# Risk factors attributed to failure of ultrasound-guided compression for post-cardiac catheterization femoral artery pseudoaneurysms

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### Abstract

Background: Femoral pseudoaneurysm is the most important access site complication following cardiac catheterization. Ultrasound-guided compression repair is a safe and effective therapeutic modality with variable failure rates and risk factors. The aim of this study was to investigate which factors were associated with a higher incidence of ultrasound-guided compression repair failure for post-cardiac catheterization femoral pseudoaneurysm.

Methods: Data were retrospectively collected from medical records at King Abdullah University Hospital during the period from January 2011 to December 2016. A total of 42 patients with post-cardiac catheterization femoral pseudoaneurysm had attempted ultrasound-guided compression repair. Data regarding patients, procedure and aneurysm-related factors were evaluated by univariate analysis and multivariate logistic regression.

**Results:** Ultrasound-guided compression repair failed in 31% of the patients. Patients with body mass index of  $\geq$ 28 kg/m<sup>2</sup>, platelet count of  $\leq 180,000/L$ , time lag (age of aneurysm) of >48 h following puncture time, aneurysmal neck diameter of  $\geq$ 4mm and communicating tract length of <8mm were associated with higher rate of ultrasound-guided compression repair failure in the univariate analysis. In the multivariate analysis, time lag (age of aneurysm) > 48 h (odds ratio = 5.7), body mass index  $\ge$  28 kg/m<sup>2</sup> (odds ratio = 7.8), neck diameter > 4 mm (odds ratio = 14.4) and tract length < 8 mm (odds ratio = 18.6) were significantly associated with ultrasound-guided compression repair failure.

Conclusion: Ultrasound-guided compression repair for patients with post-cardiac catheterization femoral pseudoaneurysm was successful in 69% of the patients. Risk factors for failed ultrasound-guided compression repair were as follows: delayed ultrasound-guided compression repair of >48 h, body mass index  $\ge$  28 kg/m<sup>2</sup>, wide neck diameter >4 mm and short aneurysmal communication tract < 8 mm.

### **Keywords**

Pseudoaneurysm, ultrasound-guided compression, femoral artery

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# Introduction

Common femoral artery (CFA) is the most common access site for diagnostic and interventional angiographies.<sup>1,2</sup> Femoral pseudoaneurysm (FPA) results from failure of puncture site closure following arterial catheterization with extravasations of blood into the surrounding tissues. The incidence of post-catheterization FPA is variable, and an incidence of 0.05%-2% was reported for diagnostic angiography.<sup>2,3</sup> The incidence might increase with interventional procedures and with routine use of duplex ultrasound imaging in the post-catheterization period.<sup>1,3-5</sup>

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FPA can cause local symptoms and signs, often hemodynamic instability and possible mortality.<sup>6</sup> The clinical presentation can be acute persistent pain at the puncture site, an expanding hematoma, a pulsating mass, feeling a thrill, decrease in hemoglobin level, hypotension, distal ischemia, tachycardia, chronic persistent pain due to compression neuropathy, clinical evidence of local site infection and it can be an incidental finding.<sup>2,3,6–10</sup> Important information can be obtained by color Doppler ultrasound such as the site of arterial defect, size of the aneurysm, neck diameter, connecting tract length, aneurysmal flow and the dimensions of surrounding hematoma.<sup>1,11</sup>

Many factors may increase the risk for the development of post-catheterization FPA such as therapeutic interventions with associated large sheath, emergency catheterization, no CFA puncture, inadequate post-sheath removal compression, obesity, anticoagulant/antiplatelet drug, atherosclerotic CFA, female gender, patients on hemodialysis, arterial hypertension and simultaneous venous and arterial catheterization.<sup>1,2,8,12</sup>

Surgical repair used to be the principal treatment modality for FPA with associated complications.<sup>13</sup> Small FPAs of 2–3 cm in diameter were reported to have spontaneous thrombosis.<sup>14</sup> However, active management is needed because of possible complication during the period of observation.<sup>15</sup> Therefore, less invasive therapeutic modalities and techniques have been introduced such as ultrasound-guided compression repair (UGCR), ultrasound-guided thrombin injection, covered stent, obliteration of aneurysmal sac by embolization and para-aneurysmal saline injection.<sup>1,3,6,7,16,17</sup>

The success rate of UGCR was reported to be high; however, failure rate of 5%–30% had been reported.<sup>3,6,15,16,18</sup> Failure of UGCR was attributed to several factors as follows: puncture site artery, emergency procedure, interventional procedures, size of aneurysm, neck diameter, tract length and use of anticoagulants.<sup>1,3,11,15,18</sup>

This study was conducted to identify the risk factors associated with UGCR failure for post-cardiac catheterization FPA to avoid them and decrease morbidity.

