Complications With Femoral Access in Cardiac Catheterization. Impact of Previous Systematic Femoral Angiography and Hemostasis With VasoSeal-Es® Collagen Plug

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Introduction and objectives. Most cardiac catheterizations are performed via femoral artery access, and hemostatic devices are commonly used. We evaluate the relationship between the strategy used for femoral arteriography and the use of VasoSeal-ES®, and local vascular complications.

Patients and method. Prospective study of 540 consecutive catheterizations with systematic femoral artery and sheath angiography. VasoSeal-ES® was used in 427 patients. Predictors of local vascular complications such as patient-related factors, anatomy and hemostasis were analyzed. Variables related to failure of the collagen plug were also studied.

Results. Punctures of the common femoral artery occurred in 35.9% of all patients (16% in the deep femoral artery and its ostium). Spasm was evident in 18% (ranging from 58.1% in the deep femoral artery to 5.2% in the common femoral artery). Puncture at the site of ramification was seen in 11.3%. Angiographically significant atheroma was seen in 17.8%. The femoral head was a valid landmark for the common femoral artery in only 63.9% of the pateints. Risk factors for local vascular complications were punctures of the common femoral artery, female sex and failure of VasoSeal-ES® to achieve hemostasis (15.8% in the first two months of use, 5.2% in the last months of the study). Complications involving superficial and deep femoral arteries occurred in 6.7% and 1.2% of the patients, respectively, in contrast to 0.6% involving the common femoral artery. Variables related to collagen plug failure were patient-related factors, weight less than 55 kg, operator-related factors and the learning curve.

Conclusions. Systematic femoral angiography provides data that aids the choice of the best hemostasis procedure to reduce local vascular complications. Punctures of the common femoral artery were more frequent than expected, and were associated with a higher complication rate. VasoSeal-ES® is a safe and useful method of hemostasis, and its infrequent failures were associated with high complication rates that were substantially reduced with experience.

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Complicaciones del acceso femoral en el cateterismo cardíaco: impacto de la angiografía femoral sistemática previa y la hemostasia con tapón de colágeno VasoSeal-ES“

Introducción y objetivos. Dado el uso generalizado del acceso femoral y del material hemostático, se plantea realizar la angiografía femoral sistemática y la hemostasia con VasoSeal-ES® para determinar los predictores de complicaciones locales y de fracaso en el uso del tapón hemostático.

Pacientes y método. Estudio prospectivo de 540 pacientes consecutivos con angiografía sistemática femoral con introductor, 427 con hemostasia con VasoSeal-ES®, en el que se realizó un análisis de las variables paciente y anatómia en relación con las complicaciones locales y los fallos en la dispensación del tapón.

Resultados. Se evidencian punciones fuera de la femoral común en el 35,9% de los casos (el 16% en la femoral profunda y su *ostium*), espasmo vascular en el 18% (máximo en la femoral profunda, del 58,1%), nacimientos de ramas contiguas a la punción en el 11,3% y ateroma angiográfico en el 17,8%. La cabeza del fémur es referencia de la femoral común en el 63,9% de los pacientes. Los factores de riesgo de las complicaciones vasculares son: las punciones fuera de la femoral común, el sexo femenino y el fallo en la dispensación del VasoSeal-ES® (el 15,8% en los primeros 2 meses de uso y el 5,2% en los últimos meses del estudio). Las complicaciones en la femoral superficial y profunda fueron del 6,7 y del 1,2%, respectivamente, frente al 0,6% en la femoral común. Las variables asociadas al fallo del tapón fueron: un peso < 55 kg, el médico dispensador y la curva de aprendizaje.

Conclusiones. Se propone la angiografía femoral sistemática para elegir el procedimiento idóneo de hemostasia y reducir las complicaciones vasculares locales. Las punciones fuera de la femoral común son más frecuentes de lo esperado, asociándose a un mayor número de complicaciones. La hemostasia con VasoSeal-ES® es segura y sus fallos están relacionados con un elevado porcentaje de complicaciones, que se reducen drásticamente con la experiencia.

