Feature

# Quality Improvement in the Catheterization Laboratory: Redesigning Patient Flow for Improved Outcomes

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## PRIME POINTS

- Vigilant observation in the first few hours after sheath removal promotes rapid recognition and treatment, which result in decreased complication rates.
- A postprocedural holding room allows intensified observation of patients, standardization of postprocedural care, and an environment for sheath removal that is limited to highly skilled practitioners.
- Previously held concepts, although common in practice, demonstrate no benefit, and actually increase patients' discomfort.

Cardiac catheterizations are high-risk, high-volume procedures that are performed in the United States more than 1.4 million times per year.[1] Vascular complications are the most common morbidity associated with cardiac catheterizations and have reported incidences as low as 0.1% and as high as 61%.[2,3] Most complications occur in patients who have had a percutaneous coronary intervention (PCI).[4-6] The American College of Cardiology (ACC) reported vascular complication rates of 1.7% in PCI patients.[7]

Cardiac catheterization requires arterial access via a small sheath through either the femoral, brachial, or radial artery. After the sheath is removed, hemostasis is achieved at the insertion site with an internal vascular closure device or via external manual/mechanical compression.

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Most complications occur within the first 2 hours after sheath removal and include hematomas, extensive ecchymosis, formation of arteriovenous fistulas and pseudoaneurysms, impaired distal circulation, and retroperitoneal bleeding.[6,8,9] Efforts to decrease complications at the vascular access site are generally focused on sheath removal and techniques to achieve hemostasis,[10,11] both of which require expertise in critical care assessment and technical skills. The purpose of this article is to describe a performance improvement project that resulted in a sustained decrease in vascular complications after cardiac catheterization.

## Background

Sharp Grossmont Hospital is a 481-bed, magnet-designated, not-for-profit community hospital in east San Diego County, California. Staff in the 2-room catheterization laboratory perform approximately

2700 procedures annually, with approximately 800 PCIs. Scheduled cardiac catheterizations are performed on both outpatients and inpatients Monday through Friday between 7:30 AM and 5:00 PM. The catheterization laboratory is available for emergency procedures 24 hours per day, 7 days per week. Approximately 350 emergency cardiac catheterizations are performed annually.

Before this improvement project, patients arrived in the catheterization laboratory from 1 of 4 telemetry units, an outpatient area, an intensive care unit (ICU), or the emergency department. After the cardiac catheterization, patients were returned to an inpatient or outpatient nursing unit for postprocedural care and recovery. However, if patients required a higher level of care after the procedure, or a change from outpatient to inpatient status, they remained in the catheterization laboratory's procedure room until a transfer could be made.

In the majority of cases, sheaths were removed by technicians in the catheterization laboratory, and hemostasis was accomplished with either a closure device or manual compression per the physician's discretion. Those sheaths not removed in the catheterization laboratory were removed by the bedside telemetry nurse or ICU nurse. Criteria for sheath removal included the following:

- Activated clotting time less than 180 seconds
- Partial thromboplastin time less than 60 seconds
- Systolic blood pressure less than 150 mm Hg

Standard practice was applying pressure at the catheter insertion site for 20 minutes, followed by 6 hours of bed rest after hemostasis for patients who had 6-French sheaths. Larger sheaths required pressure for at least 30 minutes. Site dressings were at the nurse's or technician's discretion and included pressure dressings, gauze, or transparent dressings. Outpatients were discharged after their 6 hours of bed rest and successful ambulation.

As a participant in the National ACC Registry, Sharp Grossmont Hospital's vascular complication rate of 7.5% exceeded the 2005 quarter 1 ACC benchmark of 2.5%.[12] The actual complication rate for cardiac catheterizations was probably higher because Sharp Grossmont Hospital submitted data only on the PCI population. Given the vascular groin complication rate of 7.5%, a performance improvement effort began to determine what practice changes were needed. This project was initiated by nurses, so the focus was on those practices that nurses could influence.

## Methods

The project began with a review of the literature, a survey of practices in catheterization laboratories in the local area, a query to hemostasis device vendors for best-practice recommendations, a retrospective chart review, and a concurrent evaluation of cardiac catheterization patients. A literature review from the past 10 years was conducted to determine evidence-based practices and to identify best practices for sheath removal and management of vascular complications. Other catheterization laboratories in the area were queried via telephone to identify the standard of care in the community (Table 1).

