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Recommended Citation

Oneissi, Mazen; Sweid, MD, Ahmad; Tjoumakaris, Stavropoula; Hasan, David; Gooch, MD, Michael R.; Rosenwasswer MD, Robert H.; and Jabbour, Pascal, "Access-Site Complications in Transfemoral Neuroendovascular Procedures: A Systematic Review of Incidence Rates and Management Strategies" (2020). *Department of Neurosurgery Faculty Papers*. Paper 125. <https://jdc.jefferson.edu/neurosurgeryfp/125>

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Access-Site Complications in Transfemoral Neuroendovascular Procedures: A Systematic Review of Incidence Rates and Management Strategies

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Received, August 1, 2019.

Accepted, February 10, 2020.

Published Online, May 4, 2020.

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 Congress of Neurological Surgeons

BACKGROUND: The femoral artery is the most common access route for cerebral angiography and neurointerventional procedures. Complications of the transfemoral approach include groin hemorrhages and hematomas, retroperitoneal hematomas, pseudoaneurysms, arteriovenous fistulas, peripheral artery occlusions, femoral nerve injuries, and access-site infections. Incidence rates vary among different randomized and nonrandomized trials, and the literature lacks a comprehensive review of this subject.

OBJECTIVE: To gather data from 16 randomized clinical trials (RCT) and 17 nonrandomized cohort studies regarding femoral access-site complications for a review paper. We also briefly discuss management strategies for these complications based on the most recent literature.

METHODS: A PubMed indexed search for all neuroendovascular clinical trials, retrospective studies, and prospective studies that reported femoral artery access-site complications in neurointerventional procedures.

RESULTS: The overall access-site complication rate in RCTs is 5.13%, while in non-RCTs, the rate is 2.78%. The most common complication in both groups is groin hematoma followed by access-site hemorrhage and femoral pseudoaneurysm. On the other hand, wound infection was the least common complication.

CONCLUSION: The transfemoral approach in neuroendovascular procedures holds risk for several complications. This review will allow further studies to compare access-site complications between the transfemoral approach and other alternative access sites, mainly the transradial approach, which is gaining a lot of interest nowadays.

KEY WORDS: Neuroendovascular, Femoral artery, Groin Hematoma, Femoral artery pseudoaneurysm

Operative Neurosurgery 19:353–363, 2020

DOI: 10.1093/ons/opaa096

Since the old use of interventional methods in the diagnosis and treatment of certain cerebral vascular disorders and stroke, the femoral artery has been the preferred access point for the introduction of catheters in the diagnosis and treatment of certain cerebral vascular disorders and stroke.¹⁻³ However, the transfemoral approach has been associated with a wide array of access-site complications,

ranging in severity from minor complications requiring minimal treatment to life-threatening complications requiring aggressive, life-saving surgical interventions. The most common access-site complication is groin hematoma, which may vary in size, while one of the most serious complications is retroperitoneal hematoma, which may lead to hemorrhagic shock and death if not quickly diagnosed and treated.²⁻⁵ Among other complications are access-site hemorrhages, femoral artery dissections and pseudoaneurysms, arteriovenous (AV) fistulas, peripheral artery occlusions, femoral nerve injuries, and access-site infections.² Many studies have reported various incidence rates of these complications. While the literature regarding access-site complications in coronary interventional procedures is well published,

ABBREVIATIONS: AV, arteriovenous; CI, confidence interval; OR, odds ratio; RCT, randomized clinical trial; TAVR, transcatheter aortic valve replacement; UCG, ultrasound-guided compression; VCD, vascular closure device

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publications pertaining to a comprehensive review of access-site complications are lacking for neuroendovascular procedures. In this article, we review the literature, including randomized clinical trials, retrospective and prospective cohorts, and certain case reports to provide a systematic review that summarizes incidence rates as well as management strategies for access-site complications related to the transfemoral approach in neurointerventional procedures.

METHODS

Using PubMed database, we performed a literature search without time limitations for all articles using different combinations of the terms *transfemoral*, *neurointervention*, *neuroendovascular*, *interventional neurology*, and *femoral artery*. Articles were then classified as randomized clinical trials (RCTs) and non-RCTs. Abstracts were screened to determine if the study matches our requirements, mainly being related to neurointerventional procedures. Then, full texts were read in depth to determine whether access-site complications were discussed and if incidence data were available. Articles were searched for adverse events, complications, and outcomes in the text, tables, or supplementary material. Articles that did not provide data about the incidence rates of access-site complications were excluded. For RCTs, the website clinicaltrials.gov was also searched for publicly available results that included data about adverse events and access-site complications. RCTs with no data in published articles or through clinicaltrials.gov were excluded. Additionally, case reports of rare complications were discussed in a subsection in the discussion.

Incidence rates were calculated by dividing the number of occurrences of each access-site complication by the total number of patients who underwent a neurointerventional procedure using the transfemoral approach. If one patient underwent multiple independent procedures, that patient was counted twice in the total population. The total incidence rate of access-site complications for each study is calculated by adding all incidents of access-site complications divided by the total number of patients. The average incidence rate of a certain complication among multiple studies is calculated by adding the individual number of incidents of that complication in all studies divided by the total number of patients only from studies that reported that complication. Studies that frankly report no incidents of that particular complication are included in the total population, while those that do not report the complication are not included. By excluding these studies from the total population, we overcome the bias from selective reporting among studies. Due to the nature of the manuscript, institutional review board approval and patient consent were not sought.

RESULTS

Study Selection

Our search on PubMed found 30 RCTs and 54 non-RCTs of various interventional procedures, while the search on clinicaltrials.gov gave us 29 RCTs all related to neurointerventional procedures. A total of 19 RCTs were eliminated as duplicates between the 2 searches. Out of the remaining 40 RCTs, only 16 published data about access-site complications in the trans-

femoral approach and were included in our review. Out of the 54 non-RCTs, 25 were eliminated at the level of title and abstract screening either because they are related to cardiovascular procedures or because the management was medical, not requiring an endovascular procedure, whether diagnostic or interventional. Out of the remaining 29 non-RCTs, 12 were excluded after full-text reading due to the lack of data regarding access-site complications. The remaining 17 non-RCTs were included in our review. In total, we reviewed 16 RCTs and 17 non-RCTs reporting access-site complication rates (Figure 1). Additionally, 5 non-RCTs tackling the use of different vascular closure devices (VCDs) have been separately included in our study.

