with 2 h additional bed rest was as effective and safe for successful hemostasis as a 4 h application of the device with 2 h of additional bed rest.

The logistic regression models with adjustment for patient characteristics and procedure-related factors showed that hemostasis of the femoral puncture site was not influenced by patient characteristics or procedure-related factors. Patient characteristics, including smoking history, hypertension, diabetes mellitus, dyslipidemia, chronic kidney disease, cerebrovascular disease, ischemic heart disease, chronic liver disease, and malignancy, alter the vascular endothelium and coagulation status that may affect hemostasis. However, these factors were not related to successful hemostasis of the femoral puncture site in this study. Procedure-related factors, such as the procedure type, sheath size, time of CFA access, and duration of femoral catheterization were not related to successful hemostasis of the femoral puncture site. The God's hand device can be used for hemostasis at the femoral puncture site irrespective of the patient characteristics and procedure-related factors in selected patients.

The God's Hand pneumatic compression device has several advantages over manual compression or ACDs. First, the device has a reduced need for operator assistance to achieve initial hemostasis compared with manual compression. Second, complica-

tions such as hemorrhage or bleeding can be monitored in real-time through the transparent bulb. This promotes early detection and prompt management when complications occur at the puncture site. Third, the patients feel greater stability during immobilization when the device is applied in the inguinal area compared with manual compression, although this should be evaluated further. Fourth, it is cost effective compared with the ACDs. Fifth, there was no major complication such as arterial stenosis or occlusion, which has been reported as the major complication of ACDs (18–20, 24) and suture material-related infection (25). Consequently, the pneumatic compression device has a low risk of requiring an additional invasive procedure for the management of severe complications related to the use of ACDs (26). However, there were a few disadvantages of the God's Hand device. First, ACDs provide an active approximation of the puncture site that permits early ambulation, even in fully anticoagulated patients (5, 8). In this study, patients with fully anticoagulated or moderate-to-severe hemostatic abnormalities were excluded. Second, the God's Hand device requires 4–6 h of bed rest to achieve hemostasis in patients with normal coagulation parameters, like conventional manual compression. Third, patients with a larger sheath size (>6 F) were excluded from the study. Further studies are required to verify the usefulness of the God's Hand device in these patients. Fourth, the device can potentially fail in patients showing redundant skin around the inguinal area and lower abdomen that prevents location of the central bulb of the device just above the puncture site. This problem resulted in failure of initial hemostasis and, consequently, conversion to manual compression.

This study had several limitations. First, due to its retrospective design, data collected by review of electronic medical records had limitations that prevented comparison between group A and group B. However, this limitation was overcome using the propensity score matching method (10). Second, Doppler ultrasonography was not performed for the evaluation of complications associated with hemostasis. Therefore, complications such as arteriovenous fistulae or pseudoaneurysms might have been masked. Third, introducing sheaths of 5 and 6 F were included in the current study; thus, further studies are needed to evaluate the results of hemostasis using sheaths of >6 F. Fourth, common femoral artery was accessed once or twice. Additionally, the mean procedure duration of the study was approximately 40 min. Therefore, further studies are recommended in cases with multiple attempts of femoral artery access and longer duration of procedure. Finally, the late complications of the puncture site could not be evaluated because this study was conducted retrospectively and the patients were not followed up over the long term.

In conclusion, the God's Hand pneumatic compression device is a safe and effective tool for achieving hemostasis in femoral artery puncture sites with high clinical success and low complication rates and no major complications. A total of 4 h of bed rest is sufficient to achieve hemostasis, reducing the immobilization time and increasing comfort in selected patients undergoing transfemoral catheterization. Moreover, the God's Hand device can be safely used regardless of patient characteristics or procedure-related factors.

Conflict of interest disclosure

The authors declared no conflicts of interest.

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