A 1-month retrospective chart review and a concurrent evaluation


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**Table 1** Questions used in interview about practices in the catheterization laboratory

Where do you care for patients immediately after catheterization (eg, recovery area, telemetry, intensive care, other)?

If you have a recovery area:
- Which patients go to the recovery area after cardiac catheterization (eg, all)?
- If not all patients go to the recovery area, what criteria are used to determine admission?
- What is the nurse to patient ratio in the recovery area?
- What are the skills/job requirements for the nurses in the recovery area?
- How long do patients stay in the recovery area?
- When patients leave the recovery area, what type of unit are they transferred to (eg, specialized telemetry unit, any available unit, other)?
- What is the ratio of procedure rooms to recovery beds?

If patients do not go to a recovery area:
- Where are they transferred to (eg, specialized telemetry unit, any available unit, home, other)?
- If a patient has a sheath in place at the time of transfer, how does that affect where the patient is transferred to?

Who removes sheaths from cardiac catheterization patients (eg, catheterization laboratory technician, registered nurse, specialized team, physician, nurse practitioner, other)?

After sheath removal:
- How long is pressure held?
- What type of dressing do you apply?
- Do you use sandbags?
- What is your bed rest time?
- During bed rest, how high is the head of the bed permitted to be elevated?

of all cardiac catheterization patients were undertaken to determine root cause and to quantify complications at vascular access sites. Retrospective data were collected on the type of complication, the physician performing the catheterization, the unit location for sheath removal, the person removing the sheath, mechanical or manual pressure after sheath removal, how long pressure was applied, and the time elapsed until the complication occurred.

Concurrent data collection began in the catheterization laboratory and concluded with a physical assessment of the patient 1 day after the procedure to determine the presence of vascular complications, such as hematomas, degree of ecchymosis, changes in hemoglobin, vascular injury, pseudoaneurysm, and retroperitoneal bleeding. Data were recorded on a data collection tool, and results were reported monthly on all patients who were in the hospital the day after their cardiac catheterization procedure if that day was a weekday. Outpatients who returned home the same day or patients who had a cardiac catheterization on Friday or Saturday were not included in the concurrent patient review, unless they remained hospitalized beyond the weekend. Concurrent data included the same information collected in the retrospective review plus the patient's age, the number of catheterizations/difficult groin access, use of anticoagulants, size of sheath, sheath exchange, placement of venous sheath, activated clotting time greater than 180 seconds or partial thromboplastin time greater than 60 seconds when the sheath was removed, and time to sheath removal greater than 6 hours.

The literature was inconclusive on objective criteria and definitions of a hematoma or bleeding. Reportable hematoma sizes ranged from 4 cm to 10 cm,[6,13,14] or only in association with a delayed hospital discharge.[15] Definitions of bleeding ranged from a decrease in hemoglobin level greater than 2 g/dL to a decrease of 5 g/dL or greater in hemoglobin level,[15] intracranial hemorrhage, or requiring a transfusion.[16] We reported all hematomas, differentiated by whether they were greater than or less than 5 cm. We defined bleeding as a hemoglobin decrease of 3 g/dL or greater, or requiring a transfusion. We also tracked patients with diffuse ecchymosis, defined as bruising of an area greater than or equal to 10 cm by 10 cm. Although bruising may be inconsequential medically, it was a visible and painful reminder to patients of their experience in the catheterization laboratory. All complications were further investigated for documentation, changes in laboratory values, and subjective assessment.