Study Characteristics

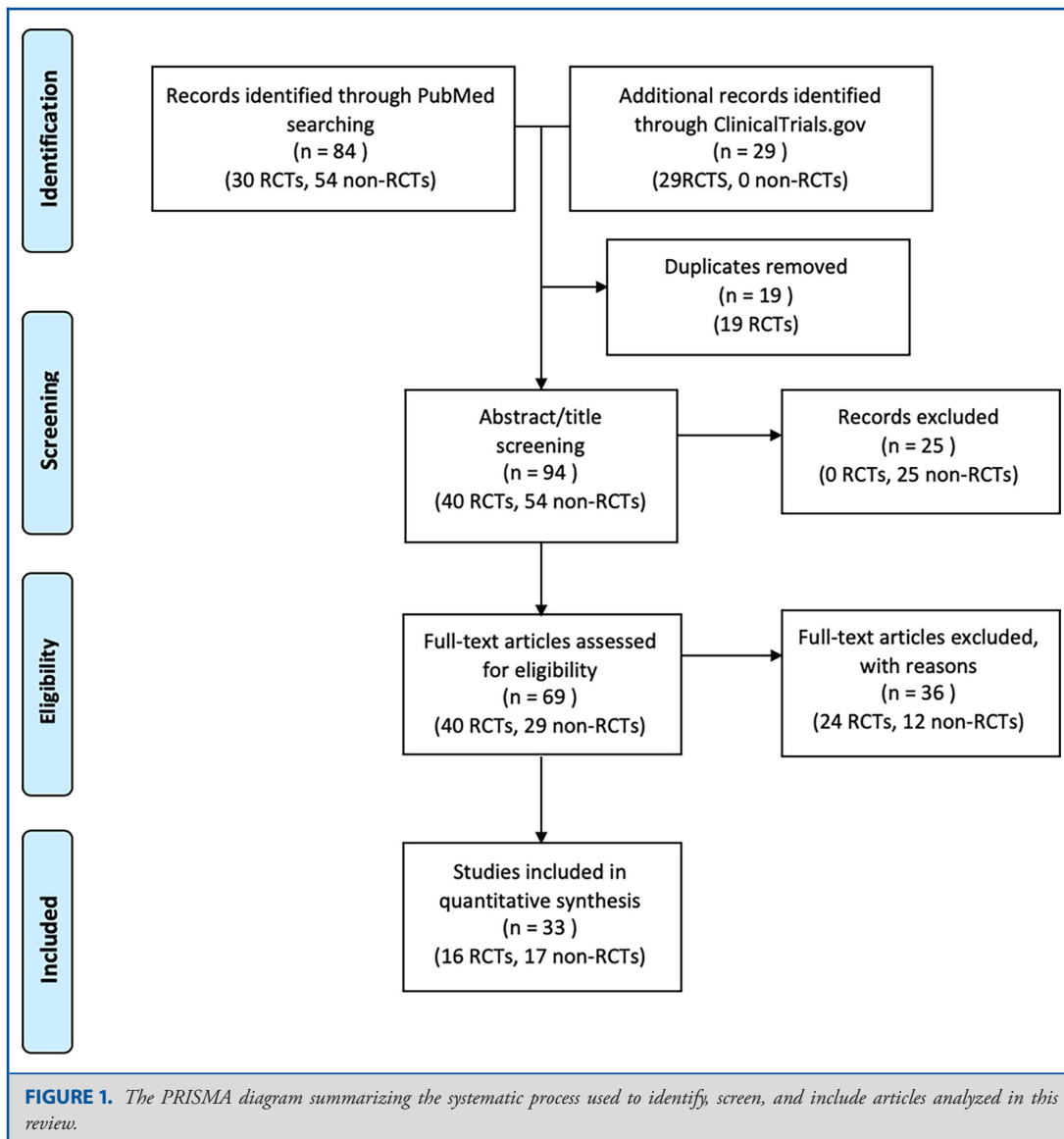
Among the 16 RCTs, 10 were related to stroke management. These were IMS-II, IMS-III, ESCAPE, EXTEND-IA, REVASCAT, RIVER JAPAN, SWIFT, THRACE, STAR, and SWIFT-PRIME. Two RCTs (PUFS and PFLEX) and 1 registry (The Buenos Aires Experience) were related to the use of pipeline device for the treatment of cerebral aneurysms. One RCT (ENACT) was related to the use of coiling in treating cerebral aneurysm, and 2 RCTs (CREST and RADCAR) were related to carotid artery stenting. Excluded RCTs were MR CLEAN, MR RESCUE, THERAPY, SYNTHESIS, PISTE, ASTER, DAWN, TREVO, ADAPT, IntrePED, PREMIER, PITA, ASPIRe, MATRIX, TEAM, ISAT, SAMMPRIS, ATENA, CLARITY, WEB-IT, WEBCAST 1, WEBCAST 2, SAPPHIRE, and ARUBA.

From the 17 non-RCTs included in our study, 7 were related to diagnostic cerebral angiography, 2 were related to cerebral aneurysm coiling, 2 were related to the use of flow diverters to treat cerebral aneurysms, 1 was related to carotid artery stenting, 1 was related to intraarterial chemotherapy delivery, 1 was related to mechanical thrombectomy, and 3 were a mixture of several neurointerventional procedures.

DISCUSSION

Access-Site Hemorrhage

Access-site hemorrhage is a relatively common complication of interventional procedures using the transfemoral approach and is considered a leading cause of groin hematomas as well as retroperitoneal hematomas. Risk factors include use of anticoagulation, insufficient manual compression, and early ambulation. For the sake of this review, we are defining access-site hemorrhage as bleeding from the puncture site without including contained subcutaneous and retroperitoneal hematomas, as these are described in separate sections. Seven RCTs report incidents of groin hemorrhage at rates ranging from 0.78% to 2.61% with an average of 2.06%, while one non-RCT reports an incidence rate of 0.59% (Table 1).⁶⁻¹³



Groin Hematoma

Groin hematoma is the most common complication when using the femoral artery as an access point in both cardiac and neurointerventional procedures.^{3,5,14} Groin hematomas occur shortly after sheath removal due to failure to control bleeding from the femoral artery. Risk factors include obesity, use of anticoagulants, large sheaths, early ambulation, and peripheral vascular disease.¹⁵ It is believed that puncturing below the femoral bifurcation as well as poor hemostatic techniques increase the risk of developing a groin hematoma (Figure 2A).^{2,15}

