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# Vascular access and cardiac complications after PCI: In- and out-of-hospital outcome issues

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Rates for percutaneous coronary intervention (PCI) in Australia doubled while coronary artery bypass graft surgery rates declined by 12% in the years 1993–2000 (Davies, 2003). Femoral artery puncture and sheath insertion is the most common form of arterial access for PCI. Management of the femoral artery puncture site and sheath removal is part of the role of cardiac nurses, not only in Australia, but also in the UK and other westernized countries. The traditional manual compression of the puncture site and the increasing variety of vascular closure devices have implications for nursing practice. Such devices may be uncomfortable for the patient, time consuming for nurses, prolong hospitalization and carry the risk of vascular complications (Ruygrok and Chou, 2005; Behan et al, 2007).

Nursing studies have focused on the prevention and management of in-hospital vascular complications. Overall these rates ranged from 6.5% to 18% (Walker et al, 2001; Chlan et al, 2005). Even though these studies tracked complications at 24 hours, they do not report out-of-hospital vascular complications. One study of recovery patterns in PCI patients reported puncture site pain in patients following discharge. The number of patients reporting puncture site pain at 2 weeks was 4 (out of 37 patients); at 4 weeks, 4 patients and 6 weeks, 2 patients. No other vascular complications were presented (Barnason et al, 2006)

Interestingly, the length of stay for PCI procedures has decreased in recent years, with cardiac nurses having less time to spend with the patient (Ruygrok and Chou, 2005). Knowledge of the clinical consequences or outcomes for the patient during recovery at home is rarely available for clinical nurses or hospital administrators. Therefore, it seems apparent that nurses need further information on the vascular and cardiac complications that patients encounter not only in the hospital but also out of the hospital. This information will enable cardiac nurses to improve the monitoring of patient outcomes and improve their practice in PCI vascular management. Identifying information about out-of-hospital recovery complications or issues can assist cardiac nurses to enhance in-hospital patient education on what to expect and what actions to take should post-recovery complications occur, and also to augment appropriate support services.

Finally, even though this study took place in Australia, health care practices are similar enough for these results to have significance for nurses working in the UK and other countries.

## Background

The research institution is a 200-bed large urban acute hospital centre that carries out approximately 500 PCI procedures annually. The majority of PCI procedures were conducted via the femoral artery, with only a very small

## ABSTRACT

**Background:** Despite the rapid increase in percutaneous coronary intervention (PCI) rates, vascular complications remain a possible source of impaired outcomes for patients. Moreover, management of complications is an integral part of cardiac nurses' roles and responsibilities.

**Aim:** The aim of this quality review was to highlight the in-hospital and out-of-hospital complications up to 12 months post-discharge following PCI.

**Methods and Results:** A review of prospectively-collected data from the Angioplasty Database run by the research institute of 1089 consecutive patients who had PCI procedures from 1 January 2005–31 December 2006 was conducted. The in-hospital vascular complications included bleeding/ooze only (22.4%) and haematoma only (7.1%). The in-hospital cardiac outcomes included one death (0.09%) following PCI. In addition, a sample of 525 (52%) patients were followed up at 1 month and 12 months post-procedure. Vascular complications were 2.5% and 4% respectively. Cardiac complications included repeat angiogram (9.7%) and repeat PCI (3.6%).

**Conclusions:** Vascular outcomes pose ongoing problems for patients both in and out of hospital. The results suggest that cardiac nurses need to further improve monitoring of their patient outcomes following PCI.

## KEY WORDS

- ◆ Coronary angioplasty
- ◆ Percutaneous coronary intervention
- ◆ Heart catheterization
- ◆ Vascular access complications
- ◆ Discharge follow-up

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number performed via the radial artery approach. This is consistent with national and international trends. Registered Nurses who had completed the education and competency program were endorsed to remove femoral sheaths. The nurses removed the femoral sheath when the activated clotting time was less than 150–170 seconds; usually 3–4 hours after return to the unit.

It was standard practice at the research institution for patients to receive oral antiplatelet medications (ticlopidine or clopidogrel) ahead of the procedure. The loading dose could be up to 600 mg. These medications continued for at least 1 month, usually 12 months or indefinitely post PCI. The use of intravenous glycoprotein IIb/IIIa inhibitors (abciximab, tirofiban) was also recorded. The patient was usually discharged the morning after the PCI, following an education session delivered by registered nurses from the unit. It is usual practice to follow up patients by telephone at 1 month and 12 months.

