

Vascular complications following cardiac catheterization at Jordan University Hospital

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Abstract

Objective: This study evaluates the rate of vascular complications following diagnostic cardiac catheterization and percutaneous intervention (PCI) at Jordan University Hospital.

Methods: We reviewed the records of 1000 consecutive patients who underwent cardiac catheterization or PCI. Vascular complications including: minor hematoma > 5 cm in diameter, pseudoaneurysm, arteriovenous fistula and major bleeding with a hemoglobin drop ≥ 3 gm/dl or bleeding requiring transfusion, limb ischemia and death related to the vascular complication. In addition, clinical variables associated with increased risk of vascular complications were recorded including age, hypertension, diabetes mellitus, chronic kidney disease, congestive heart failure, indication for the procedure, emergency vs. elective, and diagnostic catheterization vs. PCI.

Results: 1000 consecutive cases (746 catheterization, and 256 PCI) that were performed in the period from January 1st to Aug 25th 2011 were evaluated. There were six (0.6%) complications: one major (bleeding; requiring blood transfusion) and five minor (3 hematomas and 2 pseudoaneurysms). A higher vascular complication rate was recorded in certain groups, PCI versus diagnostic catheterization (1.9% vs. 0.1%, $P=0.005$), emergency versus elective procedures (6.8% vs. 0.3% $P=0.001$), and myocardial infarction versus angina (4.3% vs. 0.2%, $P=0.002$). None of the clinical variables studied in this series had an association with increased risk for vascular complications.

Conclusion: Vascular complications rate following cardiac catheterization and PCI was comparable to other published series, suggesting that manual compression with proper monitoring by doctors and nurses continues to be a safe procedure. PCI, emergency procedures, and myocardial infarction carried a significantly higher vascular complication rate

Keywords: pseudoaneurysm, cardiac catheterization, vascular complications, hematoma, Jordan, Hospital of University of Jordan.

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Introduction

Bleeding following diagnostic catheterization and percutaneous intervention (PCI) particularly retroperitoneal bleed has been identified as a major contributor to morbidity and mortality. In the last few years there have been a shift in the cardiovascular trials' outcome data from the usual triple end point of, death, myocardial infarction (MI), and target vessel revascularization (TVR); to the quadruple end point, which includes major bleeding^(1,2). The rate of vascular complications ranges between 1-4% depending on the study population, vascular closure method and the definition of vascular complications.

At our institution we perform around 2500 cardiac catheterizations and 600 PCI per year. Jordan University Hospital (JUH) is a tertiary hospital that serves a large segment of the Jordanian population residing in Amman and its metropolitan area. Despite the fact that JUH being a referral center the widely used vascular closure devices (VCD) aren't introduced yet in our daily practice mainly due to financial limitations, thus manual compression continues to be the only method used after sheath removal. What applies at our institution also applies on the other health care facilities supported by the ministry of health.

A Pubmed search showed that there was only one study done in Jordan that looked at timing and predictors of femoral hematoma following cardiac catheterization⁽³⁾, in that study 239 patients were examined prospectively. The results showed that the frequency of hematoma was 16.3% [$< 5\text{cm}$ (9.6%), $5\text{-}10\text{cm}$ (5.9%), and $> 10\text{cm}$ (0.8%)]. Most of the hematomas occurred post-procedure in 74.4%, while the rest (25.6%) occurred intraprocedural.

Variables that were associated with increased risk of hematoma development were high systolic blood pressure, advanced patient's age, preprocedural low hematocrit levels, high waist circumference, preprocedural usage of anti-coagulant-treatment, intraprocedural glycoprotein IIb/IIIa inhibitors use, and high activated clotting time (ACT) at the end of procedure.

A historic cohort design is used in our study to determine the rate of vascular complications and the variables associated with increased complication rate in our clinical setting following cardiac catheterization and PCI. Understanding these variables will identify high risk groups and allow better patient management.

Materials and Methods:

Subjects: We performed medical record review for all patients who underwent cardiac catheterization starting January 1st, 2011 to gather a sample size of 1000 consecutive patients. The medical records were reviewed for vascular complications including minor (hematoma $>5\text{cm}$ in diameter, pseudoaneurysm, arteriovenous fistula) and major (bleeding with a hemoglobin drop $\geq 3\text{gm/dl}$ or bleeding requiring transfusion), limb ischemia and death related to the vascular complication. Variables that can increase the risk of developing vascular complication were also evaluated (age, hypertension, diabetes mellitus (DM), chronic kidney disease (CKD), congestive heart failure (CHF), indication for the procedure (MI, angina), emergency vs. elective, and diagnostic catheterization vs. PCI⁽⁴⁻⁶⁾). This study was approved by the Institution Review Board (IRB).