Palabras clave: *Cateterismo cardíaco. Complicaciones. Colágeno.*

ABBREVIATIONS

AHT: arterial hypertension.

INTRODUCTION

Transfemoral access continues to be the most frequently used approach in catheterization procedures.[1,2] However, it neither eliminates the need for early ambulation[3-5] to reduce the discomfort of bed rest, nor does it decrease the length of hospitalization or cut the costs of the procedure.

Femoral anatomy has been studied through dissection and angiography.[6-9] However, a systematic visual analysis of the relation between catheter sheath entry site and vascular complications associated with puncture has not been carried out. Although figures are low (0.3%-1% in diagnostic studies and 1%-5% in therapeutic interventions), vascular complications remain the most frequent problem.[10-15] They may be related to anatomy and the actual disease affecting the vessel, insertion, or the method chosen for definitive hemostasis.[16-19] They may also be related to the increasing amount of interference with coagulation.[20-22]

Femoral access hemostasis is a blind technique, as are manual compression, collagen plug delivery or percutaneous vascular sutures.[23,24] Manual compression and VasoSeal-ES® plug placement (Datascope Corp. Montvale, NJ) are widely used noninvasive procedures .[25-28] Latest generation VasoSeal-ES® products are widely used because they eliminate the need for pre-measurement of skin-artery distance and ensure correct deployment of the plug to the entry site in the artery.[27]

We used systematic femoral artery angiography to obtain a direct view of the artery prior to securing hemostasis with VasoSeal-ES®. Our aim was to improve understanding of complications and reduce these while maintaining a program of early ambulation after catheterization.

Our objectives were: *a)* to determine the relationship between the anatomy of the femoral access site, catheter introducing sheath, puncture site location (in the common femoral artery or elsewhere), and vascular pathology; *b)* to study the predictors of local complications including those related to the patient, femoral anatomy, and the use of VasoSeal-ES® collagen plugs that are noninvasive of the lumen; *c)* to study predictors of successful or unsuccessful plug deployment, and *d)* to analyze the relationship between femoral anatomy and VasoSeal-ES® and describe the limitations of its use.

PATIENTS AND METHOD

We carried out a prospective study of an unselected sample of 540 patients consecutively undergoing diagnostic cardiac catheterization. Digital angiography of the ipsilateral femoral region, with manual injection of a contrast agent through a 6 Fr (Medtronic) sheath was systematically performed on all patients. We filmed the oblique anterior right 50º projection as it is the view that best separates the bifurcation from the common femoral artery and shows the puncture site. The femoral head was framed in the center of the vertical axis of the projection. We used the standard Seldinger technique of femoral puncture. Average age of patients was 63.7 ± 10.6 years; 33.9% were women; average weight was 74.3 ± 13.0 kg; 19.1% suffered from diabetes; 41.3% had high blood pressure; 22.4% were smokers; and 31.6% presented dislipemia.

VasoSeal-ES® collagen plugs were deployed in order to achieve local hemostasis in 427 of the 540 patients using the technique described.[25,26] In each case, this procedure was chosen in accordance with the hospital protocol for outpatients. The remaining 113 individuals were inpatients and traditional manual compression was used. The images obtained did not influence our decisions. Neither anticoagulation nor antiplatelet medication was administered, although heparin infusion continued unchanged in patients for whom it had been recommended in prior treatment.

Bifurcation of the common femoral artery was defined in relation to the femoral head, and was classified in three levels: high and mid, when the bifurcation coincided with upper and lower halves of the femoral head, respectively; and low, when the height of the bifurcation was below the femoral head. We recorded the presence of branches of the femoral artery other than the deep femoral artery and the superficial femoral artery when they originated from a point in contact with the puncture site.

Arterial spasm in the segment of the access site was defined as an image of transitory ring-shaped reduction of the lumen. We defined the bend as an angle of between 70º and 120º between the sheath and the vessel. Significant atheromatosis of the artery was taken as evidence of ≥25% stenosis in the femoral region or of multiple irregularities of the lumen.

