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Clinical Case Update

Transradial Catheterization and Intervention With Bivalirudin: Clinical and Economic Considerations

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Case Report

The patient is a 62-year-old man with known coronary artery disease (CAD) status since previous PTCA in 1995 and coronary stent procedure in 2002. While preparing for his son's wedding, the patient developed the abrupt onset of substernal chest tightness associated with shortness of breath and diaphoresis. The patient's symptoms persisted. He was brought to the emergency room of an outlying community-based hospital without cath lab capability. An initial EKG showed some nonspecific ST- and T-wave changes in the inferior leads. Initial cardiac enzymes were negative. The patient continued to have low-grade chest discomfort and was therefore emergently transferred to our tertiary care facility. Given the lack of ST elevation at presentation, the patient was transported by ground ambulance and arrived in our cath lab 90 minutes after initially presenting. On arrival, a repeat EKG showed 1 mm of ST elevation in the patient's inferior leads that promptly resolved with sublingual nitroglycerin.

The patient denied any recent episodes of chest discomfort or shortness of breath. There was no history of previous myocardial infarction (MI) or congestive heart failure. Cardiac risk factors included previous cigarette smoking (which he'd quit many years previous), hypertension, borderline diabetes, hyperlipidemia, and a positive family history of premature CAD.

The medical history was remarkable for peptic ulcer disease and bleeding hemorrhoids. The patient had undergone back surgeries and had recurrent effusions of his left knee; he had undergone a left-knee scope 1 week before admission and was told subsequent surgery of that knee may be required. His admitting medications included aspirin, enalapril, pravachol, prilosec, and metoprolol. Before transfer, the patient was given 600 mg of oral clopidogrel, 5000 units of intravenous heparin, aspirin 325 mg, and was placed on an intravenous nitroglycerin drip.

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Physical examination showed a pulse of 79 and blood pressure of 156/70. The patient was afebrile, appeared comfortable, and was in a sinus rhythm with occasional premature ventricular complexes. There was no jugular venous pressure or carotid bruits. Lungs were clear. A heart examination showed a regular rate and rhythm with a prominent fourth heart sound. There was no third heart sound or murmur present. The patient's abdomen was unremarkable. Femoral and distal pulses were intact. An Allen's test was normal bilaterally. There was a moderate tender effusion of the left knee. Laboratory studies showed a WBC of 9.2, hemoglobin of 14.8, and a platelet count of 204,000. Potassium was 4.2 with a BUN of 23, and a creatinine of 1.2. Troponin T was elevated at 1.1.

Our initial impression was that of a 62-year-old man with known CAD presenting with chest pain strongly suggestive of ischemia associated with transient ST elevation and enzymatic evidence of MI. Comorbidities included recent knee scoping with the need for possibly more surgery and a history of hemorrhoidal bleeding and distant peptic ulcer disease. The patient had an active effusion of the left knee. Our initial strategy was to take the patient emergently to the catheterization laboratory for radial catheterization and possible intervention. Given the risks of bleeding and the need for possible further knee surgery, we elected to proceed with bare-metal stent placement, if needed, and bivalirudin.

Therefore, the patient underwent emergent catheterization via a right radial approach using 6 Fr catheters. A 6 Fr MAC 4 guiding catheter successfully cannulated the left and right coronary arteries. Serial angiographic views demonstrated a long 90% proximal and mid-left-anterior descending coronary artery bifurcation stenosis with an 80% stenosis involving the ostial and proximal first diagonal

Non-PCI Outpatient Caths (per case)

	Femoral		Radial	
	Medicare	Medicaid	Medicare	Medicaid
Net Collection / Case	$ 2,801	$ 245	$ 2,594	$ 322
Variable Cost / Case	$ (2,521)	$ (2,521)	$ (2,256)	$ (2,256)
Contribution Margin / Case	$ 280	$ (2,277)	$ 338	$ (1,934)
Reduction in Variable Cost per Case				$ 265

Table 1. Non-PCI outpatient caths (per case)

STEMI and Non-STEMI Clinical Data

	Radial (n=12)	Femoral (n=10)
Age	62 (42-79)	66 (52-82)
STEMI	2	2
	Anterior	Inferolateral
	Anterior (shock)	Inferolateral (shock)
Stents		
DES	8	15
BMS	11	2
POBA	1	1
Stents/Case	1.7	1.8
Multivessel	4	3
IIB/IIIA	4	5
	All Reopro	All Integrelin
Angiomax	10	8

