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**ORIGINAL ARTICLE** 

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# Predictors of successful iatrogenic pseudoaneurysm compression dressing repair

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# Abstract

**Background:** Complications to femoral artery puncture may result in formation of a pseudoaneurysm (PSA). We investigated whether PSA obliteration may be achieved by compression dressing repair (CDR) and sought to determine the predictors of successful CDR.

**Methods:** Sixty two patients (30 male, mean age  $61.0 \pm 12.8$ ) with femoral PSAs due to cardiac catheterization were included in the study. In all patients, duplex ultrasound followed by CDR was performed to evaluate PSA morphology and flow velocities in the PSA neck.

**Results:** Forty six (74.2%) patients did not respond to CDR. Predictors of successful CDR were forward [0.18 (0.07–0.47), p = 0.0004] and reverse [0.08 (0.02–0.33), p = 0.0006] flow velocities in the PSA neck. The forward velocity was identified as an independent predictor of CDR outcome (p = 0.02).

**Conclusions:** Compression dressing repair may serve as an alternative method of femoral pseudoaneurysm management in patients with low forward and reverse velocities of the flow in pseudoaneurysm neck. The forward velocity is an independent predictor of compression dressing repair result. (Cardiol J 2010; 17, 2: 179–183)

Key words: pseudoaneurysm, compression repair, predictors

# Introduction

Complications to femoral artery puncture may result in the formation of a pseudoaneurysm (PSA) in 0.1–6% of cases [1–3]. In the 1990s, ultrasoundguided compression repair (UGCR) and then ultrasound-guided thrombin injection (UGTI) replaced traditional surgical management of PSAs as first line therapy [4–6]. UGTI was found to be superior to UGCR [7, 8]. However, thrombin injection may cause allergic reactions, particularly in patients previously exposed to bovine thrombin [9] or in peripheral embolization [8, 10]. Paschalidis et al. [11] proposed manual compression without ultrasound surveillance as an alternative method of PSA management. It was proved as successful and safe as UGCR, and more comfortable, both for the patient and the operator.

We investigated whether PSAs obliteration may be achieved by blind compression dressing

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repair (CDR) and sought to determine the selection criteria to predict which femoral PSAs would respond to this kind of therapy.

## **Methods**

Between January 2003 and December 2008, 36,359 cardiac catheterizations (20,315 diagnostic, 16,044 therapeutic) were performed at our institution. Post-catheterization care included manual compression at the puncture site followed by compression dressing application for 24 hours. In individual patients (those who were obese, had a history of venous thrombosis, or were on anticoagulants) closure devices such as the Star-Close System were used.

Patients with evidence of haematoma, pulsatile mass in the groin, bruit over puncture site, limb neuropathy or perfusion deficit underwent routine Doppler duplex examination in order to reveal complications of femoral artery puncture. Duplex ultrasound was carried out by an experienced sonographer with Vingmed VIVID-3 and VIVID-5 (General Electrics Horten Norway) equipped with transducers ranging from 3.5 to 10 MHz and recorded on magneto-optic disc. PSA evaluation included identification of the punctured artery, number of lobes, size (length, width, height, volume of the open cavity), neck morphology (width, length), dynamics of the flow in the PSA neck [maximal forward (Vf) and reverse (Vr) velocities] with ultrasound beam parallel to flow direction in the PSA neck. PSAs were defined according to the number of lobes as simple (1 lobe) or complex (> 1 lobe).

Patients were offered three methods of PSA management: CDR, UGTI or surgical repair. Traditional compression repair with ultrasound transducer or blind manual compression were not used in this study. Patients with femoral artery PSAs who objected to UGTI or surgical repair as a first line treatment, and decided to undergo CDR, were included in the study. All the patients gave their informed consent. Exclusion criteria for CDR were: location above the inguinal ligament, skin necrosis or infection over pulsatile mass, limb neurological or perfusion deficit, concomitant anticoagulation therapy. The CDR technique involved marking on the skin the site over PSA neck and precise application of compression dressing. Compression dressing was formed of 'tissue bubble' which was held in the desired place with an elastic band around the patient. The band was tightened in order to arrest or reduce the flow into the PSA cavity but without significantly compromising the flow in the underlying artery which was confirmed by Doppler. In the

presence of complex PSA, compression dressing was placed over the neck communicating the femoral artery with PSA proximal cavity. CDR was applied for a maximum of 48 hours. Patients were advised to remain immobile until CDR was terminated. Every 12-24 hours PSA was reassessed on duplex ultrasound to evaluate the progression of thrombosis within PSA or possible complications such as PSA rupture, vein thrombosis or distal artery embolization. Evidence of any complications or complete PSA obliteration resulted in CDR termination within 48 hours from the onset of the procedure. Duplex ultrasound was repeated 24 hours after successful thrombosis to confirm PSA closure. Alternative treatment such as UGTI or surgical repair was offered to patients in whom CDR failed to obliterate PSA.