Only major vascular complications of the region were recorded. These were defined by means of clinical and ultrasound studies. Complications were not mutually exclusive:

– Hematoma, defined as a throbbing mass or a build up of liquid with a maximum ultrasound diameter of ≥ 5 cm, contiguous and external to the lumen of the punctured vessel, or as bleeding that affected the hematocrit or required transfusion.

– ≥ 5 mm pseudoaneurysm in the vessel and access site segment.

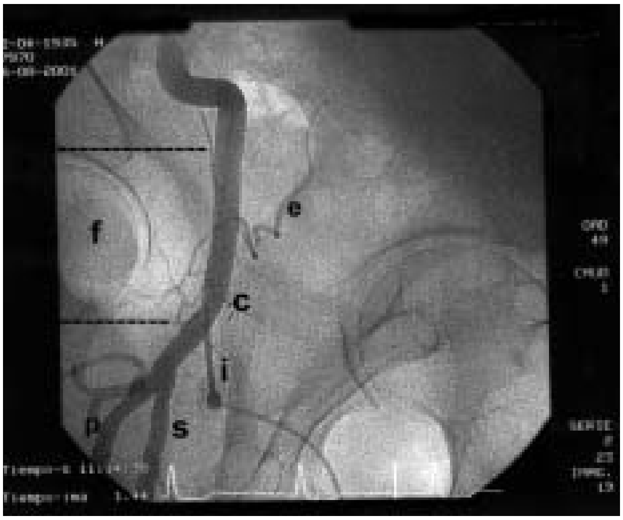

Fig. 1. Angiogram of the right femoral artery with catheter introducing sheath (oblique anterior right projection 50º). The discontinuous parallel lines indicate the upper and lower levels of the femoral head and their projection in the femoral artery. The main femoral artery bifurcation is below the femoral head, and the bone acts as a landmark to the height of the common femoral artery. The sheath reaches the common femoral artery medial coaxial to this: the ideal position. Absence of visible atheroma.
C indicates common femoral artery; e, inferior epigastric artery, boundary between the common femoral artery and the iliac artery; f, head of the right femur; i, catheter introducing sheath; p, deep femoral artery; s, superficial femoral artery.

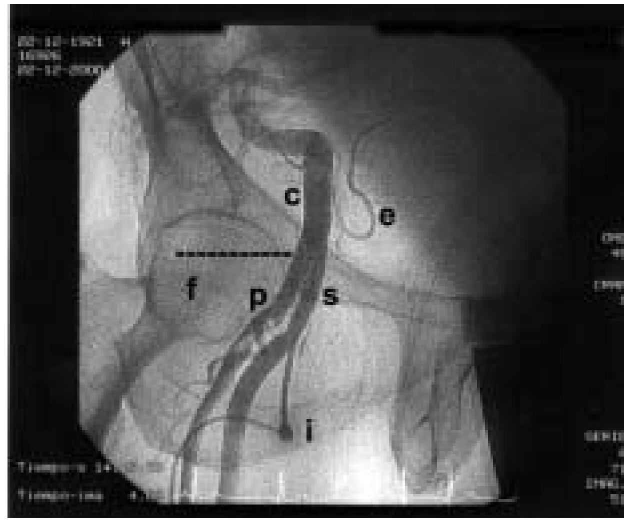

Fig. 2. Angiogram of the right femoral artery with catheter introducing sheath (oblique anterior right projection 50º). The discontinuous line indicates the level of the main femoral artery bifurcation, at the high point of the femoral head. The common femoral artery is shorter (from the inferior epigastric artery to the femoral artery bifurcation), the position of the main femoral artery bifurcation seems high, and this leads to a puncture of the superficial femoral artery. Note spasm in the area of the puncture site and the acute invasive atheroma of the lumen in the deep femoral artery.
C indicates common femoral artery; e, inferior epigastric artery, boundary between the common femoral artery and the superior gluteal artery; f, head of the right femur; i, catheter introducing sheath; p, deep femoral artery; s, superficial femoral artery.

– Arteriovenous fistulas of the femoral artery and access site segment.

– Surgery. Patients with one or other of these complications who required vascular surgery due to the severity or evolution.