Table 2. STEMI and non-STEMI clinical data

STEMI and Non-STEMI Financial Data (Per Case)

Medicare Only:	Femoral	Radial
Net Collections / Case	$ 10,771	$ 11,519
Variable Cost / Case	$ (13,461)	$ (8,496)
Contribution Margin / Case	$ (2,690)	$ 3,023
Reduction in Variable Cost / Case		$ 4,965

ALOS Comparison:	Femoral	Radial
Number of Cases in Analysis	10	12
Total Number of Patient Days	27	27
ALOS	2.7	2.3

Table 3. STEMI and non-STEMI financial data (per case)

branch. The left circumflex coronary artery was a fairly large nondominant vessel with some luminal irregularities but no significant stenosis. The right coronary was a large dominant vessel with a long area of 80% mid stenosis. The patient was given a .75 mg/kg bivalirudin bolus and 1.75 mg/kg/hr infusion for the duration of the procedure.

Using the same guiding catheter, successful Percutaneous transluminal coronary angioplasty (PTCA) and bare-metal stent placement was performed on the mid RCA (3.0 mm 28 mm stent, 3.0mm 12mm stent finished with a 3.5 mm balloon) and on the proximal and mid LAD (2.5 mm 28 mm stent, 2.5mm 23mm stent). The patient underwent PTCA alone of the jailed diagonal side branch. Good angiographic results were obtained in both territories. Post-stent course was uncomplicated, and the patient was discharged home the next day. His echocardiogram during admission had shown an ejection fraction of 40% with regional wall motion abnormalities in the anterior walls, apex, apical septum and apical inferior walls. At 6-month follow-up, the patient was asymptomatic with an ejection fraction of 62% and a normal lexiscan cardiolite stress test. He did ultimately require left-knee surgery.

Hospital Economic Considerations of Transradial Catheterization and Intervention

We know the initiation of a transradial program with bivalirudin improves patient satisfaction, reduces procedural complications, decreases access- and non-access-site bleeding, reduces payer costs, and perhaps improves morbidity and mortality.[1–17] What is not clear is the economic implications of a transradial program on hospitals' variable costs and profits. For that reason, we have initiated analyses to evaluate the effects of transradial procedures on hospital bottom lines.

The first group of patients to be evaluated were the outpatient catheterizations that did not require further intervention. **Table 1** demonstrates the financial analysis for 34 patients, 19 of whom underwent catheterization from the transfemoral approach and 15 of whom underwent a transradial approach. As shown, variable costs per case were $265 less with the transradial approach. This finding was very similar to that seen by Cooper et al's analysis.[1]

The second group of patients analyzed were those at the opposite end of the spectrum, those with ST-segment elevated MI (STEMI) and without STEMI. Twenty-two patients were evaluated, 12 in the radial group and 10 in the femoral group. **Table 2** shows the clinical data for those patients. The ages were similar. There were 2 STEMIs and 1 cardiogenic shock in each group. The number of stents per case

was similar at 1.7 in the radial group and 1.8 in the femoral group, although there were more bare-metal stents in the transradial group and more drug eluting stents in the transfemoral group. Four patients in the transradial group and 3 in the transfemoral group had multivessel intervention. Finally, 10 of 12 patients in the transradial group and 8 of 10 patients in the transfemoral group received bivalirudin. IIb/IIIa inhibitors were used in 4 transradial patients and 5 transfemoral patients.

Table 3 shows the financial data for these patients. Transradial procedures' variable costs per case were $4,965 less than those of transfemoral patients, with a significant difference in contributions to margins per case. Also of interest in this strictly Medicare-collections group: Transradial procedures positively contributed to margins and transfemoral procedures did not. These differences in variable costs per case were accompanied by small-but-significant reductions in length of stay. Certainly, the disparity between of bare-metal stents and drug-eluting stents in the groups may contribute to the difference but cannot explain the degree of disparity.