## Aims

The aim of this project was to highlight, through data from in-hospital surveys and telephone follow up, the ongoing complications experienced up to 12 months after PCI. The following questions were examined:

- ♦ What is the incidence of in-hospital vascular complications and cardiac complications post-PCI?
- ♦ What is the reported incidence of out-of-hospital vascular complications and cardiac complications in the first 1 month and 12 months following PCI?
- ♦ Identify ways that nurses can enhance the discharge and recovery management of patients post-PCI.

## Methods

### Study design and subjects

This was a review of prospectively collected data from the Angioplasty Database run by the research institute of 1089 consecutive patients who had PCI procedures carried out over the 2 year period from 1 January 2005 to 31 December 2006.

### Study protocol

Data were collected from patients post-PCI on return to the cardiology unit or the cardiac surgical unit. Nurses completed an Angioplasty Database form for all post-PCI patients. This form included information about patient demographics, indication for the procedure, closure device used and complications experienced. Data were subsequently entered into the Angioplasty Database by the interventional cardiology research nurse. This research nurse also conducted the telephone follow-up interviews with patients at 1 month and 12 months post-discharge. These interviews provided information on mortality and morbidity, ongoing vascular complications and cardiac symptoms.

In this review we define in-hospital vascular complications as haematoma, bleeding/ooze at the puncture site, pseudoaneurysm and retroperitoneal haematoma. The presence of a haematoma was recorded alongside the

length and width (in cm) of the haematoma. 'Bleeding/ooze at the puncture site' referred to bleeding or oozing that arose from the groin wound post-PCI. The definition did not differentiate between arterial and venous bleeding. Pseudoaneurysm was defined as an area of local swelling and/or presence of bruit on auscultation, confirmed by ultrasound or Doppler study.

Data were recorded on groin complications via the telephone follow-up at 1 month and 12 months. These symptoms included: pain in the groin, haematoma still present, bruising and numbness in the area. Also, any patient reports of out-of-hospital treatment for pseudoaneurysm were recorded. Patients' reports included treatments such as surgical repair, thrombin closure, ultrasound and any other related procedures. For cardiac events, the telephone interview provided data from either the patient or family regarding death, myocardial infarction, stroke, the need for repeat PCI, and coronary artery bypass graft surgery required.

## Ethical approval and statistical analysis

Ethical approval was granted by the UnitingCare Health Human Research Ethics Committee. The researchers did not contact individual patients for consent to review the database, as patients had already signed a form on admission, consenting to the collection and use of their personal information. This was a descriptive study, presented as summaries (e.g. percentages and means, standard deviations or medians) of the patient and procedure characteristics.

## Results

### Demographic and baseline data

The results report the outcomes of 1089 procedures carried out over a 2 year period. There were 548 procedures

**Table 1.**  
**Patient characteristics**

<i>n</i> = 1027		
Variable	<i>n</i>	%
Male	767	74.7
Female	260	25.3
Hypertensive	717	69.8
Diabetic	233	22.7
Hyperlipidaemia	600	58.4
Family history	250	24.3
Smoker	141	13.7
Stable angina	445	43.3
Unstable angina	333	32.4
Post-MI	178	17.3
Acute MI	39	3.8
Rescue acute MI	4	0.4

MI = myocardial infarction

**Table 2.**  
**Vascular complications**

All procedures <i>n</i> = 1089	
Vascular complication	Procedures <i>n</i> (% of total)
All complications	389 (35.7%)
Bleeding/ooze only	244 (22.4%)
Haematoma only	77 (7.1%)
Bleeding/ooze and haematoma	65 (6%)
Ultrasound diagnosis of pseudoaneurysm	2 (0.37 %)
Haematoma and nil treatment for pseudoaneurysm	1 (0.1%)

in 2005 and 541 in 2006, conducted on a total of 1027 patients (526 in 2005 and 501 in 2006). There were 971 patients with one procedure recorded in the data base for this 2 year period. There were 50 patients who had 2 recorded procedures and 6 patients had 3 recorded procedures. The patient characteristics, comorbidities and chest pain status are recorded in *Table 1*.