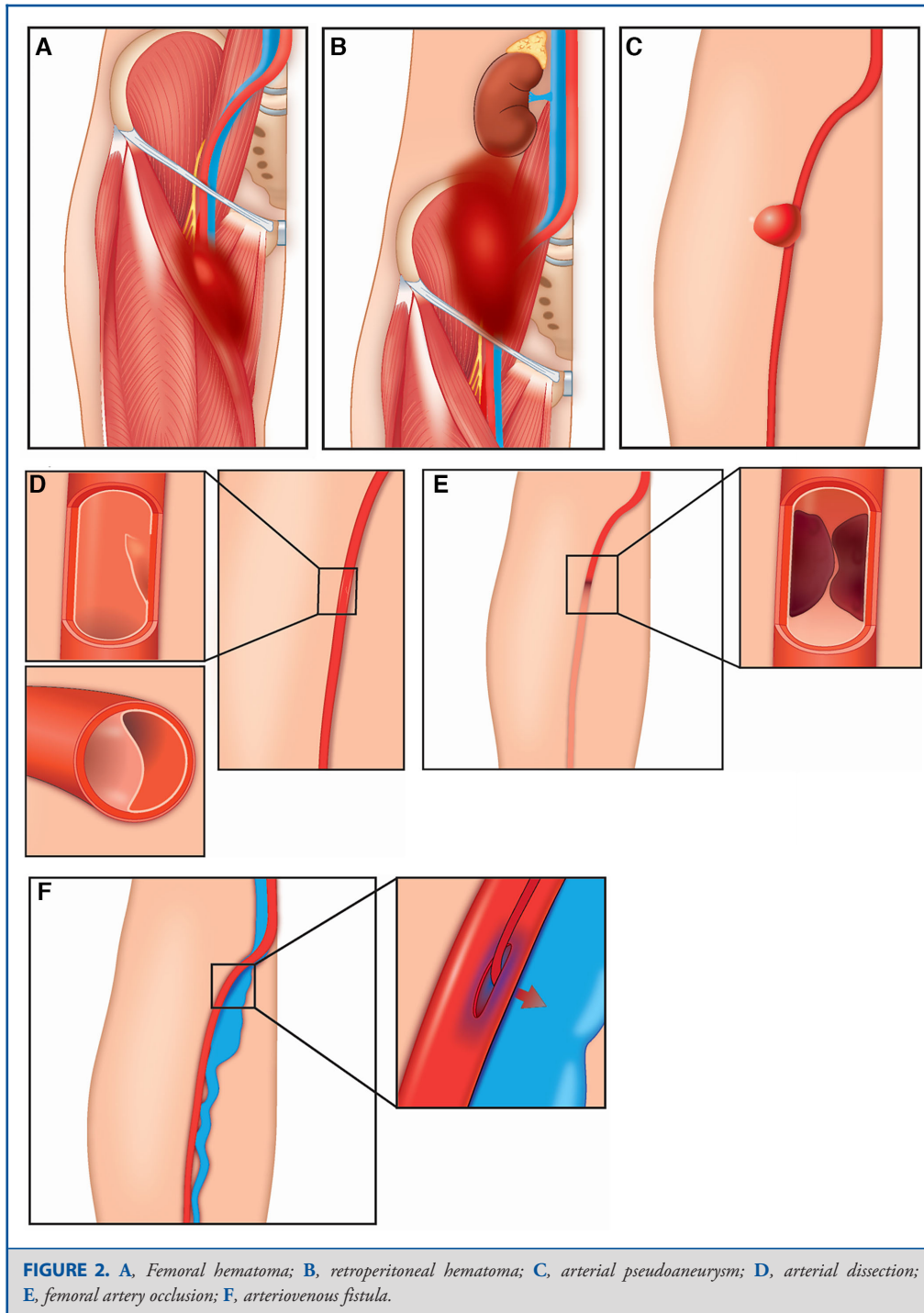
A total of 12 RCTs reported incidence rates of groin hematomas between 0.23% and 10.68% with an average of 2.49%,^{6-10,12,13,16-20} while non-RCTs reported an incidence rate of 0.03% to 8.1% with an average of 2.89%.^{5,14,21-29} Differences

in occurrence rates are partly due to the differences in defining what constitutes a hematoma. Additionally, some studies only reported hematomas that are larger than a certain size threshold. The ESCAPE and REVASCAT trials reported incidence rates of groin hematoma as high as 9.09% and 10.68%, respectively, while rates were as low as 0.63% and 0.99% in the CREST and STAR trials, respectively (Tables 1 and 2).^{7,13,17,20}

The literature regarding the use of VCDs to reduce the risk of groin hematomas compared to manual compression is variable. A prospective multicenter registration study by Sato et al³⁰ showed a significant decrease in incidence rates of groin hematomas when AngioSeal STS Plus VCD (Terumo) is used vs manual compression (5.04% vs 34.55%, P -value < .001). Moreover, hemostasis time was significantly shorter in the VCD group than

TABLE 1. Transfemoral Complications in Randomized Clinical Trials

Study	Year	N (total)	Groin hematoma		Groin hemorrhage		Retroperitoneal hematoma		Femoral aneurysm		Artery occlusion		Femoral nerve injury		Wound infection		All complications		
			n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	
STROKE	IMS-II ⁴⁶	81																	
	IMS-III ⁶	434	16	3.69	6	1.38	2	0.46	1	0.23	1	0.23	1	0.23	1	0.23	27	6.22	
	ESCAPE ¹⁷	165	15	9.09													15	9.09	
	EXTEND-IA ¹⁹	35	1	2.86													1	2.86	
	REVASCAT ⁷	103	11	10.68	2	1.94			1	0.97							14	13.59	
	RIVER JAPAN ⁴⁵	49							1	2.04	1	2.04					2	4.08	
	SWIFT ⁹	113	2	1.77	1	0.88	2	1.77	1	0.88	1	0.88	1	0.88	1	0.88	9	7.96	
	THRACE ¹⁶	204	3	1.47													3	1.47	
	STAR ²⁰	202	2	0.99					1	0.5							3	1.49	
	SWIFT PRIME ¹⁰	98	1	1.02	1	1.02	1	1.02									3	3.06	
	Buenos Aires ¹⁸	53	5	9.43													5	9.43	
Pipeline	PuFS ³⁶	107							1	0.93							1	0.93	
	PfLEX ⁸	50	1	2	1	2	1	2									3	6	
Coil	ENACT ³⁷	92							1	1.09							1	1.09	
Carotid	CREST ¹³	1262	8	0.63	33	2.61	4	0.32									67	5.31	
	RADCAR ²	128	6	4.69	1	0.78	1	0.78									8	6.25	
	Total n	71	45		13		13		6		3		1		2		163		
	Total N	2847	2188		2284		2284		982		596		241		547		3176		
	Average incidence rate	2.49%	2.06%		0.57%		0.57%		0.61%		0.5%		0.41%		0.37%		5.13%		



in the manual compression group (4.4 vs 150.7 min, $P < .001$). On the other hand, incidence rates in 5 non-RCTs reporting groin hematoma as a complication of the transfemoral approach while using VCDs ranged between 0.49% and 5.04% with an average rate of 1.38% (Table 3).³⁰⁻³⁴

Retroperitoneal Hematoma

Retroperitoneal hematoma, a relatively rare complication of femoral puncture, develops either due to an uncontrolled groin hematoma that expands in size or a femoral puncture above the level of the inguinal ligament (Figure 2B).^{4,15} It is considered