## Results

### *Literature Review*

Publications on sheath removals were limited before 2001.[8] As new anticoagulants and closure devices were introduced, many studies contributed valuable information associated with vascular complications. Those factors commonly associated with an increased risk of vascular complications included

- age greater than 70 years[3]
- female sex[3,6]

- sheaths left in place for more than 6 hours[2,14]
- interventional procedure with anticoagulation[2,6]

Factors such as keeping the head of the bed flat, using pressure dressings, and placement of sandbags, although common in practice, have shown no benefit and actually increase patients' discomfort.[2,17]

At one time, only physicians removed sheaths outside of the catheterization laboratory. A study[14] of 200 patients at 1 center demonstrated improved outcomes for patients when the bedside nurse removed sheaths instead of delaying sheath removal until the physician was available. In contrast, the SANDBAG study,[2] which involved more than 4000 patients at 82 different centers, showed that manual sheath removal by nurses was an independent predictor of increased bleeding. Harper[1] reported that detection of vascular complications was best made by frequent observation of the puncture site, recognition of at-risk patients, and communication, not through routine measurement of vital signs. Therefore, we embarked on an assessment of our cardiac catheterization patients to determine if the incidence of bleeding was higher when a nurse removed the sheath.

Internal vascular closure devices, developed as an alternative to manual compression, have demonstrated complication rates similar to the rates for manual compression.[15,18] The duration of bed rest can be shortened with these devices, but patients' outcomes appear to be no different than the outcomes achieved with manual compression.[15,18]

### *Survey Results*

Telephone surveys were conducted with 5 Southern California hospitals that performed a minimum of 1000 cardiac catheterizations per year. Three of the hospitals had a pre/postprocedural area for patient preparation, recovery, and sheath removal. Nurse to patient ratios in these "recovery-type" areas were 1 to 2. The fourth hospital did not have a pre/postprocedural area. All PCI patients with sheaths in situ were cared for after the procedure in a specialty unit with a nurse to patient ratio of 1 to 3. Patients remained in this unit until sheaths were removed and intravenous administration of anticoagulants was discontinued. The fifth hospital had a specific team in the catheterization laboratory that removed all sheaths, regardless of where the patient was located. All patients in the surveyed hospitals were transferred to either a designated telemetry unit or the ICU after the procedure.

Complication rates were not available from the surveyed hospitals because the data were not collected or the hospitals were not willing to share it. Representatives from vendors of hemostasis devices were universal in their response that sheath removal should be done by experienced personnel, regardless of discipline. The representatives defined "experienced" as having achieved at least 10 consecutive and successful sheath removals within 1 month.

### *Retrospective Chart Review*

A retrospective chart review was conducted on all cardiac catheterization patients for a 1-month period (n = 148). A total of 19 (12.8%) vascular complications occurred. Fifteen (79%) of the complications occurred in patients receiving anticoagulants, and 13 (68%) of the complications occurred in patients with manual compression for hemostasis and no closure devices. Twelve (63%) of the complications of sheath removal occurred after the patient was transferred out of the catheterization laboratory. Additionally, 15 (79%) of the complications occurred within 2 hours of sheath removal (Table 2). The mean length of stay for patients with vascular complications was 2.97 days, as compared with 1.98 days for patients without complications.

### *Concurrent Patient Review*

Initial monthly data from 56 patients revealed 25 complications in 21 patients for an overall complication rate of 45%. Of the 12 patients who had hematomas, 8 patients (67%) had their sheaths removed outside of the catheterization laboratory. Additionally, documentation of postprocedural care and sheath removal techniques was inconsistent. Documentation showed various standards of practice, such as

**Table 2** Potential contributing factors for vascular complications gathered from retrospective chart review (n = 148)

| Potential contributing factors | No. (%) |
|---|---|
| Receiving anticoagulants | 15 (79) |
| Manual hold | 13 (68) |
| Sheath removal outside catheterization laboratory | 12 (63) |
| Within 2 hours of sheath removal | 15 (79) |
| Total complications | 19 (100) |

frequency of site assessment, duration of direct pressure, placement of the external compression device, type of dressing applied, and management of bleeding at the site.

## Implemented Changes

Based on the results from the literature review, surveys, and retrospective and prospective patient reviews, 6 independent strategies emerged for consideration:

1. Reeducate the telemetry nurses on sheath removal and site care.
2. Replace bulky pressure dressings with transparent dressings to improve visibility of any oozing or hematoma development at the vascular insertion site and to allow easier access to palpate the vascular access site.
3. Create a recovery area (holding room) for the catheterization laboratory.
4. Transfer patients to a designated nursing unit after interventions in the catheterization laboratory.
5. Create a team of specially trained staff to remove sheaths on each unit receiving patients from the catheterization laboratory.
6. Implement an on-call schedule for technicians in the catheterization laboratory to remove all sheaths, regardless of the patient's location.

