



Major femoral vascular access complications after coronary diagnostic and interventional procedures: A Danish register study☆



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ABSTRACT

Background: Vascular access complications after coronary angiography (CAG) and percutaneous coronary intervention (PCI) are known to increase morbidity, prolong hospitalization and raise hospital costs. Therefore, risk factor identification and improvement of safety strategies for vascular management are important. We aimed to assess the incidence of major vascular complications related to femoral access, and to identify potential risk factors.

Methods: Over a period of six years, 23,870 index procedures (CAG) were performed in two centres, prospectively entered in the database and retrospectively analysed. Data was obtained from the Eastern Danish Heart Registry and cross-matched with data from the Danish Vascular Registry. Index procedures were defined as the first trans-femoral procedure. Demographic, procedural and mortality data, as well as information on access complications requiring surgery within 30 days were collected. Mortality data were collected for minimum 12 months.

Results: We identified 130 (0.54%) access complications requiring surgery; 65 pseudoaneurysms (0.28%), 46 arterial occlusions (0.19%), 15 hematomas (nine groin and six retroperitoneal hematomas) (0.06%), and 4 arterial dissections (0.02%). Risk factors for complications were left sided femoral access (OR 4.11 [2.29–7.37] $p < 0.001$), peripheral arterial disease (PAD) (OR 2.42 [1.48–3.94] $p < 0.0001$) and female sex (OR 2.22 [1.51–3.24] $p < 0.0001$).

Conclusion: Vascular complications related to femoral access in coronary diagnostic and interventional procedures are low (0.54%). Risk factors were left sided access, PAD, and female sex.

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1. Introduction

Seven million invasive coronary procedures are performed annually worldwide [1]. Trans-femoral catheterization allowing for larger sheaths and devices is preferred, though trans-radial technique is increasingly used especially in Europe [2]. The technique for arterial access and closure of the puncture site is vital to minimize local vascular complications after trans-femoral percutaneous interventions. Further, antithrombotic medication and an eventual need of large catheters enhance the risk of bleeding as well as the formation of pseudoaneurysm or intimal dissection. After catheterization, improved haemostasis and early mobilization are

true advantages of vascular closure devices (VCD) but haemorrhage and ischemia are calculated risks.

Complications related to the access site involve increased morbidity, mortality and extra health care costs [3]. Multiple predictors of major complications, including both demographic and procedural characteristics, have previously been investigated [4–6].

In this two-centre observational study of patients, undergoing percutaneous coronary diagnostic and interventional procedures we aimed to assess the incidence of major vascular complications related to femoral access, and to identify potential risk factors.

2. Methods

2.1. Study sample

This retrospective analysis is based on cross validation of two prospectively collected databases 1) The Eastern Danish Heart Registry with data on percutaneous coronary diagnostic and interventional procedures in eastern Denmark and 2) The Danish Vascular Registry with data on all vascular procedures in the country [7]. The inclusion criteria were defined as any first time trans-femoral coronary angiography (CAG) (index procedure). Index procedures included a percutaneous coronary intervention (PCI) in the same setting when indicated. The study period was January 2006 through October 2012. Exclusion criteria

Abbreviations: BMI, body mass index; CAG, coronary angiography; NSTEMI, non-ST-segment elevation myocardial infarction; PAD, peripheral arterial disease; PCI, percutaneous coronary intervention; STEMI, ST-segment elevation myocardial infarction; VCD, vascular closure device.

☆ All authors take responsibility for all aspects of the reliability and freedom from bias of the data presented and their discussed interpretation.

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were missing registration of vascular access side and, follow-up time, add-on procedures involving ventricular assist devices and re-interventions. The preferred access route for both study centres was the femoral artery.

Demographic data and procedural characteristics, and data on mortality were collected from the Heart Registry while thirty-day major vascular access complications were obtained from the Vascular Registry.

2.2. Procedures

According to the Danish national protocol, patients with ST-segment elevation myocardial infarction (STEMI), non-ST-segment elevation myocardial infarction (NSTEMI) or unstable angina receive antithrombotic medication before a CAG and PCI. Patients undergoing CAG of other reasons did not necessarily receive antithrombotic medication.

The standard setting was a right sided femoral artery puncture while left or bilateral access was used when the right side was contraindicated or had failed. At the end of the procedure, the access was closed with either manual compression or a VCD. During the study period, the *Angio-Seal™* and *FemoSeal™* (both from St. Jude Medical, Saint Paul Minnesota United States) devices were used. The recommended ambulation time was 2 h after VCD deployment. For manual compression approximately 10 min of pressure was applied followed by an ambulation time of minimum 2 h.

The study was approved by the Danish Data Protection Agency (ref. no. 2007-58-0015).

2.3. Definition and outcome measures

The primary outcome of this study was to identify major vascular complications related to femoral access. Major vascular access complications were defined as events requiring vascular surgical intervention within 30 days after the index procedure: femoral artery occlusion, pseudoaneurysms, severe hematomas, and arterial dissections. Artery occlusion was defined as acute onset of limb ischemia or onset of severe claudication. Pseudoaneurysms were outlined as those treated by ultrasound guided percutaneous thrombin injection or open surgery, in case of thrombin injection failure. Severe hematoma was identified as those with ongoing bleeding and arterial dissections. Complications without surgery were classified as minor and were excluded. The secondary outcome measures included death of all causes. The follow-up time was set to a minimum 12 months.