# Statistical analysis

All values were expressed as mean  $\pm$  standard deviation. P value < 0.05 was required to fulfil statistical significance. Differences between successful and failed compression groups were evaluated by Student's unpaired test for continuous variables and analysis for discreet variables. Consecutive Doppler parameters were incorporated into univariate logistic regression model, which considered echo-parameters as independent variables and the result of compression therapy as a dependent variable. Receiver operating characteristics (ROC) analysis was used to evaluate the prognostic value of CDR predictors. The parameters which influenced CDR-probability with a significance level of p < 0.05entered multivariate logistic regression analysis to determine the independent association of duplex ultrasound parameters with CDR outcome. A cutoff value of p < 0.05 was used to determine entry of the next parameter into the model. Diagnostic performance of the most powerful independent predictor of CDR at various thresholds was used to generate a receiver operating characteristic (ROC) curve. All calculations were performed using a commercially available statistical package SAS 9.1.3 (SAS Institute Inc., Cary, NC, USA).

# Results

In 123 patients (51 male, mean age  $61.4 \pm 12.7$ ) iatrogenic PSAs (121 femoral and two iliac external) were discovered on duplex ultrasound  $3.8 \pm 2.7$  days post-catheterization. In all the patients, compression dressing application was followed by standard post-catheterization care with manual compression. The complication rate of cardiac cath-

	Successful CDR (n = 16)	Failed CDR (n = 46)	р
Age	59.1 ± 14.8	61.7 ± 12.1	0.29
Gender (male)	7 (38.8%)	19 (41.3%)	0.91
Body mass index	30.1 ± 2.6	28.3 ± 3.1	0.17
Procedures:			
Coronary angiogram	5 (31.3%)	12 (26.1%)	0.83
Therapeutic:	11 (68.7%)	34 (73.9%)	0.74
Coronary stenting	8 (50%)	32 (69.7%)	
Peripheral stenting	2 (12.5%)	1 (2.1%)	
Amplatzer insertion	1 (6.2%)	1 (2.1%)	
Surgery	0	1 (2.1%)	
Aspirin	14 (87.5%)	41 (89.1%)	0.87
Aspirin + clopidogrel	11 (68.8%)	34 (73.9%)	0.74

#### Table 1. Study group characteristics.

 ${\rm CDR}-{\rm compression}\;{\rm dressing}\;{\rm repair}$ 

Table 2. Characteristics	of pseudoaneurysm	(PSA) morphology
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PSA characteristics	Successful CDR (n = 16)	Failed CDR (n = 46)	р
Location:			
Common femoral artery	15 (93.8%)	22 (66.7%)	0.08
Superficial femoral artery	1 (6.2%)	11 (33.3%)	0.09
Length [mm]	22 ± 9	26 ± 9	0.19
Depth [mm]	16 ± 7	16 ± 5	0.94
Width [mm]	15 ± 7	18 ± 6	0.17
Volume [mL]	$3.6 \pm 2.6$	$4.7 \pm 3.4$	0.28
Neck width [mm]	$3.2 \pm 2.9$	$3.4 \pm 1.4$	0.71
Neck length [mm]	7.8 ± 4.1	$8.0 \pm 4.4$	0.90
Forward velocity [m/s]	$2.2 \pm 0.8$	3.8 ± 1.2	< 0.0001
Reverse velocity [m/s]	$0.9 \pm 0.4$	$1.9 \pm 0.4$	< 0.0001

CDR — compression dressing repair

eterization was 0.34%. Three patients were primarily referred for surgical repair because of PSA location above inguinal ligament (n = 1) and limb perfusion deficit (n = 2). In 40 patients UGTI was performed as the first line treatment as decided by the patients. Eighteen patients were excluded from the study due to concomitant anticoagulation therapy (heparin, dicumarol). The study group consisted of 62 patients (30 male, mean age 61.0 ± 12.8) in whom CDR was attempted. For clinical characteristics, see Table 1.

Diagnostic cardiac catheterization was performed in 17 patients and 45 patients underwent interventional procedures. In all patients catheter size 6 F was used. On duplex ultrasound 41 simple and 21 complex PSAs (2–4 lobes) were identified. PSA morphology characteristics are presented in Table 2. In 16 (25.8%) patients CDR successfully closed PSA. Mean compression time was  $41.8 \pm 11.1$  hours. The time of successful compression did not differ significantly between simple and complex PSAs ( $44.5 \pm 9.5 vs \ 38.3 \pm 13.3 h, p = 0.12$ ). Three (4.8%) patients were referred for surgical treatment due to PSA rupture and haemorrhage during CDR. In the other 43 (69.4%) patients, successful UGTI was performed.

No statistically significant differences were noted for age, sex, and concomitant medications between groups with successful and failed CDR (Table 1).

Univariate analysis of PSA morphology identified Vf and Vr as predictors of successful CDR (Table 3).