Almost three-quarters of the patients were men. The median age of the patient group was 67 years, ranging from 34 to 91 years. The majority of patients, not surprisingly, had noted risk factors for coronary artery disease. The most prevalent comorbidities were hypertension (69.8%) and hyperlipidaemia (58.4%).

### In-hospital vascular complications

Of the 1089 procedures 389 (35.7%) were recorded as experiencing vascular complications. The incidence of vascular complications is contained in *Table 2*. Worthy of note is the 22.4% incidence of bleeding/ooze only and 7% haematoma only.

The vascular complications (*n*=389) were further broken down by the closure devices used immediately after the PCI (*Table 3*). The Angio-Seal device and digital pressure were the most commonly used closure methods. Of the 184 procedures where Angio-Seal was used, 70.1% had bleeding/ooze only and 15.8% had bleeding/ooze and haematoma. For patients where the sheath/digital pressure approach was used (*n*=171) 55% had bleeding/ooze only and 15.8% had haematoma and bleeding/ooze. Sheath/digital pressure recorded a 28.6% haematoma rate.

The angioplasty database form traced the time nurses were spending in managing bleeding/ooze and their choice of intervention. Bleeding/ooze with or without haematoma was recorded in 309 of the 389 vascular complications. The majority of the bleeding was controlled in less than 30 minutes in 103 cases (62.8%). Control of bleeding was gained within 31 minutes to 2 hours in 64 procedures (20.7%). Control of bleeding taking longer than 2 hours occurred in 51 procedures (16.5%). The nurses' choice of intervention was application of digital pressure or use of the FemStop device. Digital pressure alone was used in 43% of the 309 cases. The FemStop device alone was used in 28% of cases and a combination of both devices in 26% of cases.

The nurses' treatment of haematoma was also tracked via the database. Haematoma with or without bleeding/ooze occurred in 143 of the 389 procedures with vascular complications recorded. Digital pressure alone was applied in 50% of the procedures, while FemStop alone was applied in 18% of cases. A combination of digital pressure and the FemStop device was used in 20.3% of cases. However, the tool did not track the time that nurses were spending managing haematoma.

The length and width of haematoma was also recorded using the data collection tool. The haematoma size was recorded in only 103 out of 143 procedures where a haematoma was formed. The median length and width of the haematoma was 3 cm.

**Table 3.**  
**Vascular complications by closure device**

<i>(n</i> =389)						
Closure method	Bleeding/ooze only	Haematoma only	Bleeding/ooze and haematoma	Haematoma and pseudoaneurysm (nil treatment)	Pseudoaneurysm (ultrasound)	Total
Perclose	2 (66.7)	0	1 (33.3)			3 (100)
Angio-Seal	129 (70.1)	24 (13)	29 (15.8)		2 (1.1)	184 (100)
Digital pressure	94 (55)	49 (28.6)	27 (15.8)	1 (0.6)		171 (100)
RadiStop	2 (100)	0	0			2 (100)
Other	15 (60)	3 (12)	7 (28)			25 (100)
Not specified	2 (50)	1 (25)	1 (25)			4 (100)

As is often the case, the data collected on length of stay is highly skewed and so the median estimate is used as a summary: total length of stay was 2 days (range 0–4 days), with post-procedural length of stay being 1 day (range: 0–32 days)(Lee et al, 2003). The median length of stay of 2 days is similar to that reported nationally in Australia (Davies, 2003). There was no difference in the median estimates of length of stay between patients who had a vascular complication and those who did not.

### In-hospital cardiac complications post-PCI

The number of in-hospital cardiac complications included the use of the intra-aortic balloon pump for 12 (1.1%) of the 1089 procedures, and a blood transfusion in two cases (0.2%). There was 1 (0.1%) reported death following PCI and 3 deaths (0.3%) during the same hospital admission. There was no incidence of coronary artery bypass graft surgery or acute myocardial infarction as a result of PCI. There were 17 incidences (1.56%) recorded as ‘other’ where no further details were given.

### Out-of-hospital vascular and cardiac complications occurring within 1 month and 12 months after discharge

Patients who underwent PCI in 2005 (525) were telephoned at 1 month and between 2–12 months post-discharge. The data for the 2006 patients was not included as, at the time of writing, not all patients had been followed-up at 12 months.