Statistical analysis

Univariate comparison of qualitative data was carried out by the χ^2 or Fisher exact test. Multivariate logistical regression analysis was used to study those variables that proved significant or nearly significant, with a backwards stepwise procedure to exclude those that failed to reach P=.05. Data were analyzed with the statistical software package SPSS 8.

RESULTS

Anatomic description of femoral artery vascular area in relation to catheter introducing sheaths

Figure 1 shows the area of the normal femoral artery with a coaxial sheath and the punctured common femoral artery. The main femoral artery bifurcation is located below the femoral head. The common femoral artery is of a similar length and width to that of the superoinferior artery of the femoral head. No significant sized branch originates near the puncture site. Nor did we find significant spasm or atheroma in the area.

Table 1 shows the anatomical variables studied. We identified entry sites other than the common femoral artery in 35.9% of patients (Figures 2 to 4): 8.0% were in the deep femoral artery (Figures 3 and 4); 16.8% in the main bifurcation in the deep femoral artery and superficial femoral artery, with a similar number of punctures in their ostia (Figure 4). We found branches starting in the area adjacent to the puncture site in 11.3% of patients (Figures 3 and 5).

The femoral head was used as a landmark point for the common femoral artery in 63.9% of patients when bifurcation was at the lower level (Figure 1). In the remaining 36.1%, the femoral head acted as a landmark to the main bifurcation of the common femoral artery or the superficial or the deep femoral arteries and not the common femoral artery itself (Figure 2).

We encountered spasm of the punctured artery in 18.0% of patients. In 58.1% of these, this was in the deep femoral artery and in 33.3% in the superficial femoral artery (Figures 2 and 5). In the common femoral artery, the frequency of spasm was significantly lower (5.2%; $P \leq .001$).

We discovered significant atheroma in 17.8% of patients (Figures 3, 4 and 6), including those with acute

TABLE 1. **Angiographic anatomy of the femoral artery vascular area (n=540)**

Puncture site location	Femoral common	64.1% (346/540)
	Superficial femoral artery	11.1% (60/540)
	Deep femoral artery	8.0% (43/540)
	Deep femoral artery ostium	8.0% (43/540)
	Superficial femoral artery ostium	8.1% (44/540)
	Bifurcation central zone	0.7% (4/540)
Presence of branches originating adjacent to the puncture site entry point		11.3% (61/540)
Introducing angle		2.2% (12/540)
Level of femoral artery main bifurcation	High femoral artery bifurcation	3.5% (19/540)
Relative to the femoral head	Mid femoral artery bifurcation	32.4% (175/540)
	Low femoral artery bifurcation	63.9% (345/540)
	Angiographic atheroma	17.8% (96/540)
	Absence of superficial femoral artery	2.0% (11/540)
	Absence of deep femoral artery	0%
	Calcification	0.6% (3/540)
Spasm	Total	18.0% (97/540)
	In common femoral artery	5.2% (18/346)
	In superficial femoral artery	33.3% (20/60)
	In deep femoral artery	58.1% (25/43)
	In ostium of superficial femoral artery	22.7% (10/44)
	In ostium of deep femoral artery	53.5% (23/43)
	In femoral-carina bifurcation	25.0% (1/4)

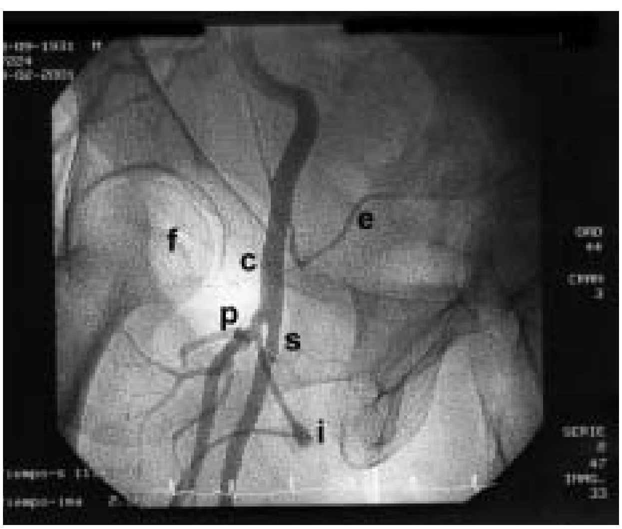

Fig. 3. Angiogram of the right femoral artery with catheter introducing sheath (oblique anterior right projection 50º). Puncture in the proximal deep femoral artery, in the area of acute atheroma and adjacent to branches to the thigh. Angle of sheath entry significant with regard to punctured artery.