Cut-off Vf =2.8 m/s would predict the result of compression therapy with 86.7% sensitivity and 79.6% specificity and Vr = 1.4 m/s with 86.7% sensi-

**Table 3.** Logistic regression: univariate analysis— predictors of successful compression.

Variable	OR/unit (± 95% CI)	р
Forward velocity	0.18 (0.07–0.47)	0.0004
Reverse velocity	0.08 (0.02–0.33)	0.0006

OR — odds ratio, CI — confidence interval



**Figure 1.** Receiver-operating characteristics curve for the forward velocity of the neck-through flow for the discrimination of successful compression repair; Vf — forward velocity in pseudoaneurysm neck.

tivity and 72.9% specificity. By multivariate analysis Vf was identified as an independent predictor of successful CDR (p = 0.02). The diagnostic performance of Vf was used to generate ROC curve (Fig. 1).

## Discussion

Iatrogenic PSAs develop as the result of failure to seal the arterial puncture and the blood jet creates a cavity in the surrounding tissues. Complications of PSA formation include haemorrhage, skin and tissue ischemia, and distal embolization. Several studies have reported spontaneous thrombosis of PSAs not exceeding 35 mm in diameter, 6 mL in volume or with progressive centripetal thrombus formation [12–14]. However, failure in obliteration of small PSAs was also observed and no definite data for safe and conservative PSA management has been established yet [14]. In 1991

traditional surgical management of iatrogenic PSAs was replaced by UGCR, first introduced by Fellmeth et al. [4]. Early reports showed excellent results of UGCR with regard to safety and efficacy. However, this method has several drawbacks. UGCR is time-consuming, uncomfortable for the patient, who frequently cannot endure the procedure without analgesia and/or sedation, and for the operator. Modification of this method, such as manual compression without ultrasound guidance, was found to be as successful and safe as UGCR but more comfortable for the patient and less fatiguing for the operator [11]. Concomitant anticoagulation or antiplatelet therapy increases failure of compression repair and reopening rate [15–17]. This method, however, is not free of complications such as rupture, distal embolization or vein thrombosis and should not be applied in patients with PSAs located above inguinal ligament, large haematomas, skin ischemia or infection, limb perfusion or neurological deficit.

In the present study, we tested a less aggressive method of PSA obliteration, i.e. compression dressing application in order to reduce the flow into PSA cavity and enable spontaneous thrombosis. Our results showed much higher failure rate of 74.2% compared to the results of UGCR. This can be explained by a number of factors.

Firstly, we used a different protocol for compression repair. Although the therapy was continued with precise compression dressing application, we could not provide any evidence that the flow velocities in the PSA neck were reduced during compression. Secondly, our study group consisted of patients treated with antiplatelet medications. Over 75% of patients were receiving dual antiplatelet therapy (aspirin, clopidogrel or ticlopidine) during CDR.

Our study showed a significant relationship between the dynamics of the flow in the PSA neck and the results of compression repair.

Forward and reverse velocities in the PSA neck were found to be excellent predictors of CDR outcome. To the best of our knowledge, this is the first study reporting such a relationship. Kent et al. [14] analyzed velocity of flow in the PSA cavity. Their findings showed insignificantly decreased velocities in PSAs that thrombosed spontaneously, compared to PSA which failed to close without any intervention. However, as the authors point out, swirling blood flow within the PSA cavity made the adjustment of insonation angle and accurate velocity measurement very difficult.

According to our protocol, we measured forward and reverse velocities in the PSA neck. The forward velocity in the PSA neck was identified as an independent prognostic factor of CDR. Vigorous inflow into PSA cavity and, in consequence, high pressure gradient between femoral artery and PSA cavity, make PSA compression difficult. Furthermore, high-velocity blood stream may prevent PSA obliteration by mechanical disruption of the thrombus. In contrast to other studies [13–14] we did not observe a relationship between the PSA size and compression repair result (Table 2). This can be explained by the different compression repair method, aiming at a reduction, but not cessation, of inflow into the PSA cavity.

### **Clinical implications**

Despite the fact that the overall success of CDR was unsatisfactory, we were able to identify and measure Doppler parameters that separate compressible from non-compressible PSAs. Therefore, we showed that in patients without anticoagulation therapy and low forward and reverse velocities into PSA cavity, CDR may serve as an alternative method of femoral PSA management. This finding is especially relevant in areas in which thrombin injections or ultrasound guided compression repair is not available.

#### Limitations of the study

The major limitation of the study is the technique of CDR. The same compression strength could not be applied to all the patients due to their body mass. There was no method to measure or compare it. Furthermore, it was not possible to evaluate whether any restriction of inflow into the PSA cavity was achieved under compression. Therefore, the reproducibility of the compression technique remains in question. However, the major findings of this study identifying unfavorable PSA morphology should still be helpful in making decisions regarding the method of PSA treatment.

#### Conclusions

We conclude that compression dressing repair may serve as an alternative method of femoral pseudoaneurysm management in patients with low forward and reverse velocities of the flow in pseudoaneurysm neck. The forward velocity was identified as an independent predictor of compression dressing repair outcome.

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