The cardiac and vascular follow-up data are presented in *Table 4*. Interestingly, groin complications presented ongoing problems for patients, with a 2.5 % incidence at 1 month and total of 4% incidence at 12 months. Owing to low numbers formal assessment of any associations between groin complications at 1 month and 12 months and patient characteristics is difficult.

Cardiac issues were also ongoing throughout the first 12 months after discharge. The incidence of all causes of death at 12 months was 3%. Events that required re-admissions to hospital over the 12 months included repeat angiogram 9.7%, repeat angioplasty 3.6% and coronary artery bypass graft surgery 1.3%.

### Discussion

The major finding of this review is that vascular complications are ongoing problems for patients both in and out of hospital. Overall, the incidence of in-hospital vascular complications was considerable at 35% (389 of 1089 procedures). Moreover, bleeding/ooze and haematoma were the two most common problems experienced by patients following PCI.

Digital pressure for sheath removal and the Angio-Seal device were the predominant methods of obtaining haemostasis. The Angio-Seal device was associated with more bleeding/ooze and fewer cases of haematoma in comparison with digital pressure with femoral sheath removal. However, femoral sheaths were associated with more haematomas and fewer bleeding/ooze episodes

**Table 4.**  
**Telephone follow-up data for patients undergoing PCI in 2005**

(n=525)		
Outcome	1 month follow-up	12 month follow-up
Death	5 (1.0%)	16 (3.0%)
MI	1 (0.2%)	2 (0.4%)
Stroke	2 (0.4%)	7 (1.3%)
Cardiac rehab	344 (65.5%)	449 (85.4%)
Repeat angiogram	9 (1.7%)	51 (9.7%)
Repeat angioplasty	6 (1.1%)	19 (3.6%)
Repeat lesion	0	8 (1.5%)
Repeat vessel	3 (0.6%)	7 (1.3%)
CABG	3 (0.6%)	7 (1.3%)
Groin complications	13 (2.5%)	21 (4.0%)
Surgical repair	1 (0.2%)	2 (0.4%)
Thrombin close	0	0
Ultrasound	0	0
Other	1 (0.2%)	3 (0.6%)
Angina	45 (8.6%)	97 (18.4%)

CABG = Coronary artery bypass graft surgery

compared with the Angio-Seal device.

Some caution needs to be taken as nurses’ reports of bleeding/ooze may at times have only been venous ooze rather than actual arterial bleed. Further, there may have been an over-reporting of bleeding owing to the broad definition given. Major bleeding reported may have been over-represented in comparison with minor bleeding, which includes subcutaneous capillary ooze from the Angio-Seal device. Angio-Seal manufacturer guidelines recommend that nurses monitor for subcutaneous tract ooze (St Jude Medical, 2007), though it is unclear from the data collected what was tract ooze and what was major bleeding. So it seems apparent that this should be addressed with future data collection.

One study of 10 669 PCI patients noted only a 10.27% incidence of in-hospital vascular complications (Kuchulakanti et al, 2004) whereas in this study a significant 35% of patients experienced vascular complications. Kuchulakanti et al (2004) also identified haematoma as the most common vascular complication whereas the current report identified bleeding/ooze as the most common.

Problems were noted in this review with the recording of haematoma size (length and width). Data were only available for 103 out of 143 procedures because there were inconsistencies in completing this section of the angioplasty database form. The data collection form required the nurse to tick a box if a haematoma was present, and

then record the size (length and width). However, in 28% of cases the haematoma box was ticked but no size was recorded, or the size was recorded but no haematoma was noted.

The issue of inadequate definitions is also represented in the literature. In their meta-analysis of vascular complications, Nikolsky et al (2004) reported 30 studies which noted haematoma development. The haematoma sizes ranged from <5cm, 2–6cm, 5–10cm, >10cm, >20cm to any palpable mass requiring blood transfusion and prolonging hospitalization. Nikolsky et al (2004) noted that the definition criteria for haematoma were so wide that it was excluded as a primary end point in analysis.

Vascular complications continued after discharge for the post-PCI patient. While most of the groin complications tabled, above occurred within the first month after discharge (2.5%), a surprising 1.5% of patients reported ongoing symptoms for up to 12 months after discharge. Clearly, the short length of hospital stay for a PCI procedure does not equate to a short-term problem for the patient. Discharge from hospital for some patients represents ongoing problems over the first 1–12 months post PCI. For cardiac nurses there is a need for out-of-hospital telephone follow-up service to continue to support patients post-PCI. Not only will information gained at follow-up better inform nurses about their patients, but it will provide feedback to inform future patients of what to expect when they go home following PCI.