Not all of the strategies were implemented. Our first tactic was reeducation of the telemetry nurses. The instruction included a change to transparent dressings, proper sheath removal, and hemostasis management techniques. A weeklong, mandatory education campaign resulted in no improvement in vascular complications 1 month later. Given that our PCI patients were spread over 4 different telemetry units, probably fewer than 5% of these nurses would have an opportunity to remove a sheath in the near future. It was unrealistic to expect these nurses to achieve competence in this high-risk/low-volume setting.

It was decided to create a 4-bed postprocedural recovery area (holding room), with a nurse to patient ratio of 1 to 2, and to limit sheath removals to catheterization laboratory technicians and critical care nurses. Competency in sheath removal was granted to personnel in the holding room after successful completion of an in-service education module and successful demonstration of sheath removal. By changing patient flow with the holding room, we could have sheaths removed in a high-risk/high-volume environment. Initially the holding room was operational from 8:30 AM to 5:00 PM Monday through Friday, with the objective of ensuring adequate hemostasis for at least 1 hour after sheath removal or placement of a closure device, before transfer back to the nursing unit. Any bleeding or oozing was treated immediately with manual compression, and patients were not transferred until the nurse assessed the site as stable. The site was considered stable when no bleeding, oozing, or hematoma formation had occurred for 1 hour. For some patients, this extended their time in the holding room to 4 to 6 hours or more. On the basis of the decrease in hematomas and other complications (Figure 1), the holding room hours were extended to 7:00 AM to 9:00 PM. Even with the extended hours, the holding room could not accommodate all patients

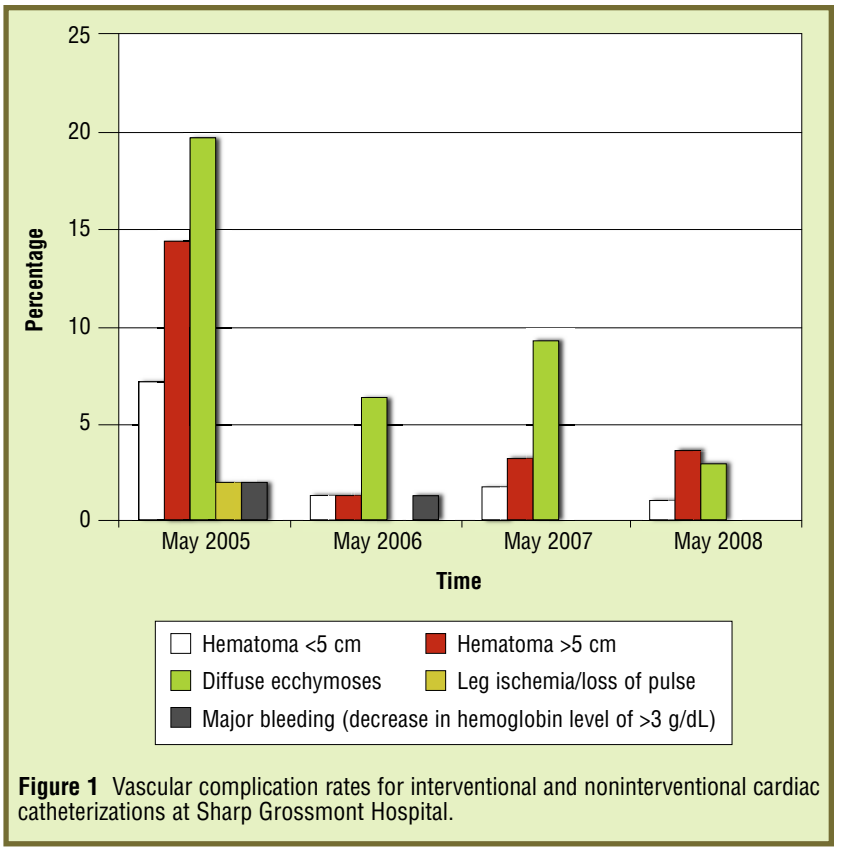


**Figure 1** Vascular complication rates for interventional and noninterventional cardiac catheterizations at Sharp Grossmont Hospital.