TABLE 2. Transfemoral Complications in Observational Studies

Study	Year	N	Groin hematoma		Groin hemorrhage		Retroperitoneal hematoma		Femoral (pseudo) aneurysm		Arteriovenous fistula		Artery occlusion		Femoral nerve Injury		Wound infection		All complications			
			n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Huckman et al ²⁶	1979	361	6	1.66																6	1.66	
Heiserman et al ¹⁴	1994	1000	81	8.1																83	8.3	
Willinsky et al ²⁹	2003	2899	14	0.48					1	0.03										15	0.52	
Kaufmann et al ²⁷	2007	19 390	828	4.27										9	0.05				2	0.01	839	4.33
Dawkins et al ²²	2007	2924	12	0.41																15	0.51	
Fifi et al ²³	2009	3636	1	0.03			1	0.03	1	0.03				2	0.06				1	0.03	6	0.17
Shen et al ⁵	2018	644	10	1.55			1	0.16	1	0.16	1	0.16							0	0	12	1.86
Mendiz et al ¹¹	2016	674			4	0.59	2	0.3	1	0.15										7	1.04	
Im et al ¹⁷	2009	370							1	0.27										2	0.54	
Cavalcanti et al ³⁸	2013	22					1	4.55												1	4.55	
Gelman et al ²⁴	1999	392	10	2.55									1	0.26						11	2.81	
Horowitz et al ²⁵	1998	1929	10	0.52					12	0.62	0	0	18	0.93					2	0.1	42	2.18
Kelkar et al ⁵³	2013	2918																		3	0.1	
Qureshi et al ⁵²	2018	270													4	1.48				4	1.48	
Shah et al ²⁸	2015	472	2	0.42					1	0.21										3	0.63	
Lubicz et al ³⁹	2011	20																		1	5	
Burrows et al ²¹	2014	93	1	1.08			1	5	3	3.23									2	2.15	6	6.45
Total n		975	4		4		5		20		2		30		4		4		10		1056	
Total N		33740	674		674		4352		10347		2943		25347		270		27966		38014		38014	
Average incidence rate			2.89%		0.59%		0.11%		0.19%		0.07%		0.12%		1.48%		0.04%		0.04%		2.78%	

TABLE 3. Transfemoral Complications in Observational Studies Using Different Vascular Closure Devices (VCDs)

Study	VCD	Year	N (total)	Groin hematoma		Groin hemorrhage		Retroperitoneal hematoma		Femoral aneurysm (pseudo)		Arteriovenous fistula		Artery occlusion		Femoral nerve injury		Wound infection		Total complications	
				n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%	n	%
Sato et al ³⁰	Angio-seal	2017	119	6	5.04	1	0.84	-	-	-	-	-	-	-	-	-	-	1	0.84	8	6.72
Geyik et al ³¹	Angio-seal	2007	1443	7	0.49	14	0.97	5	0.35	4	0.28	-	-	2	0.14	-	-	2	0.14	33	2.29
Goto et al ³²	EXOSEAL	2017	332	8	2.41	7	2.11	1	0.3	1	0.3	-	-	-	-	-	-	-	-	17	5.12
Grandhi et al ³³	Mynx	2014	937	17	1.81	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	0.32
Grandhi et al ³⁴	EXOSEAL	2015	441	7	1.59	-	-	-	-	0	0	-	-	7/102	6.86	-	-	0	0	7	-
Total n			45	22		22		6		6				9				6		86	
Total N			3272	1894		1775		2216		1545				2940				3272			
Percentage			1.38%	1.16%		0.34%		0.27%		0.58%				0.20%				2.63%			

one of the most serious and difficult-to-diagnose complications. Symptoms are nonspecific and may include suprainguinal tenderness and fullness (most common), severe back and lower quadrant abdominal pain, and lower extremity pain. Patients may also develop hypotension that may require blood transfusions or urgent surgical intervention.^{4,35}

From the reviewed 40 RCTs, 8 reported the incidence of retroperitoneal hemorrhage ranging from 0.32% to 1.77% with an average of 0.57% (Table 1).^{6,8-10,12,13,36,37} Four non-RCTs reported incidence rates between 0.03% and 5% with an average of 0.11% (Table 2).^{11,23,38,39} However, it is worth noting that 2 of these studies with incidence rates of 4.33% and 5% have a relatively low total number of enrolled subjects of 22 and 20, respectively, and only one incidence of retroperitoneal hematoma in each, which accounted for the relatively high incidence rate.

Although relatively rare, retroperitoneal hematoma is a serious complication that may lead to death if not treated properly. The management of retroperitoneal hematoma is mainly conservative for hemodynamically stable with intensive care unit observation, fluid resuscitation, blood transfusion, and reversal of anticoagulation. In unresponsive cases, further intervention is warranted, with preference for percutaneous interventional procedures over surgery.^{35,40,41} Options include embolization by coiling, gelatin, and/or polyvinyl alcohol. Other options include balloon tamponade of the common femoral artery and balloon catheter delivery of intra-arterial thrombin. Surgical intervention is entertained if less invasive procedures fail.⁴²

Femoral Artery Pseudoaneurysm and Dissection

Femoral artery pseudoaneurysm is a known but uncommon complication of interventional procedures, especially via the transfemoral approach. A pseudoaneurysm is a hematoma with persistent communication with the artery, and it is usually limited to the area surrounding the common femoral artery (Figure 2C).⁴³ Although not always present, a differentiating aspect of femoral pseudoaneurysms from other groin hematomas is the presence of pulsation due to the persistent communication between the pseudoaneurysm and the artery.⁴⁴ A femoral puncture below the bifurcation is a risk factor.^{2,3,43} Other risk factors include advanced age, obesity, gender (female > male), use of anticoagulants, and lower platelet count.³

Six RCTs report incidence rates of femoral pseudoaneurysms between 0.23% and 2.04% with an average of 0.61% (Table 1).^{6,7,9,20,45,46} The incidence rate in 7 non-RCTs ranged between 0.03% and 3.23% with an average of 0.19% (Table 2).^{5,11,21,23,25,28,29}

On the other hand, femoral artery dissection is an injury to the vessel wall leading to the disruption of its layers without complete rupture (Figure 2D). Arterial dissection leads to blood flow disturbance and may result in arterial occlusion. Three non-RCTs report incidence rates of femoral or iliac artery dissection between 0.1% and 0.27%, with an average rate of 0.14% (Table 2).^{14,22,47}

The management of femoral pseudoaneurysms is usually conservative. Observation plays an important role until a certain size threshold. The widely used threshold is 3 cm. Another approach is ultrasound-guided compression (UGC) of the pseudoaneurysm neck to block its blood flow for an average of 30 min while maintaining femoral artery blood flow. Stasis of blood in the pseudoaneurysm leads to its thrombosis. Another approach with higher success rate is duplex-guided thrombin injection, in which thrombin is injected in the aneurysm sac. Surgical intervention is preserved for large pseudoaneurysms with superimposed skin necrosis, infection, or nerve compression.³

Peripheral Arterial Occlusion

Many factors contribute to arterial occlusion in the peripheral circulation after transfemoral catheterization, including arterial stenosis, thrombosis, and dissection (Figure 2D and 2E). Symptoms include lower limb pain, claudication, cold limb, or pale color of lower extremity. Symptoms may appear within 24 h postcatheterization but can also be delayed or appear only after long-distance ambulation. In severe cases, lower extremity ischemia may occur requiring aggressive interventional or surgical treatment.