There is support in the literature for better monitoring of patients following any cardiac procedure. Kuchulakanti et al (2004) point to the ongoing nature of cardiac and vascular complications reported via telephone follow-up of patients post-PCI. Furthermore, reported vascular complications were a significant predictor of mortality at 12 months. They called for diligent efforts to minimise vascular complications and to follow up patients in case of future coronary events (Kuchulakanti et al, 2004)

Similarly, there are cardiac issues that represent an ongoing problem for some patients, such as repeat angiogram, angioplasty or coronary artery bypass graft surgery (Kuchulakanti et al, 2004). All of these procedures entail readmissions to hospital that are often associated with anxiety for the patient and family. They also carry additional procedural risks, and involve an extended recovery period. Clearly, for a small group of patients; the 2–3 day angioplasty hospitalization may not be the end of their treatment experiences.

## Limitations

The major limitations of this report result from the use of a retrospective analysis of data obtained via the Angioplasty Database and the lack of reliability testing of the data stored in the database. The report highlights data quality issues, like the lack of clear definitions for aspects of data collected. As such, this made the interpretation of aspects of the data difficult. Feedback has been provided about the data collection tool and the data elements are currently being defined and the tool has been upgraded.

The lack of consistent recording of haematoma size by the nurses has been previously identified. Without adequate documentation on haematoma size this review cannot provide an evaluation of performance in terms of how significant those haematomas may have been.

## Implications for nursing practice and further research

This report has highlighted that ongoing cardiac and vascular issues exist for a certain percentage of patients after discharge following PCI. These were associated with repeat readmission to hospital and exposed the patient to the risks and anxiety associated with further medical interventions. Nurses need to consider the content of their teaching plans in order to better prepare the patient and family to monitor and deal with possible vascular and cardiac complications following PCI procedures.

This report has recognized the value of the out-of-hospital telephone support service in not only monitoring and tracking longer-term patient outcomes but also the individual counselling benefits that talking with an expert nurse can provide. Given the short length of stay and ongoing complications associated with PCI, it is recommended that all institutions offer a nurse-led telephone support service for their patients and families. The short length of stay means that patients are left to recover at home without the added support of experienced cardiac nurses. The organization where the study was undertaken is situated in a large city with many patients coming in from rural areas, who have limited access to cardiac specialist nurses in their communities. The introduction of out-of-hospital support services would greatly assist patients in the recovery phase and augment local medical services.

It is recommended that the interventions nurses use to treat bleeding/ooze and haematoma be more clearly defined and recorded with a view to develop a risk assessment tool. For example, interventions such as the application of digital pressure or the Femstop device for more than 30 mins could be used as an indicator to develop a stratification of mild, moderate or high-risk alert for the patient developing a more serious vascular complication, such as pseudoaneurysm. This type of tool could be beneficial for organizations employing more nurses who are new to the cardiac nursing specialty. It would assist in detecting high-risk patients.

Finally, further research is needed to address the variable size of haematoma definitions used by the institution under review. A research project could aim to produce a standardized assessment tool that would measure the size of the haematoma and correlate this with the volume of blood contained in the haematoma (by ultrasound). These findings could then be linked to clinical consequences for the patient.

## Conclusions

The review has identified that femoral vascular and cardiac complications represented ongoing issues for

## KEY POINTS

- ♦ Management of the femoral vascular access site remains a nursing responsibility following PCI
- ♦ Vascular and cardiac complications are ongoing problems for patients both in and out of hospital.
- ♦ Some cardiac complications are associated with readmission to hospital
- ♦ For cardiac nurses there is an obvious need for out of hospital telephone follow up services to provide continued support for patients after PCI

groups of patients in and outside hospital after PCI. Out-of-hospital telephone support services are required to monitor such complications and to better provide support for the patients and families during recovery.

Review of in-hospital and out-of-hospital vascular complications has provided a baseline awareness of the standards of nursing practices. Raised awareness should further empower nurses to participate in better data collection and recording and be involved in pertinent research endeavours to augment more appropriate support services for their cardiac patients.

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