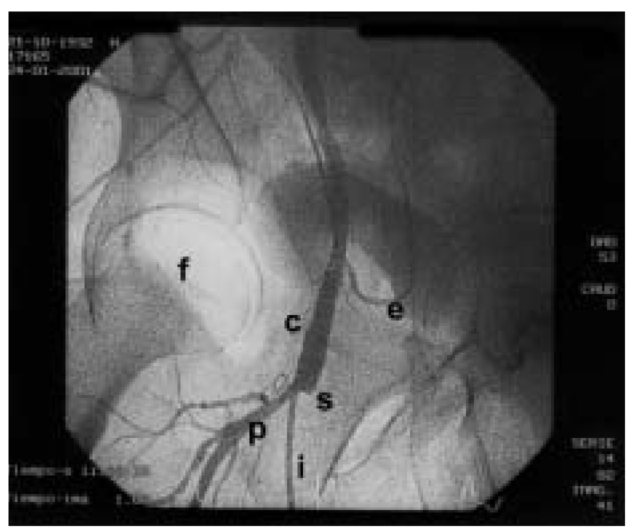

Fig. 4. Angiogram of the right femoral artery with catheter introducing sheath (oblique anterior right projection 50º). Puncture in deep femoral artery ostium in the absence of the superficial femoral artery (s) due to occlusion. Acute atheroma of the area with narrowing at the site of the deep femoral artery. Example of a situation in which the nearness of the ostium to the deep femoral artery and the puncture site could lead to incorrect measurement of skin-artery distance and possible incorrect disposition of intraluminal hemostatic material, or vascular distortions caused by sutures.
C indicates common femoral artery; e, inferior epigastric artery, boundary between the common femoral artery and the superior gluteal artery; f, head of the right femur; i, catheter introducing sheath; p, deep femoral artery; s, superficial femoral artery

irregularities of the lumen (Figure 6). We also found previously undiagnosed occlusion of the superficial femoral artery in 2.0% (Figure 4).

Analysis of variables associated with vascular complications

Univariate analysis did not identify any significant relationship between the presence of femoral artery vascular complications and the variables surgeon, age, diabetes, arterial hypertension (AHT), smoking, dislipemia, atheroma or spasm in the punctured artery.

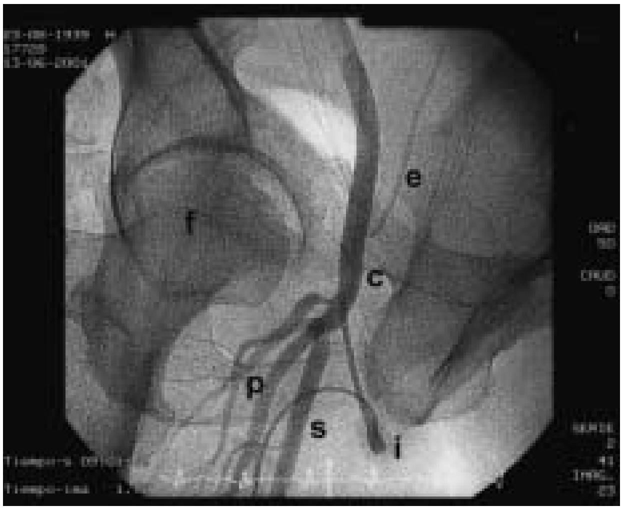

Fig. 5. Angiogram of the right femoral artery with catheter introducing sheath (oblique anterior right projection 50º). Puncture in the lower common femoral artery. Note the presence of a significant branch to the thigh at the base of the branch adjacent to the puncture site. There is slight spasm of this branch and at the site of the superficial femoral artery.
C indicates common femoral artery; e, inferior epigastric artery, boundary between the common femoral artery and the superior gluteal artery; f, head of the right femur; i, catheter introducing sheath; p, deep femoral artery; s, superficial femoral artery