Peripheral artery occlusion is a relatively rare complication of the transfemoral approach in neurointerventional procedures. Three RCTs report incidence rates between 0.23% and 2.04%, with an average rate of 0.5% (Table 1).^{6,9,45} Four non-RCTs report incidence rates between 0.05% and 0.93% with an average of 0.12% (Table 2).^{23-25,27} Reported cases included 1 popliteal artery and 1 iliac artery thrombosis, while the other cases were unspecified. Higher incidence rates of arterial occlusion ranging between 0.14% and 6.86% were reported when VCDs were used for hemostasis (Table 3).^{1,31} Corley et al⁴⁸ reported a case of right common femoral artery occlusion in a 26-yr-old female undergoing a transfemoral interventional procedure for AVM embolization. A 6F AngioSeal closure device was used to close the arteriotomy. The patient had the typical symptoms, and right common femoral artery occlusion was confirmed by radiology. Intraoperatively, it was found that the AngioSeal device was occluding the artery.

AV Fistula

An AV fistula is an abnormal communication between an artery and a vein (Figure 2F).⁴³ AV fistula formation is a rare complication of femoral artery catheterization. A puncture below the femoral bifurcation at the superficial femoral artery is a risk factor.^{2,49} Other risk factors include arterial hypertension, female gender, left groin puncture, and mode and intensity of anticoagulation. AV fistulas lead to left-to-right hemodynamic shunting, which may reduce blood flow in the downstream vascular bed and may lead to cardiac failure if left untreated.⁵⁰

None of the 40 reviewed RCTs reported any case of AV fistula, while 3 non-RCTs reported incidence rates between 0% and 0.27% with an average rate of 0.07% (Table 2).^{5,25,47}

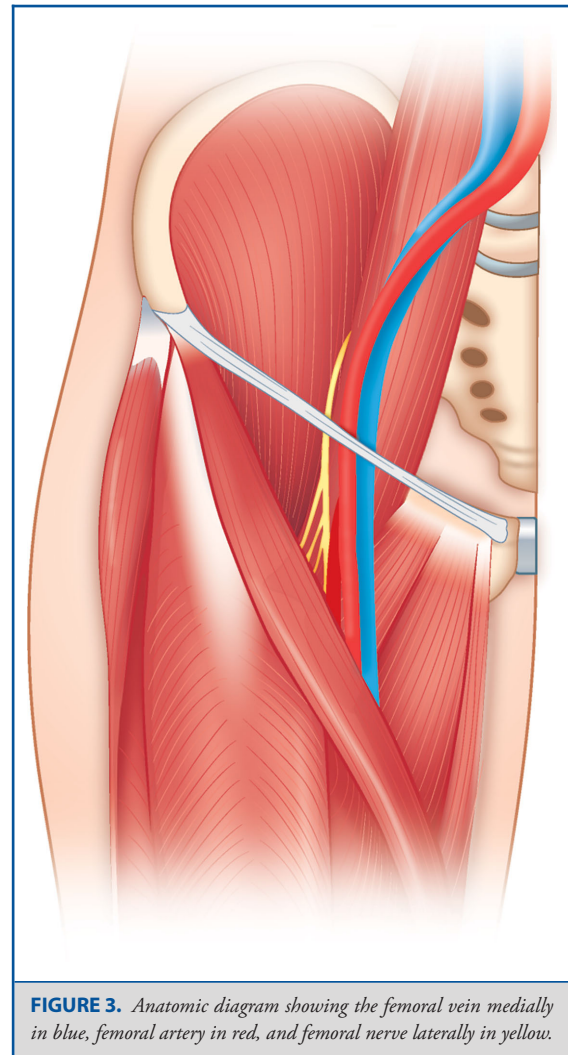


FIGURE 3. Anatomic diagram showing the femoral vein medially in blue, femoral artery in red, and femoral nerve laterally in yellow.

The management of AV fistulas comprises observation in most asymptomatic cases.⁵¹ Other techniques include UGC, endovascular embolization, or stent placement and surgery. Indications for intervention include fistulas that do not heal spontaneously after 4 wk, progressive enlargement, steal syndrome, venous hypertension, and heart failure.^{50,51}

Femoral Nerve Injury

The femoral nerve enters the thigh through the femoral triangle lateral to the femoral artery separated from it by continuous iliopsoas fascia (Figure 3). Due to the multiple manipulations in the vicinity of the femoral artery, the femoral nerve is at risk of compression injury. It manifests as pure sensory symptoms including pain, paresthesia, and sensory loss. Additionally, the injury may affect the anterior, medial, and lateral cutaneous branches of the femoral nerve.⁵²

Two RCTs, SWIFT and RADCAR, reported incidence rates between 0% and 0.88% with an average rate of 0.41%

TABLE 4. Minor vs Major Complications in the Different Study Groups

	Complication type		P value
	Minor n/N (%)	Major n/N (%)	
RCTs	116/2847 (4.07%)	25/2719 (0.92%)	<.0001
Non-RCTs	979/34 414 (2.84%)	71/33 729 (0.21%)	<.0001
Non-RCTs with VCDs	67/3272 (2.05%)	27/3272 (0.83%)	<.0001

(Table 1).^{9,12} Qureshi et al⁵² reported 4 incidents in 270 patients (1.48%). Usually, symptoms resolve in a period between 1 wk and 2 mo. Treatment is only symptomatic to relieve pain and paresthesia.

Access-Site Infection

Surgical site infection is a common complication of all invasive procedures, especially with the introduction of permanent foreign bodies. In neurointerventional procedures, groin infection is a rare but serious complication, especially with the use of femoral artery closure devices. In 2 RCTs, IMS-III and SWIFT, the incidence rates were 0.23% and 0.88%, respectively, with an average of 0.37%. The use of VCDs was not specified in these trials.^{6,9} On the other hand, non-RCTs reported incidence rates between 0% and 2.15%, with an average rate of 0.04%, without specifying whether VCDs were used or not.^{5,21,23,25,27,53} In non-RCTs where VCDs were used at the femoral arteriotomy sites, the incidence rates ranged between 0% and 0.84% with an average rate of 0.23% (Table 3).^{30,31,33,34,54}

To prevent procedure-associated infections, the Centers for Disease Control (CDC) recommends the use of sterile techniques in catheterization procedures. Prophylactic use of antibiotics is not recommended unless the patient is immunocompromised or a definite wound contamination is suspected during the procedure.⁵⁵

Minor vs Major Complications

Access-site-related complications can be categorized as minor vs major complication. The former includes groin hematoma and groin hemorrhage, while the latter includes retroperitoneal hematomas, AV fistulae, femoral artery pseudoaneurysms, femoral artery dissection, femoral nerve injury, arterial occlusion, and wound infection. Table 4 shows the distribution of complications between these 2 groups in both RCTs and non-RCTs. In all study groups, the incidence rate of minor complications is significantly higher than that of major complications (P -value < .0001).