The mechanisms contributing to these differences include reducing bleeding complications. Recent clinical trials underscore the importance of preventing access-site and non-access-site bleeding. Verheugt et al[2] demonstrated that, while access-site-only bleeding was a frequent source of bleeding, more than 60% of patients who experienced TIMI major/minor bleeding had it at another source. One-year mortality was fourfold higher in those with non-access bleeds and two-fold higher in those with access-only bleeds compared with no bleeding. Technique can help prevent bleeding: A recent metanalysis of 3,244 patients showed that vascular complications were reduced from 2.8% in the transfemoral group to 0.39% in the radial group.[3]

When these complications are reduced, so are the costs associated with access-site and non-access-site bleeding alike. Kugelmass et al showed an incremental cost associated with vascular complications of $4,278.[4] The Mayo Clinic reported a cost of $5,883 per case with bleeding events.[5] The ACUITY study showed an incremental cost of $2,282 with a minor bleeding episode and $8,658 with a major bleeding episode.[6] Finally, GUSTO reported costs of $4,310 for a minor bleed, $6,980 for a moderate bleed, and $14,006 for a major bleed.[7] These costs are driven by the need for additional diagnostic vascular imaging, additional lab costs, blood transfusions, vascular repair procedures, increased length of stay, and a delayed return to work. It's also worth noting that radial procedures allow more rapid turnover in the cath lab and same-day areas, decreased intensity of nursing care post-procedure, shorter stays, and earlier returns to work and normal activities.

A word of caution is appropriate: Our efforts are the beginning of an attempt to delineate the effects of a transradial program on hospital bottom lines and should stimulate further economic analyses, not provide the final word on the matter. We believe that these initial queries are, at the very least, interesting.

Transradial: All Sides Win

Hospitals
- Same or better outcomes
- Lower costs, improved margins
- Decreased lengths of stay
- Improved patient satisfaction
- Marketing opportunity (differentiation)

Payers
- Reduced complications
- Reduced costs
- Earlier returns to work
- Improved patient satisfaction
- Improved feasibility of same-day discharge
- Improved survival(?)

Patients
- More choice (97% prefer transradial)
- Less bleeding
- Less morbidity/mortality(?)
- Early ambulation
- Improved quality of life

Physicians
- Reduced access-site issues
- More stability

Discussion

As percutaneous coronary intervention has evolved, the balance between ischemic complications and periprocedural bleeding has shifted. Studies now demonstrate an association of increased short-term and long-term mortality and morbidity with episodes of moderate to severe bleeding.[3,8,9] Further, given that a significant amount of that bleeding occurs at the access site, it is not surprising that strategies to reduce access site bleeding and overall bleeding improve patient outcomes.[10–16]

Avoiding bleeding is important both in terms of outcomes and costs. One-year mortality is higher in those with both non-access bleeds and access-only bleeds compared with no bleeding. Associated expens-

es can be highly variable, the result of extra care and services that affect departments hospital-wide.

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The use of bivalirudin and transradial access for diagnostic and interventional procedures are two strategies. Several studies have demonstrated that both reduce bleeding complications.

Transradial procedures create a winning situation for all. From a patient-experience perspective, 97% of patients who have had both transfemoral and transradial procedures prefer transradial. There is improved quality of life, less bleeding, early ambulation, earlier return to work, less morbidity, and perhaps less mortality. when compared with the transfemoral approach.[1,8–13] For physicians, there are reduced access-site issues, more patient stability, and more comfort with same-day discharge, a practice that continues to evolve in the United States. For hospitals, a radial program offers potentially better outcomes, decreased lengths of stay, improved patient satisfaction, perhaps lower procedural costs with improved margins, and differentiation from other facilities. Finally, payers benefit from reduced complications, reduced costs, improved patient satisfaction, and earlier returns to work.

The use of bivalirudin has been associated with a reduction in bleeding complications in acute MI, ACS, and PCI.[14–16] Further, the HORIZONS study — a large, randomized controlled trial — demonstrated reduced mortality in acute MI with bivalirudin.[16,17] As our patient demonstrates, perhaps the most important aspect of PCI is the preprocedural assessment of moderate and severe comorbidities that may predict future events from ischemic and bleeding standpoints. Based on that assessment, treatment strategies can be developed to minimize either occurrence. In our experience, marrying transradial procedures and bivalirudin let us better achieve that goal.

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