**Table 3** Risk assessment influencing decisions about patient flow

| | Low risk | Medium risk | High risk |
|---|---|---|---|
| **Action** | Patient bypasses holding room and is returned directly to room on the nursing unit or outpatient area | Patient recovered in holding room<br>If assessed as stable, available to transfer to room on the nursing unit or outpatient area | Patient recovered in the holding room<br>If no bed is available in holding room, patient recovers in catheterization laboratory's procedural room for 1 hour, until stable, or until a bed is available in the holding room |
| **Assessment** | Pacemaker insertions or generator replacements with venous access only | Diagnostic heart catheterization or vascular study without anticoagulation, manual pressure for hemostasis (no closure device) | Confused patient unable to comply with instructions after procedure |
| | Electrophysiology study procedures with no anticoagulation | Development of a cardiac dysrhythmia, altered level of consciousness, or significant hypotension that requires treatment | Patient treated with anticoagulants, multiple arterial punctures, high groin access above inguinal ligament, or has a hematoma develop during procedure |
| | Diagnostic heart catheterization or vascular studies with no anticoagulant and a successful vascular closure device | Persistent oozing at insertion site with or without closure device | Sheath left in place for later removal<br>Failed closure device with external compression device in place |

from the catheterization laboratory. Therefore, during high census, staff members prioritized patients for the holding room according to the patients' risk for complications (Table 3). Additionally, ICU patients were returned directly to their units, where the nurses removed the sheaths.

We decided that transferring patients from the catheterization laboratory to a designated nursing unit was unrealistic because it was not possible to reserve beds for patients after treatment in the catheterization laboratory. The practice continued with transferring patients from the catheterization laboratory to any available bed in 1 of the 4 telemetry units. Given that catheterization patients were distributed throughout the nursing units, we decided it was also unrealistic to create a team on each telemetry unit to remove sheaths. When a patient was transferred to a telemetry unit with a sheath in place, a technician in the catheterization laboratory took "call" for these sheath removals.

## Improvements in Patients' Outcomes

Improved outcomes in vascular complications were observed within 1 month of implementing the holding room and the on-call technician in the catheterization laboratory. The total rate of vascular complications decreased from 44.6% in May 2005 (total hematomas, diffuse ecchymosis, leg ischemia, >3 g/dL decrease in hemoglobin level) to 9.9% in May 2006 and sustained through May 2008 (Figure 1). The annual May spot check of data on complications of cardiac catheterization showed sustained improvements through 2008 (Figure 1).

This hospital's data appear higher than the ACC data because we tracked visible complications as well as complications that resulted in increased morbidity (Figure 2). Nonetheless, Sharp Grossmont Hospital's ACC data for PCI patients reflected similar improvements; the vascular complication rate from January to March 2005 was 7.5%, in contrast to the ACC benchmark rate of 2.5%. From January to March 2008, the PCI vascular complication rate was 3%, in contrast to the ACC benchmark rate of 1.8% (Figure 2). Clearly, the gap between Sharp Grossmont Hospital's results and the ACC benchmark rate has narrowed.

## Challenges and Lessons Learned

Change requires timely, valid, and reliable data that are actionable. Although Sharp Grossmont Hospital participated in the ACC registry, the reported data lagged. A tool had to be developed to track complications on a monthly basis to assess if our changes affected patients' outcomes. Initially, we wanted the telemetry nurses to collect the data after cardiac catheterization, but we found greater compliance when this activity was assigned to nurses in the holding room. The data from this improvement project demonstrated that education alone was insufficient. When education was combined