The Use of Ultrasound Guidance

Several studies have investigated the role of ultrasound guidance in reducing transfemoral access-site complications. One study by Dudeck et al⁵⁶ showed a significant decrease in time to arterial puncture and number of attempts for successful puncturing only in patients with weak femoral pulse or leg

circumference >60 cm. Another recently published randomized controlled trial (SURF) showed that there was no difference in the complication rates between standard and ultrasound guidance ($P = .76$). However, ultrasound guidance reduced mean access time (93 vs 111 s; $P = .009$), attempts (1.47 vs 1.9; $P < .0001$), and venipuncture (4.1% vs 9.2%; $P < 0.0001$) and improved first-pass success (73% vs 59.7%; $P = .0001$).⁵⁷ On the other hand, a single-center retrospective cohort study on 387 patients undergoing transcatheter aortic valve replacement (TAVR) found that the routine use of ultrasound in transfemoral TAVR was associated with significant reductions in access-related vascular and bleeding complications (odds ratio [OR] = 0.42 [95% CI, 0.25-0.70; $P < .01$]).⁵⁸ Another recent meta-analysis of 5 RCTs found that ultrasound guidance significantly improves time to access (weighted mean difference: 24.90 min, 95% CI 12.41-37.38), first-pass success rate (OR 2.97; 95% CI 1.49-5.92), and total complication rate (OR 0.42, 95% CI 0.23-0.77) but did not have any significant influence on the incidence rate of individual complications like groin hematoma, retroperitoneal hematoma, or pseudoaneurysm.⁵⁹

Access-Site Complications in Cardiovascular and Other Interventional Procedures

Before we end our discussion, it is important to review the literature in this matter relating to cardiovascular and other interventional procedures. Several studies reported incidence rates of access-site complications in transfemoral catheterization ranging from 1% to 10%.⁶⁰⁻⁶² Compared to the transradial approach, transfemoral access had a higher overall rate of access-site complications in the AUCITY trial (3.7 vs 1.4%; $P < .0001$). This trial also showed that the rates of bleeding complications are also higher in the transfemoral approach (4.5 vs 1.9%; $P < .0001$). Moreover, the rate of pseudoaneurysm was also significantly higher in the transfemoral approach (0.6 vs 0.2%; $P = .006$).^{63,64} Additionally, the MATRIX trial showed a significant decrease in bleeding complication in the transradial approach (1.6 vs 2.3%; $P = .013$).^{64,65} On the other hand, the RIVAL trial did not show significant differences in terms of primary or secondary endpoints between radial and femoral approaches.^{64,66} A meta-analysis of 12 RCTs by Agostoni et al⁶¹ concluded that the transradial approach was significantly superior to femoral access in terms of the risk of entry site complications in cardiovascular diagnostic and interventional procedures (0.3% vs 2.8%; OR 0.20, 95% CI 0.09-0.42; $P < .0001$).

Limitations

One of the limitations faced during our study is the differences in the definitions of access-site complications among different trials, along with the difference in the threshold for reporting these complications. This difference may lead to underestimation of the incidence rates in some studies due to underreporting when thresholds are higher. Another limitation is that some studies were only interested in reporting specific

complications without the others, which led us to exclude their population when calculating the average incidence rates, thus leading to a smaller total population. Moreover, a major limitation is the lack of studies that specifically target access-site complications in neurointerventional procedures. Studies found in the literature mention access-site complications in terms of incidence only, without providing specific patient information like age, anticoagulation status, present comorbidities, or previous interventions at the same site. Those studies also fail to provide details about the technique used, sheath size, and level of heparinization or anticoagulation. Due to the lack of this data, we were only able to present the data mostly as a systematic review.

CONCLUSION

The transfemoral approach in neuroendovascular procedures holds risk for several complications, including groin hematoma and hemorrhage (most common), retroperitoneal hematoma, AV fistula, femoral artery pseudoaneurysm, peripheral arterial occlusion, femoral nerve injury, and surgical wound infection (least common). The literature lacks a comprehensive review of all these complications, specifically in the neuroendovascular field. This review will allow further studies to compare access-site complications between the transfemoral approach and other alternative routes, mainly the transradial, which is gaining a lot of interest nowadays.

Disclosures

Dr Jabbour is a consultant for Medtronic. The other authors have no personal, financial, or institutional interest in any of the drugs, materials, or devices described in this article. Dr Jabbour is a consultant for MicroVention. Dr Tjoumakaris is a consultant for Stryker.