Fig. 6. Angiogram of the right femoral artery with catheter introducing sheath (oblique anterior right projection 50º). Acute diffuse atheroma of the femoral artery territory. Puncture immediately above the main femoral artery bifurcation in the segment of the acute atheroma. Significant irregularity of vessel walls that could impede correct deployment of materials.
C indicates common femoral artery; e, inferior epigastric artery, boundary between the common femoral artery and the superior gluteal artery; f, head of the right femur; i, catheter introducing sheath; p: deep femoral artery; s, superficial femoral artery.

Statistically significant relationships were found with: sex (4.9% of complications were in women versus 0.6% in men; *P*=.001); and body weight: patients ≤55 kg presented a higher percentage of complications (9.4% vs 1.4%; *P*=.018) (Table 2).

Vascular complications associated with puncture site location were significantly more frequent in the superficial femoral artery and deep femoral artery (vessels and ostia) versus those in the common femoral artery (Table 3).

The relationship between complications due to procedure and successful achievement of hemostasis did not produce significant differences with regard to the choice of manual compression or VasoSeal-ES®. However, unsuccessful VasoSeal-ES® deployment was associated with a higher percentage of complications. This was statistically significant in comparison with complications following successful VasoSeal-ES® deployment, or manual compression (Table 4).

Significant independent variables related to vascular complications of the femoral artery in the final multiple logistical regression model were: puncture outside of the common femoral artery (odds ratio [OR]=5.3; 95% confidence interval [CI], 1.1-26.2; *P*=.042) and unsuccessful VasoSeal-ES® deployment (OR=11.4; 95% CI, 3.0-43.8; *P*=.0004). Female sex was on the borderline of statistical significance (OR=5.0; 95% CI, 0.99-25.0; *P*=.051).

TABLE 2. **Significant variables related to local vascular complications according to the univariate analysis**

	Complications	*P*
Sex		
Men	0.6% (2/357)	
Women	4.9% (9/183)	.001
Body weight		
≤55 kg	9.4% (3/32)	
≥55 kg	1.4% (7/494)	.018
Location of puncture site		
Common femoral artery	0.6% (2/346)	
Other than common femoral artery	4.6% (9/194)	.002
Hemostasis		
Manual	1.8% (2/113)	
Global VasoSeal-ES®	2.1% (9/427)	NS
Successful VasoSeal-ES®	1.0% (4/399)	
Failed VasoSeal-ES®	17.9% (5/28)	.001
Total	2.0% (11/540)	

Under «Complications» we define the percentage of complications in the variable under study. In parentheses, we show the number of patients with complications referred to the total number of patients for the variable.
NS indicates nonsignificant.

Analysis of unsuccessful VasoSeal-ES® deployment

VasoSeal-ES® collagen plugs were used to achieve hemostasis in 427 patients. Deployment was successful in 399 (93.4%) but failed for 28 (6.6%) patients. Results of univariate analysis appear in Table 5.

TABLE 3. **Vascular complications by puncture site location (n=540)**

	Puncture in common femoral artery (n=346)	Puncture in superficial femoral artery (vessel and ostium) (n=104)	Puncture in deep femoral artery (vessel and ostium) (n=86)	*P*
Hematomas	0%	6.7%	0%	<.001
Pseudoaneurysms	0.6%	2.9%	1.2%	.104
Surgery	0.3%	1.9%	1.2%	.058
Total patients with complications	0.6%	6.7%	1.2%	.002

An individual patient may present one or more complications. The variable femoral artery surgery indicates the complications cited that, moreover, required surgery. The value of *P* indicates the significance of the comparison between punctures in the common femoral artery and any other femoral approach.