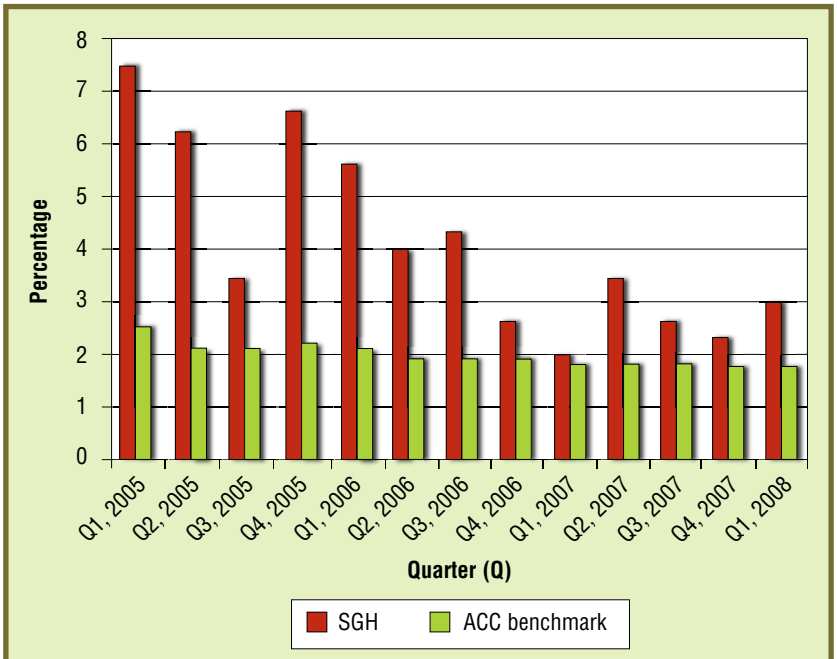


**Figure 2** Vascular complication rates in patients undergoing percutaneous coronary intervention: Sharp Grossmont Hospital (SGH) versus benchmark of American College of Cardiology (ACC).

with frequent assessment and repetition of care practices related to the vascular access site, the staff became competent in sheath removal and rapid recognition of complications and treatment regimens. Vascular complications require immediate action and intervention. Administrators supported the change when the data justified the effort of creating a postprocedural area.

The data also helped broaden the accountability for technicians and nurses in the catheterization laboratory. Before the data were collected, personnel in the catheterization laboratory believed that complications were minimal with only anecdotal complaints and that telemetry nurses should be able to remove sheaths. The data provided evidence that complications were occurring, and that, although nurses from outside the catheterization laboratory can successfully remove sheaths, ample opportunity to practice the skill was needed. The personnel in the catheterization laboratory accepted responsibility for sheath removal, whether that occurred in a postprocedure room or on the nursing unit. They responded to data so that they could improve patients' experience by reducing complications and improving satisfaction and comfort.

Initially, technicians and nurses from the catheterization laboratory thought that the postprocedure holding room was unnecessary, adding additional movement of patients and inconvenience. Monthly reporting of the decreasing complication rates served as positive reinforcement for the additional effort that was needed to change patient flow.

Creating a new patient care area in a hospital with space limitations and high patient census required interdepartmental negotiation, collaboration, and cooperation. Patients who have had a procedure in the catheterization laboratory require an area that promotes patients' privacy and comfort, while also providing a high intensity of care with access to emergency resuscitation equipment. The physical environment ideally is one that permits intense care as needed. These requirements were difficult to fulfill and required trial locations. The catheterization laboratory's holding room was relocated 4 times in 2 years. The initial location was a shared space in the open, preoperative holding area. The high acuity of the patients who had undergone a procedure in the catheterization laboratory was disruptive and created anxiety in the preoperative patients. Therefore, the holding room was moved to other locations that ultimately were designated for other uses. The current location is a shared space with more private patient rooms. Staff from the catheterization laboratory have been able to negotiate space for the holding room because of the ongoing data that demonstrate improved outcomes for patients.

## Conclusion

Vascular complication rates after cardiac catheterization were reduced, with an improvement process that included a review of the literature, identification of practices in similar organizations, and monitoring of complication rates.

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To learn more about cardiac catheterization, read "Femoral Artery Closure After Cardiac Catheterization" by Wallace J. Hamel in *Critical Care Nurse,* 2009;29(1):39-46. Available at **www.ccnonline.org**.

This improvement process resulted in creation of a postprocedural holding room that intensified observation of patients, standardized postprocedural care, and limited sheath removal to a highly skilled cadre of practitioners. Recognition of arterial sheath removal as a high-risk process required us to change our process. Skill in arterial sheath removal, combined with vigilant assessments and recognition and treatment in the early postprocedural period by nurses, resulted in dramatic and sustained decreases in the occurrence of vascular complications. CCN

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Financial Disclosures
None reported.

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