### Materials and methods

This is a retrospective study carried out at King Abdullah University Hospital (KAUH) for a period of 72 months (January 2011 to December 2016). The study included all patients with post-cardiac catheterization FPA who underwent UGCR attempts. The medical records were reviewed for demographic data (age, gender and body mass index (BMI)), comorbidities (peripheral artery disease, coronary artery disease, arterial hypertension and diabetes mellitus (DM)), indication for catheterization, catheterization report (involved artery for puncture, used sheath sizes and diagnostic/interventional procedure), pre- and post-catheterization anticoagulant/antiplatelets used, time lag after completion of catheterization to attempt compression of FPA (age of aneurysm), post-catheterization complaint related to the FPA, ultrasonic report (location of the aneurysm, neck diameter, communicating tract length and aneurysmal maximum diameter), outcome of UGCR attempts, further management if UGCR failed, post-catheterization hemoglobin level, precompression platelet count, the need for blood transfusion, recurrence, complication and death.

Cardiac catheterization is carried out through the common femoral access using the best pulse as a guide for access; an oral loading dose of 300 mg clopidogrel is given within 12 h of catheterization time; intravenous (IV) 5000 IU heparin is given in the immediate pre-catheterization time; diagnostic coronary angiogram is performed using a 5F sheath; and the sheath will be changed to larger size if therapeutic interventions are required. The sheath is removed immediately following completion of diagnostic coronary angiography with direct continuous manual compression at the puncture site for 20 min. The sheath for interventional procedure is removed after 6 h of observation in the intensive coronary care unit with direct manual compression for at least 20 min. Clopidogrel will be continued with an oral daily dose of 75 mg for 6–12 months post interventional procedure.

Ultrasound-guided compression technique is the first line of treatment at KAUH. Following the confirmation of FPA, a written informed consent for UGCR was obtained, and under adequate analgesia (IV 1-2 mg midazolam hydrochloride), compression is performed with a US transducer (3.5-7.0 MHz) with direct and continuous visualization to maintain vessel luminal flow all through the compression cycles, with an initial cycle of 10-20 min compression of the pseudoaneurysmal neck/pseudoaneurysm to eliminate flow within the pseudoaneurysm and initiation of thrombosis. Compression is released in cycles to assess for possible thrombosis of pseudoaneurysm or cessation of flow through the neck and tract; UGCR will be repeated for three cycles with 10 min release interval in between each cycle; followup ultrasound is performed within 12h of last successful compression attempt; and at 2 months, the patient will be observed as inpatient; in case of recurrent aneurysmal flow or partial thrombosis of aneurysmal sac, UGCR will be repeated again in a second session for three cycles, and if failed the patient will be prepared for further management.

Using a sample of 42 patients and a level of significance of 0.05, the study had a power of 80% to detect an odds ratio (OR) of 2.5 for any of the studied variables. Data were described using mean values and percentages. Chi-square test and Fisher exact test were used to compare UGCR failure rates according to the studied characteristics. Binary logistic regression was used to determine factors associated with UGCR failure. A p-value of  $\leq 0.05$  was considered statistically significant.

### Results

Forty-two patients with FPA were treated by UGCR. Twentyseven (64.3%) were males and 15 (35.7%) were females. The mean age was 55 years ( $52 \pm 11.3$  and  $65 \pm 11.5$  for males and females, respectively). The problems presented were groin swelling in 20 (47.6%), groin pain in 11 (26.2%) and groin pain