TABLE 4. **Vascular complications according to the method of hemostasis and the result of hemostasis with VasoSeal-ES®**

	Manual compression (113 cases)	VasoSeal-ES® overall (427 cases)	VasoSeal-ES® failed delivery (399 cases)	VasoSeal-ES® successful delivery 28 cases)	*P*
Hematomas	1.8%	1.4%	.8%	10.7%	.006
Pseudoaneurysms	0.9%	1.4%	0.8%	10.7%	.004
Surgery	0.9%	0.9%	0.5%	7.1%	.024
Total patients with complications	1.8%	2.1%	1.0%	17.9%	<.001

An individual patient may present one or more complications. The variable femoral artery surgery indicates the complications cited that required surgery. The value of P indicates the comparison of the percentage of complications arising in cases of unsuccessful VasoSeal-ES® delivery with all other patients.

TABLE 5. **Percentage of unsuccessful VasoSeal-ES® delivery with reference to the different variables**

		Failures in the delivery of VasoSeal-ES® (%)	
Total failures		6.6% (28/427)	
Operators delivery systems	1	5.6% (6/107)	
	2	7.7% (3/39)	
	3	3.8% (2/53)	
	4	6.0% (6/100)	
	5	2.7% (2/72)	
	6	16.1% (9/56)	.006
Sex	Men	4.2% (12/283)	
	Women	11.1% (16/144)	.007
Body weight (kg)	<55	38.1% (8/21)	.001
	56-95	4.4% (16/360)	
	>95	7.7% (2/26)	
Introduction of VasoSeal-ES®	First 2 months	15.8% (6/38)	.029
	Following 4 months	6.0% (13/217)	
	Following 5 months	5.2% (9/172)	
Location of puncture site	Common femoral artery	5.0% (14/280)	
	Other than common femoral artery	9.5% (14/147)	.073
	Superficial femoral artery	10.5% (4/38)	
	Deep femoral artery	9.1% (3/33)	
	Bifurcation deep femoral artery ostium	8.1% (3/37)	NS
	Bifurcation superficial femoral artery ostium	11.1% (4/36)	
Femoral artery disease	Atheroma	7.5% (6/80)	
	Absence of atheroma	6.3% (22/347)	NS

NS: indicates nonsignificant.

Unsuccessful deployment was statistically significant in relation to operator (*P*=.006) due to the high percentage of errors made by 1 operator. No significant differences were found in relation to the other 5 operators. Failure was also significant in relation to weight (*P*=.02). Percentages were greater among patients weighing ≤55 kg (38.1%) or ≥95 kg (7.7%) versus those in the more common weight range 55-95 kg (4.4%).

The proportion of failures in the first 2 months of VasoSeal-ES® use was significantly greater than in the period following, when significant differences did not arise.

Fewer failures appeared when the puncture site was in the common femoral artery (5%) than when it was not (9.5%), but this difference was not statistically significant (*P*=.073).

No relationship was found between unsuccessful delivery and the presence of femoral artery atheroma or occlusion of branches of the superficial or deep femoral arteries by advanced atheroma.

In the final logistical regression model, in which the dependent variable was unsuccessful deployment of VasoSeal-ES®, a high level of statistical significance remained in relation to operator 6 (OR=4.0; 95% CI, 1.5-10.5; *P*=.0057); weight ≤55 kg (OR=12.1; 95% CI, 4.1-35.7; *P*≤.0001); and the use of VasoSeal-ES® during the first 2 months after its introduction (OR=4.9; 95% CI, 1.6-14.7; *P*=.0052).

No patients developed allergic reactions or local infection.

DISCUSSION

Femoral artery angiography ensures the physician is aware of the location of the puncture site, the presence of spasm in the area, the existence of branches adjacent to the traumatized area and, of course, of the extent of femoral artery vascular disease. Consequently, it is easier to determine the risk of local vascular complications and decide at the outset whether the most appropriate procedure for securing hemostasis is traditional manual compression, mechanical compression devices, plugs (whether invasive or noninvasive with regard to the lumen), or sutures.[28-33] Provision can also be made for the most adequate follow up measures should complications arise.