Patient preparation and pharmacotherapy protocol: No anticoagulation is used prior to

elective procedures. Unfractionated heparin 5000 International Units was given in the emergency department prior to PCI for emergency cases (i.e. ST segment elevation myocardial infarction, Non-ST segment elevation myocardial infarction and unstable angina with any of the following: hemodynamic instability, heart failure, ventricular tachycardia and persistent chest pain). Non emergent acute coronary syndrome (ACS) cases were given low molecular weight heparin till the day of the procedure where the morning dose was held, which gave a window of at least 12 hours between the last dose and the procedure. If the patient needed PCI following the diagnostic procedure, unfractionated heparin was the only anticoagulant used in a weight adjusted dosing. In regard to antiplatelet therapy, aspirin 325mg was routinely given prior to any procedure. Clopidogrel 600 mg is administered prior to the procedure only in those presenting with ACS. For elective non-ACS cases, clopidogrel 600 mg was given if intervention is pursued following diagnostic angiography. Intravenous antiplatelet agents were not available.

Procedure: Access through the femoral artery was performed in all patients by a physician (cardiologist or a senior cardiology fellow). Six French sheaths were used in all patients. The protocol for sheath removal was manual compression; the sheath was removed immediately following diagnostic catheterization and at four hours after PCI. Compression after catheterization was performed by an experienced catheterization laboratory technician or nurse for 10 minutes, while compression time for PCI was 20 minutes.

Monitoring: Regular access site evaluation was routinely done following the procedure

and at the time of discharge. The nurse caring for the patient examined the access site for possible vascular complications and recorded the findings in the nurse's note. The physician caring for the patient examined the access site following compression and for any issues noticed by the nurse. Patients who had catheterization were observed in the catheterization laboratory holding area and discharged from there, and those who had PCI were admitted to the CCU for a minimum of 24 hours. Regular clinic follow-up with access site examination is scheduled at (1-2 weeks) following the procedure.

Statistics: Descriptive statistics, frequency counts, and relative frequencies of categorical factors were calculated and compared for statistical significance using chi-square testing and Fisher's exact test, P value ≤ 0.05 was considered significant (SPSS version 14).

Results:

One thousand patients were included during the period from Jan 1st to Aug 25th 2011. 746 patients had diagnostic cardiac catheterization and 254 patients had PCI during the study period. Six patients developed complications (0.6%): one had major bleeding and five patients developed minor complications including three hematomas and two pseudoaneurysms (one of them required surgical repair).

The baseline clinical and procedural covariates of all patients with and without vascular complications are shown in (table 1). The complication rate was significantly higher in PCI vs. catheterization (1.9% vs. 0.1%, P-value=0.005), emergency vs. elective procedures (6.8% vs. 0.3%, p=0.001) and MI vs. angina (4.3% vs.0.2%, p=0.002), see (table 2).

Age, gender, hypertension, CHF, CKD and

DM did not increase the risk of developing vascular complications.

Table 1. Baseline clinical and procedural covariates

Patient Characteristics	N (%)
Age \geq 60 years	527 (53%)
Gender (Males)	545 (54%)
Hypertension	727 (73%)
Diabetes mellitus	460 (46%)
Congestive heart failure	89 (8.9%)
Chronic kidney disease	16 (1.6%)
Stable angina	185 (19%)
Unstable angina	721 (72%)
Myocardial infarction	94 (9%)
Cardiac catheterization	746 (75%)
PCI*	256 (25%)
Elective	956 (96%)
Emergency	44 (4%)

* PCI: Percutaneous Coronary Intervention

Discussion:

This study aimed to show a representative sample of how the majority of public health care operates in Jordan regarding patients who

undergo elective and emergency cardiac catheterization, describing the details of pharmacotherapy in the different patient's scenarios, using the traditional manual compression for vascular hemostasis and most importantly evaluating the rate of vascular complications and the associated clinical variables.

Our study showed that manual compression performed by experienced personal carries a low rate of vascular complications even when compared to published reports; however the majority of our patients 74.6% had diagnostic catheterization where the access site complications are less. The bulk of vascular complications in this study occurred in certain high risk groups including patients who underwent PCI, those who required emergency procedures and patients diagnosed to have MI at presentation. Clearly more complications will occur with PCI than with diagnostic catheterization due to the use of anticoagulants and antiplatelet agents in the interventional procedures.

Table 2. Frequency of vascular complications and their associations with clinical variables

Risk factor	N	Complications N (%)	p Value
Age \geq 60	527	4 (0.8%)	NS*
Gender (male)	545	3 (0.5%)	NS
Hypertension	727	2 (0.3%)	NS
CHF*	89	1 (1.1%)	NS
DM*	460	1 (0.2%)	NS
CKD*	16	0 (0.0%)	NS
MI*	94	4 (4.3%)	0.002
PCI*	254	5 (2%)	0.005
Emergency	44	3 (6.8%)	0.001

*CHF: Congestive heart failure, DM: Diabetes mellitus, CKD: Chronic kidney disease MI: Myocardial infarction, PCI: Percutaneous coronary intervention. NS: Not significant.