Patient-related risk variables	UGCR outcome		Total	p-value
	Success N (%)	Failure N (%)	N (%)	
Gender				
Male	18 (66.7)	9 (33.3)	27 (64.3)	0.74
Female	11 (73.3)	4 (26.7)	15 (35.7)	
Age (years)				
≤55	14 (66.7)	7 (33.3)	21 (50)	I
>55	15 (71.4)	6 (28.6)	21 (50)	
Body mass index				
<28	23 (82.1)	5 (17.9)	28 (66.7)	0.015
≥28	6 (42.9)	8 (57.I)	14 (33.3)	
Hypertension		( )	( )	
No	13 (65)	7 (35)	20 (47.6)	0.74
Yes	16 (72.7)	6 (27.3)	22 (52.2)	
History of IHD				
No	18 (69.2)	8 (30.8)	26 (61.9)	0.756
Yes	11 (68.8)	5 (31.2)	16 (38.1)	
Aspirin				
No aspirin use	5 (100)	0 (0)	5 (11.9)	0.302
Aspirin used	24 (64.9)	13 (35.1)	37 (88.1)	
Clopidogrel	_ ( )			
No clopidogrel	17 (60.7)	(39.3)	28 (66.7)	0.169
Clopidogrel used	12 (85.7)	2 (14.3)	14 (33.3)	0.107
Aspirin/clopidogrel	12 (00.7)	2 (1	11 (00.0)	
Aspirin/clopidogrel not combined	17 (60.7)	(39.3)	28 (66.7)	0.16
Aspirin/clopidogrel combined	12 (85.7)	2 (14.3)	14 (33.3)	0.10
Hemoglobin (g/dL)	12 (00.7)	2 (1	11(00.0)	
≤10	(68.8)	5 (31.2)	16 (38.1)	0.755
>10	18 (69.2)	8 (30.8)	26 (61.9)	0.755
Platelet count	10 (07.2)	0 (30.0)	20 (01.7)	
≥  80	21 (84.0)	4 (16.0)	25 (59.5)	0.018
<180	8 (47.1)	9 (52.9)	17 (40.5)	0.010
Blood transfusion	(1.17)	/ (32.7)	17 (10.3)	
No	23 (69.7)	10 (30.3)	33 (78.6)	0.816
Yes	6 (66.7)	3 (31.0)	9 (21.4)	0.010

**Table I.** Demographic and health risk factors of patients in relation to UGCR of femoral pseudoaneurysm following femoral catheterization for coronary artery diseases.

IHD: ischemic heart disease; UGCR: ultrasound-guided compression repair.

with pulsatile hematoma in 11 (26.2%). None of the patients included in this study presented with ischemia, infections, arterial-venous communications or skin necrosis. Hemoglobin level of  $\leq 10 \text{ g/L}$  was found in 16 (38.1%) patients.

UGCR was successful in 29 (69%) patients. Eighteen (42.8%) had successful UGCR in the first trial while eight (19%) and three (7.1%) patients needed second and third trials, respectively. None of the patients with successful compression had recurrence of the FPA within 2 months post compression.

UGCR was failed in 13 patients (31%). Of them, nine patients underwent open surgical repair, two patients were treated with covered stent (originated from superficial femoral artery and high surgical risk) and four failed compression repair were observed. Two of the observed patients had spontaneous thrombosis after 2 months. No mortality was recorded related to post-catheterization FPA in this study group.

The rate of UGCR failure was higher among patients with a BMI of  $\geq 28 \text{ kg/m}^2$  and platelet count of  $\leq 180,000/\text{L}$  in the univariate analysis (Table 1). Time lag (age of aneurysm) of >48 h following puncture time, aneurysmal neck diameter of  $\geq 4 \text{ mm}$  and communicating tract length of < 8 mm in the univariate analysis (Table 2).

In the multivariate analysis, time lag before diagnosis >48 h (OR=5.7), BMI  $\ge$  28 kg/m<sup>2</sup> (OR=7.8), neck diameter >4 mm (OR=14.4) and tract length <8 mm (OR=18.6) were significantly associated with UGCR failure (Table 3).

Procedure and aneurysm- related risk characteristics	UGCR outcome		Total	p-value
	Success N (%)	Failure N (%)	N (%)	
Intervention				
Diagnostic intervention	16 (76.2)	5 (23.8)	21 (50)	0.504
Therapeutic intervention	13 (61.9)	8 (38.1)	21 (50)	
Punctured artery				
Femoral	23 (67.6)	(32.4)	34 (81.0)	0.983
Non-femoral	6 (75.6)	2 (25.0)	8 (19.0)	
Sheath size (F)				
≤5	16 (80.0)	4 (20.0)	20 (47.6)	0.258
>5	13 (59.1)	9 (40.9)	22 (52.4)	
Time lag before diagnosis (h)				
≪48	22 (81.5)	5 (18.5)	27 (64.3)	0.046
>48	7 (46.7)	8 (53.3)	15 (35.7)	
Aneurysmal size (cm³)				
<3	23 (74.2)	8 (25.8)	31 (73.8)	0.406
≥3	6 (54.5)	5 (54.5)	11 (26.2)	
Neck diameter (cm)			, , , , , , , , , , , , , , , , , , ,	
≤0.4	18 (85.7)	3 (14.3)	21 (50)	0.045
>0.4	11 (52.4)	10 (47.6)	21 (50)	
Tract length (mm)				
≥8	25 (78.1)	7 (21.9)	32 (76.2)	0.023
<8	4 (40.0)	6 (60.0)	10 (23.8)	

**Table 2.** Procedural and aneurysmal risk characteristics in relation to UGCR of femoral pseudoaneurysm following femoral catheterization for coronary artery diseases.