REFERENCES

- Gandhi CD, Al Mufti F, Singh IP, et al. Neuroendovascular management of emergent large vessel occlusion: update on the technical aspects and standards of practice by the Standards and Guidelines Committee of the Society of NeuroInterventional Surgery. *J Neurointerv Surg*. 2018;10(3):315-320.
- Rajpal G, Basheer N. Complications and avoidance in neurointerventional surgery. *Indian J Neurosurg*. 2018;7(2):90-95.
- Stone PA, Campbell JE, AbuRahma AF. Femoral pseudoaneurysms after percutaneous access. *J Vasc Surg*. 2014;60(5):1359-1366.
- Murai Y, Adachi K, Yoshida Y, Takei M, Teramoto A. Retroperitoneal hematoma as a serious complication of endovascular aneurysmal coiling. *J Korean Neurosurg Soc*. 2010;48(1):88-90.
- Shen J, Karki M, Jiang T, Zhao B. Complications associated with diagnostic cerebral angiography: a retrospective analysis of 644 consecutive cerebral angiographic cases. *Neurol India*. 2018;66(4):1154-1158.
- Broderick J. Interventional Management of Stroke (IMS) III Trial. 2006. <https://ClinicalTrials.gov/show/NCT00359424>. Accessed June 24, 2019.
- Jovin TG, Chamorro A, Cobo E, et al. Thrombectomy within 8 hours after symptom onset in ischemic stroke. *N Engl J Med*. 2015;372(24):2296-2306.
- Martínez-Galdámez M, Lamin SM, Lagios KG, et al. Periprocedural outcomes and early safety with the use of the Pipeline Flex Embolization Device with Shield Technology for unruptured intracranial aneurysms: preliminary results from a prospective clinical study. *J Neurointerv Surg*. 2017;9(8):772-776.
- Medtronic Neurovascular Clinical Affairs. SOLITAIRE™ FR With the Intention for Thrombectomy (SWIFT) Study; 2010 <https://ClinicalTrials.gov/show/NCT01054560>. Accessed June 24, 2019.
- Medtronic Neurovascular Clinical Affairs. Solitaire™ With the Intention for Thrombectomy As Primary Endovascular Treatment (SWIFT PRIME) Trial; 2012. <https://ClinicalTrials.gov/show/NCT01657461>. Accessed June 24, 2019.
- Mendiz OA, Fava C, Lev G, Caponi G, Valdivieso L. Transradial versus transfemoral carotid artery stenting: a 16-year single-center experience. *J Interv Cardiol*. 2016;29(6):588-593.
- Ruzsa Z, Nemes B, Pinter L, et al. A randomised comparison of transradial and transfemoral approach for carotid artery stenting: RADCAR (RADIAL access for CARotid artery stenting) study. *Eurointervention*. 2014;10(3):381-391.
- Silver FL, Mackey A, Clark WM, et al. Safety of stenting and endarterectomy by symptomatic status in the Carotid Revascularization Endarterectomy Versus Stenting Trial (CREST). *Stroke*. 2011;42(3):675-680.
- Heiserman JE, Dean BL, Hodak JA, et al. Neurologic complications of cerebral angiography. *Am J Neuroradiol*. 1994;15(8):1401.
- Kosmidou I, Karpaliotis D. CHAPTER 23 - vascular complications after percutaneous coronary intervention. In: Jeremias A, Brown DL, eds. *Cardiac Intensive Care*. 2nd ed. Philadelphia: W.B. Saunders; 2010:270-274.
- Bracard S, Ducrocq X, Mas JL, et al. Mechanical thrombectomy after intravenous alteplase versus alteplase alone after stroke (THRACE): a randomised controlled trial. *Lancet Neurol*. 2016;15(11):1138-1147.
- Goyal M, Demchuk AM, Menon BK, et al. Randomized assessment of rapid endovascular treatment of ischemic stroke. *N Engl J Med*. 2015;372(11):1019-1030.
- Lylyk P, Miranda C, Ceratto R, et al. Curative endovascular reconstruction of cerebral aneurysms with the Pipeline Embolization Device: The Buenos Aires experience. *Neurosurgery*. 2009;64(4):632-643.
- Campbell BCV, Mitchell PJ, Kleinig TJ, et al. Endovascular therapy for ischemic stroke with perfusion-imaging selection. *N Engl J Med*. 2015;372(11):1009-1018.
- Medtronic Neurovascular Clinical Affairs, ev3 International. Solitaire FR Thrombectomy for Acute Revascularisation; 2010. <https://ClinicalTrials.gov/show/NCT01327989>. Accessed June 24, 2019.
- Burrows AM, Cloft H, Kallmes DF, Lanzino G. Periprocedural and mid-term technical and clinical events after flow diversion for intracranial aneurysms. *J Neurointerv Surg*. 2015;7(9):646-651.
- Dawkins AA, Evans AL, Wattam J, et al. Complications of cerebral angiography: a prospective analysis of 2,924 consecutive procedures. *Neuroradiology*. 2007;49(9):753-759.
- Fifi JT, Meyers PM, Lavine SD, et al. Complications of modern diagnostic cerebral angiography in an academic medical center. *J Vasc Interv Radiol*. 2009;20(4):442-447.
- Gelman M, Chakeres DW, Newton HB. Brain tumors: complications of cerebral angiography accompanied by intraarterial chemotherapy. *Radiology*. 1999;213(1):135-140.
- Horowitz MB, Dutton K, Purdy PD. Assessment of complication types and rates related to diagnostic angiography and interventional neuroradiologic procedures. *Interv Neuroradiol*. 1998;4(1):27-37.
- Huckman MS, Shenk GI, Neems RL, Tinor T. Transfemoral cerebral arteriography versus direct percutaneous carotid and brachial arteriography: a comparison of complication rates. *Radiology*. 1979;132(1):93-97.
- Kaufmann TJ, Huston J 3rd, Mandrekar JN, Schleck CD, Thielen KR, Kallmes DF. Complications of diagnostic cerebral angiography: evaluation of 19,826 consecutive patients. *Radiology*. 2007;243(3):812-819.
- Shah VA, Martin CO, Hawkins AM, Holloway WE, Junna S, Akhtar N. Groin complications in endovascular mechanical thrombectomy for acute ischemic stroke: a 10-year single center experience. *J Neurointerv Surg*. 2016;8(6):568-570.
- Willinsky RA, Taylor SM, Terbrugge K, Farb RI, Tomlinson G, Montaner W. Neurologic complications of cerebral angiography: prospective analysis of 2,899 procedures and review of the literature. *Radiology*. 2003;227(2):522-528.
- Sato M, Matsumaru Y, Sakai N, et al. Usefulness of an access-site hemostasis device in neuroendovascular treatment. *Acta Neurochir*. 2017;159(12):2331-2335.
- Geyik S, Yavuz K, Akgoz A, et al. The safety and efficacy of the Angio-Seal closure device in diagnostic and interventional neuroangiography setting: a single-center experience with 1,443 closures. *Neuroradiology*. 2007;49(9):739-746.