2.4. Statistical analyses

Descriptive statistics for categorical variables were presented as frequencies with percentages in parentheses, and continuous variables were presented as medians with IQR in parentheses. Differences between groups were analysed using nonparametric statistics. Logistic regression analyses were used to identify variables associated with access complications. Baseline demographic and procedure dependent variables were first tested with univariate analyses and variables with $p < 0.10$ were included in a subsequent multivariate, age-adjusted analysis. Differences between groups were determined using non-parametric statistics with a significance level of $p < 0.05$.

The following variables were tested as categorical: gender, smoking, hypertension, diabetes mellitus, previous stroke, peripheral arterial disease (PAD), body mass index (BMI), arterial vessel closure method, procedure type, hospital, access side, priority (acute, sub-acute (during same hospitalization), elective), indication, and sheath size. Continuous variables were: age, procedure time, iodine contrast volume, radiation dose product, and fluoroscopy time.

Survival was presented as Kaplan–Meier plot and tested with log-rank and Cox regression analysis was used for the identification of variables associated with mortality. Assumption of the Cox model was tested and fulfilled. All analyses were performed on IBM SPSS Statistics for Windows, Version 22.0 (Armonk, NY: IBM Corp).

3. Results

3.1. Study sample characteristics

During the six years and ten month study period 23,870 patients had an index procedure which met the inclusion criteria out of all 33,531 procedures performed (Fig. 1). The diagnoses were STEMI in 4739 (20%), NSTEMI/unstable angina in 7022 (30%), stable angina in 5833 (24%), and other in 6276 (26%). A majority had only a CAG performed, but in 8367 (35%) a PCI was performed on the same day. Baseline demographic and procedure characteristics of index procedures are presented in Table 1.

In total 3372 (14%) puncture sites were closed by manual compression and 20,498 (86%) by VCD, of which the *AngioSeal* was used in 16,193 (79%) cases. During the study period, the use of VCD closures increased from 63% in 2006 to 98% in 2012 (Fig. 2). No other trends in the index procedures were observed.

One-hundred-and-thirty patients (0.54%) experienced a major vascular complication related to femoral access (Table 2). The most common

type was pseudoaneurysm (N: 65, 0.28%), followed by arterial occlusion (N: 46, 0.19%), hematoma, nine groin and six retroperitoneal, (N: 15, 0.06%), and arterial dissection (N: 4, 0.02%). In the subset of arterial occlusions amputation occurred in two patients due to additional complications within 30 days. Thromboendarterectomy was done in 43 of the cohort of 46 arterial occlusions and when a VCD was present, it was removed. Three patients were managed with a standard femoral bypass procedure.

Pseudoaneurysms were not significantly more frequent after manual compression as compared to VCD (0.50% vs. 0.24%, $p = 0.198$). Successful ultrasound guided thrombin injection were managed in 58 cases while open surgery in the remaining seven patients were deemed necessary.

A univariate analysis based on demographic and procedural risk factors aimed to identify variables associated with major vascular access complications. Female sex, BMI $< 18.5 \text{ kg/m}^2$, the presence of PAD, manual compression, left or bilateral access and low radiation exposure dose were all associated with increased risk (Table 3). Subsequent multivariate analysis revealed that only female sex, the presence of PAD and left side access still remained significant; all at a $p < 0.001$ level (Table 3), and BMI $< 18.5 \text{ kg/m}^2$ and manual compression at a $p = 0.038$ and $p = 0.047$, respectively. Glycoprotein IIb/IIIa inhibitor and bivalirudin were not associated (OR 0.92 (0.57–1.48) $p = 0.51$).

Major vascular access complications occurred in 108 (0.5%) right and 19 (2.9%) left sided access procedures ($p < 0.001$). In 230 patients with bilateral approach (after right sided access failure), there were three complications; two on the right and one on the left side (Table 1).

Of all 1802 patients with PAD, 259 (14.4%) right side access was contraindicated or failed (N = 205 left side access, N = 54 bilateral access). In the group of right side access only 2.8% had PAD. Patients with left sided or bilateral approach had a three times higher proportion of PAD than patients with right side approach (OR 3.18 (2.84–3.58) $p = < 0.001$).

Six (4.6%) patients registered with major vascular access complication died < 30 days after the index procedure compared to 728 (3.1%) in the non-major vascular access complication cohort (OR 1.53 (0.67–3.48) $p = 0.3$). The deaths had no relation to the vascular injury. Long-term follow-up was in median 46 [IQR 22–68] months. The survival rates at one and five years were 87 and 58% in patients who experienced major vascular access complications as compared to 92 and 79% in those without (Fig. 3). In the univariate cox regression model access complication (HR 1.6 (1.2–2.2) $p = 0.002$), male sex (HR 1.2 (1.2–1.3) $p = 0.001$) and PAD (HR 1.8 (1.6–2.0) $p = 0.001$) were significant predictors of death.

4. Discussion

The main finding of this study was a low incidence (0.54%) of major vascular access complication following trans-femoral percutaneous coronary diagnostic and interventional procedures. Second, left sided access, the presence of PAD and female sex were independently associated with a major vascular access complication. Third, major vascular access complication were associated with increased long-term mortality.

Our incidence of major vascular access complication (0.54%) is in accordance with previous studies, reporting a complication rate in demand of surgical intervention in 0.6% of cases [8,9]. Other studies have reported complication rates of up to 1.9% [4,5], but these studies also included minor access complications in which blood transfusion was deemed necessary and without the need for surgical intervention. Leaving out minor complications, our study underestimated the true incidence of access complications. Though minor complications may not prolong hospital stay, they will increase costs and decrease patient satisfaction. A recent study indicated that each major access complication was associated with an extra expense in excess of \$4000 [10].

It is well described, that closure is more difficult in case of atherosclerotic plaques and calcifications in the femoral region [11]. Other studies have also shown that women suffer a two times higher risk of access

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