UGCR: ultrasound-guided compression repair.

# Discussion

Previous studies recommend UGCR as an initial and safe management modality with a successful rate that ranges from 68% to 95%.<sup>2,11,15,18,19</sup> It is the first-line management for post-catechization FPA at KAUH. Previous study at KAUH showed a success rate of 78.5%.<sup>7</sup> However, this study showed a 69% success rate. This variation may be a reflection of operative-dependent technique of UGCR.

In this study, a BMI of  $\geq 28 \text{ kg/m}^2$  was found to be a risk factor for UGCR failure. This was consistent with previous studies which showed that increased BMI is a recognized risk factor for the development of FPA and UGCR failure.<sup>1,2,8,11,12,15</sup> This might be due to difficulty in landmark identification for arterial access and inadequate post-procedural compression for hemostasis with increasing BMI of patients.<sup>20</sup>

Platelet counts of <200,000/L were reported as an independent risk factor for the development of post-catheterization pseudoaneurysm.<sup>5,21</sup> In this study, platelet counts of  $\leq 180,000/L$  were found to be associated with failed UGCR in the univariate analysis.

An inverse relationship between FPA neck diameter and the success rate of UGCR is shown in this study. Neck diameter of  $\geq$ 4 mm was associated with higher failure rate. This result supports the finding of the previous reports, where larger neck diameter of FPA of >4 mm had higher blood flow and is associated with difficulty in neck obliteration and

 
 Table 3.
 Multivariate analysis of factors associated with ultrasound-guided compression repair failure.

Variables	OR	95% confic interval	95% confidence interval							
Time lag bef	Time lag before diagnosis (h)									
≪48										
>48	5.7	1.2	9.7	0.032						
Neck diameter (mm)										
≪4	I									
>4	14.4	1.218	36.9	0.034						
Tract length (mm)										
≥8	l l									
<8	18.6	1.5	32.0	0.023						
Body mass index (kg/m <sup>2</sup> )										
<28	1									
≥28	7.8	1.1	53.6	0.037						

OR: odds ratio.

thrombosis.<sup>22</sup> On the other hand, Schaub et al.<sup>18</sup> found no association between neck diameter and failure of UGCR. A significant relationship was noticed between UGCR failure rate and the age of aneurysm of >48 h from the time of catheterization to initial attempt of UGCR. The failure rate of 53.3% for delayed compression for more than 48 h compared to 18.5% for FPA compressed within 48 h of catheterization.

Eisenberg et al.<sup>11</sup> found an association between chronic aneurysm and failed UGCR and supposed that maturated pseudointima of chronic aneurysm might hinder thrombosis necessary for successful UGCR. A high failure rate of UGCR (64.3%) was reported in association with delayed diagnosis and subsequent compression.<sup>23</sup> However, the age of post-catheterization FPA was not found to be associated with compression failure.<sup>11,18,24</sup> Tract length of <8 mm showed association with failure of UGCR in our study. On the other hand, Schaub et al.<sup>18</sup> reported that a short communicating tract of <10 mm was associated with failure of UGCR, whereas Samuels et al.<sup>25</sup> showed that a short neck of 0.9 mm was associated with failed spontaneous thrombosis of observed aneurysms.

The size of the aneurysm and the need for anticoagulants in the post-procedural period were reported to be a significant risk factor for UGCR failure.<sup>11,16,18,23,24</sup> However, others found no association between post-procedural anticoagulant use and UGCR failure.<sup>26,27</sup> Our study showed no association between UGCR failure and the size of the aneurysm and the need to use post-catheterization antiplatelet aspirin/clopidogrel alone or in combination. Factors that did not show a higher failure rate of UGCR were patient's age, gender, arterial hypertension and sheath size used.

The retrospective nature of the study and the small size of the studied sample constituted the main limitations of this study.

## Conclusion

UGCR for patients with post-cardiac catheterization FPA showed a failure rate of 31%. Factors that may be attributed to this failure were time lag before diagnosis of >48 h, neck diameter of >4 mm, tract length of <8 mm and BMI of  $\geq$ 28 kg/m<sup>2</sup>. Early diagnosis of post-catheterization FPA and extra precautions when treating patients with increased BMI might improve the success rate of post-cardiac catheterization UGCR.

#### **Declaration of conflicting interests**

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

#### Ethical approval

Ethical approval to conduct this study was obtained by IRB at KAUH 2018/110.

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#### Informed consent

Written informed consent was not obtained from all the subjects prior to study initiation, and it was waived by the institutional review board and/or the ethics committee.

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