32. Goto S, Ohshima T, Ishikawa K, et al. Suitability of a 7-F ExoSeal vascular closure device for femoral artery punctures made by 8-F or 9-F introducer sheaths. *J Endovasc Ther.* 2017;24(4):516-520.
33. Grandhi R, Kanaan H, Shah A, et al. Safety and efficacy of percutaneous femoral artery access followed by Mynx closure in cerebral neurovascular procedures: a single center analysis. *J Neurointervent Surg.* 2014;6(6):445-450.
34. Grandhi R, Zhang X, Panczykowski D, et al. Incidence of delayed angiographic femoral artery complications using the EXOSEAL vascular closure device. *Interv Neuroradiol.* 2015;21(3):401-406.
35. Kent KC, Moscucci M, Mansour KA, et al. Retroperitoneal hematoma after cardiac catheterization: prevalence, risk factors, and optimal management. *J Vasc Surg.* 1994;20(6):905-913.
36. Becske T, Kallmes DF, Saatici I, et al. Pipeline for uncoilable or failed aneurysms: results from a multicenter clinical trial. *Radiology.* 2013;267(3):858-868.
37. Hill MD, Martin RH, Mikulis D, et al. Safety and efficacy of NA-1 in patients with iatrogenic stroke after endovascular aneurysm repair (ENACT): a phase 2, randomised, double-blind, placebo-controlled trial. *Lancet Neurol.* 2012;11(11):942-950.
38. Cavalcanti DD, Abila AA, Martirosyan NL, McDougall CG, Spetzler RF, Albuquerque FC. Endovascular management of distal ACA aneurysms: single-institution clinical experience in 22 consecutive patients and literature review. *AJNR Am J Neuroradiol.* 2013;34(8):1593-1599.
39. Lubicz B, Collignon L, Raphaeli G, De Witte O. Pipeline flow-diverter stent for endovascular treatment of intracranial aneurysms: preliminary experience in 20 patients with 27 aneurysms. *World Neurosurg.* 2011;76(1-2):114-119.
40. Long CA, Kwolek CJ, Watkins MT. Chapter 61 - Vascular Trauma. In: Creager MA, Beckman JA, Loscalzo J, eds. *Vascular Medicine: A Companion to Braunwald's Heart Disease.* 2nd ed. Philadelphia: W.B. Saunders; 2013:739-754.
41. Muftuoglu M, Topaloglu U, Aktekin A, Odabasi M, Ates M, Saglam A. The management of retroperitoneal hematomas. *Scand J Trauma Resusc Emerg Med.* 2004;12:152-156.
42. Sajjani N, Bogart DB. Retroperitoneal hemorrhage as a complication of percutaneous intervention: report of 2 cases and review of the literature. *Open Cardiovasc Med J.* 2013;7(1):16-22.
43. Altin RS, Flicker S, Naidech HJ. Pseudoaneurysm and arteriovenous fistula after femoral artery catheterization: association with low femoral punctures. *Am J Roentgenol.* 1989;152(3):629-631.
44. Perdue GD, Smith RB. Postangiographic false aneurysms of the femoral artery. *JAMA.* 1973;223(13):1511.
45. Johnson, Company JKKM. Reperfuse Ischemic Vessels With Endovascular Recanalization Device in JAPAN (RIVER JAPAN); 2013. <https://ClinicalTrials.gov/show/NCT01895634>. Accessed June 24, 2019.
46. The IMS II Trial Investigators. The interventional management of stroke (IMS) II Study. *Stroke.* 2007;38(7):2127-2135.
47. Im SH, Han MH, Kwon OK, et al. Endovascular coil embolization of 435 small asymptomatic unruptured intracranial aneurysms: procedural morbidity and patient outcome. *AJNR Am J Neuroradiol.* 2009;30(1):79-84.
48. Corley JA, Kasliwal MK, Tan LA, Lopes DK. Delayed vascular claudication following diagnostic cerebral angiography: a rare complication of the AngioSeal arteriotomy closure device. *J Cerebrovasc Endovasc Neurosurg.* 2014;16(3):275-280.
49. Kim D, Orron DE, Skillman JJ, et al. Role of superficial femoral artery puncture in the development of pseudoaneurysm and arteriovenous fistula complicating percutaneous transfemoral cardiac catheterization. *Cathet Cardiovasc Diagn.* 1992;25(2):91-97.
50. Kelm M, Perings SM, Jax T, et al. Incidence and clinical outcome of iatrogenic femoral arteriovenous fistulas. *J Am Coll Cardiol.* 2002;40(2):291-297.
51. Toursarkissian B, Allen BT, Petrinc D, et al. Spontaneous closure of selected iatrogenic pseudoaneurysms and arteriovenous fistulae. *J Vasc Surg.* 1997;25(5):803-809.
52. Qureshi AI, Babar S, Kherani D, et al. Femoral neuropathy following transfemoral neuroendovascular procedures. An analysis of a prospective registry. *J Neuroimaging.* 2019;29(2):268-271.
53. Kelkar PS, Fleming JB, Walters BC, Harrigan MR. Infection risk in neurointervention and cerebral angiography. *Neurosurgery.* 2013;72(3):327-331.
54. Cherr GS, Travis JA, Ligush J, et al. Infection is an unusual but serious complication of a femoral artery catheterization site closure device. *Ann Vasc Surg.* 2001;15(5):567-570.
55. Chambers CE, Eisenhauer MD, McNicol LB, et al. Infection control guidelines for the cardiac catheterization laboratory: society guidelines revisited. *Cathet Cardiovasc Intervent.* 2006;67(1):78-86.
56. Dudeck O, Teichgraber U, Podrabsky P, Lopez Haenninen E, Soerensen R, Ricke J. A randomized trial assessing the value of ultrasound-guided puncture of the femoral artery for interventional investigations. *Int J Cardiovasc Imaging.* 2004;20(5):363-368.
57. Nguyen P, Makris A, Hennessy A, et al. Standard versus ultrasound-guided radial and femoral access in coronary angiography and intervention (SURF): a randomised controlled trial. *Eurointervention.* 2019;15(6):e522-e530.
58. Elbaz-Greener G, Zivkovic N, Arbel Y, Radhakrishnan S, Fremes SE, Wijeyesundera HC. Use of two-dimensional transasonographically guided access to reduce access-related complications for transcatheter aortic valve replacement. *Can J Cardiol.* 2017;33(7):918-924.
59. Sorenson TJ, Nicholson PJ, Hilditch CA, Murad MH, Brinjikji W. A lesson from cardiology: the argument for ultrasound-guided femoral artery access in interventional neuroradiology. *World Neurosurg.* 2019;126:124-128.
60. Nathan S, Rao SV. Radial versus femoral access for percutaneous coronary intervention: implications for vascular complications and bleeding. *Curr Cardiol Rep.* 2012;14(4):502-509.
61. Agostoni P, Biondi-Zoccai GG, de Benedictis ML, et al. Radial versus femoral approach for percutaneous coronary diagnostic and interventional procedures. *J Am Coll Cardiol.* 2004;44(2):349-356.
62. Chandrasekhar J, Hibbert B, Ruel M, Lam BK, Labinaz M, Glover C. Transfemoral vs non-transfemoral access for transcatheter aortic valve implantation: a systematic review and meta-analysis. *Can J Cardiol.* 2015;31(12):1427-1438.
63. Hamon M, Rasmussen LH, Manoukian SV, et al. Choice of arterial access site and outcomes in patients with acute coronary syndromes managed with an early invasive strategy: the ACUITY trial. *Eurointervention.* 2009;5(1):115-120.
64. Cesaro A, Moscarella E, Gragnano F, et al. Transradial access versus transfemoral access: a comparison of outcomes and efficacy in reducing hemorrhagic events. *Expert Rev Cardiovasc Ther.* 2019;17(6):435-447.
65. Valgimigli M, Gagnor A, Calabro P, et al. Radial versus femoral access in patients with acute coronary syndromes undergoing invasive management: a randomised multicentre trial. *Lancet North Am Ed.* 2015;385(9986):2465-2476.
66. Jolly SS, Yusuf S, Cairns J, et al. Radial versus femoral access for coronary angiography and intervention in patients with acute coronary syndromes (RIVAL): a randomised, parallel group, multicentre trial. *Lancet North Am Ed.* 2011;377(9775):1409-1420.

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