At the time of an emergency procedure the physicians work under difficult and stressful circumstances at different times of the day or night treating very sick patients who present with MI with or without pulmonary edema and hemodynamic instability, these patients can be restless due to pain and /or shortness of breath which may explain the higher chance of vascular injury and development of complications.

Vascular complications related to cardiac catheterization through the femoral approach have long been recognized; despite the advances in technology including smaller sheath sizes, less aggressive and more calculated approach in anticoagulation, the use of different vascular closure devices, they continue to be a nightmare for the interventional cardiologist. Retroperitoneal bleeding is the most drastic complication especially when causing significant blood loss requiring blood transfusion or open surgical repair. Recent cardiovascular studies have included procedural bleeding as a primary end point signifying its importance.

Major bleeding can also lead to acute ischemic events adding to its high morbidity and mortality. The pathophysiology of ischemia following major bleeding may be explained by the following mechanisms: Bleeding is a marker for a systemic inflammatory response that increases the risk of subsequent thrombosis, early bleeding might also lead to premature cessation of dual antiplatelet therapy increasing the rate of cardiovascular events, and finally blood transfusion may increase the risk of cardiovascular events^(1,7).

A major shift in access site from the transfemoral approach to the transradial has been developed and was adopted in many, but not all, institutions worldwide to avoid the potentially lethal bleeding complications^(8,9). The radial approach also has a great advantage over the femoral approach in its ability to ambulate patients almost immediately after finishing the procedure and thus achieving considerable patients' satisfaction. Operators find it difficult initially to move away from their comfort zone with femoral to radial access, which may need a considerable time before being fully adopted.

Finally, it is important to remember that manual compression was compared to VCDs in few trials and was comparable in its safety and efficacy. VCDs have the potential to reduce time to hemostasis, facilitate patient mobilization, decrease hospital stay, and improve patient satisfaction^(10,11). However, VCDs add to the cost of the procedure which is not negligible in the setting of limited financial resources. Contrary to earlier published data; age, hypertension, CHF, CKD and DM were not associated with increased risk of vascular complications.

Conclusions:

Vascular complications rate following cardiac catheterization and PCI was comparable to other published series, suggesting that manual compression with proper monitoring by doctors and nurses continues to be a safe procedure. PCI, emergency procedures, and myocardial infarction carried a significantly higher vascular complication rate.

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الاختلالات الوعائية بعد القسطرة القلبية في مستشفى الجامعة الأردنية

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الملخص

الهدف: تعدُّ الإختلالات الوعائية سببا رئيسا للوفاة والعجز الصحي عند تتبع إجراء القسطرة القلبية أو التداخل الشرياني. تحدف هذه الدراسة لمعرفة معدل حدوث هذه الإختلالات وما هي المعايير السريرية المرتبطة بها.

الطريقة: تم مراجعة ملفات المرضى الذين خضعوا لإجراء قسطرة أو تداخل شرياني في مستشفى الجامعة الأردنية خلال الفترة الواقعة من كانون الثاني-2011 إلى آب-2011 حيث تم تسجيل الإختلالات الوعائية والمعايير السريرية المرتبطة بها.

النتائج: تم مراجعة 1000 ملف (742 قسطرة، 256 تداخل شرياني)، خلال الفترة المذكورة أعلاه وأظهرت 6 اختلالات وعائية (0.6%)، واحدة كبرى (نزف حاد احتاج إلى نقل دم)، و5 اختلالات صغرى (3 تجمع دموي و2 أم دم كاذبة). و كان معدل حدوث الإختلالات الوعائية مقاربا لما نشر في أبحاث سابقة. أما بالنسبة إلى المعايير السريرية فقد لاحظنا أن (التداخل الشرياني vs. 1.9%) (0.1%, P=0.005، الحالات الطارئة (6.8% vs. 0.3% P= 0.001)، وجود احتشاء في عضلة القلب (4.3% vs. 0.2%, P=0.002). كان مرتبطا بشكل قوي بحدوث الإختلالات الوعائية.

الاستنتاجات: معدل الإختلالات الوعائية في مستشفى الجامعة الأردنية مقارب إلى نتائج الأبحاث السابقة. المعايير السريرية (التداخل الشرياني، الحالات الطارئة، وجود احتشاء في عضلة القلب)، مرتبطة بشكل قوي بحدوث الإختلالات الوعائية.

الكلمات الدالة: الإختلالات الوعائية، القسطرة القلبية، مستشفى الجامعة الأردنية.