Earlier research reported that puncture sites not located in the common femoral artery were associated with a higher rate of post-catheterization vascular complications.[1,4,6,13,17] In this study, these were more frequent that expected and we were particularly surprised to find 8% of punctures in the deep femoral artery (16% if we include punctures in the ostium). Furthermore, the frequency of punctures in the femoral artery bifurcation (17%), adjacent to the femoral artery ostium mentioned and the puncture site was remarkably high. These are potentially dangerous with invasive methods of securing hemostasis. Punctures away from the common femoral artery were associated in our study with a higher percentage of spasm in the traumatized area. We found no direct relationship between spasm and vascular complications. We do not know whether spasm influences the outcome of invasive hemostasis procedures affecting the lumen or vessel wall. We were also concerned to find 12% of branches to the thigh adjacent to the puncture site in danger of being occluded during attempts to secure hemostasis. These anatomic characteristics appeared in ≥35% of approaches. Clinical and angiographic repercussions of the different invasive procedures to hemostasis in vulnerable areas of femoral artery anatomy are unknown. The procedures we used did not indicate a link between evidence of atheroma and the appearance of vascular complications.

The use of the femoral head as a landmark for the common femoral artery was of limited validity given that in 30% of our patients it coincided with the femoral artery bifurcation or with its branches. This could lead to punctures in vulnerable segments below the common femoral artery (Figure 2).[7,16,17] Our findings contradict other reports[8,19] that identify this as the ideal common femoral artery puncture site in more than 90% of patients.

Plugs or percutaneous sutures are widely used to secure hemostasis after transfemoral access. They are delivered blind and some are invasive.[10,26-28] We chose collagen plugs because they are noninvasive and thus offered us the opportunity to repeat the procedure in the hours or days after its first use. Studies comparing collagen plugs or other percutaneous procedures to achieve hemostasis, all employ VasoSeal-ES® products as these were the first available and provided a learning experience for other more recent ones.[10,27,30] Although there are many published comparisons of procedures for hemostasis, none have used the current VasoSeal-ES® model, which differs from the original product in that it measures the real skin-artery distance, and one model fits all sheath sizes. The results of these studies cannot be considered conclusive and no product clearly stands out from the others.[21,24,25,28,33]

Instructions on the most common suture procedure (Perclose), limit its use to the common femoral artery and, surprisingly, no reference is made to systematic prior femoral angiography. However, it is suggested that the most common procedure involving the permanent introduction of intravascular material (AngioSeal) should not be used outside of the common femoral artery unless previous femoral artery angiography is one of the routine procedures carried out by operators. This study set no anatomic limits on the use of VasoSeal-ES®. It did not even mention femoral artery puncture sites other than those in the common femoral artery.

In our study, complications related to VasoSeal-ES® were within the lower limits of those reported elsewhere,[23,26,28,33] after the first two months. They did not represent an increase when compared with the use of manual compression. This is contrary to results described by other researchers who report an increase in complications on beginning to use one type of hemostasis material or another.[3,21,22,30] We found the higher percentage of unsuccessful VasoSeal-ES® deliveries (5.1% after the learning curve was completed) was related to local complications. Consequently, we had to consider these patients as a special risk group who needed a different follow-up in the period after cardiac catheterization. This may be common to other types of instrumental procedures to hemostasis although we found no reference to it in the literature.

CONCLUSIONS

Angiographic studies of femoral artery anatomy and the disposition of the catheter introducing sheath can be of great value in choosing procedure to hemostasis, and contributing to the reduction of local vascular complications.

The angiographic study identifies the vulnerable areas of the femoral artery puncture site as it relates these to a greater number of complications: punctures in the superficial and the deep femoral arteries and ostium add up to 35% of the total with an unexpectedly high percentage in the deep femoral artery and ostium (15.5%).

The introduction of VasoSeal-ES® allowed us to maintain a program of outpatient transfemoral approach catheterization without increasing the number of complications. The VasoSeal-ES® delivery learning curve, which varies greatly from operator to operator, and low patient body weight are risk factors related to femoral artery vascular complications as they are linked to unsuccessful collagen plug delivery.

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