COOPERATIVE STUDIES

Early Ambulation After 5 French Diagnostic Cardiac Catheterization: Results of a Multicenter Trial

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Because earlier ambulation and discharge after cardiac catheterization may result in the increased utilization of outpatient facilities, a prospective five center clinical pilot trial assessing the safety and outcome of early ambulation after routine left heart catheterization was performed in 287 patients. Catheterization routines at each clinical center were unchanged throughout the study. After the diagnostic catheterization using 5 French (F), preformed, large lumen catheters and arterial puncture compression (mean 15 min, range 5 to 52), 260 patients were ambulated by a physician at a mean time of 2.6 h (range 1.8 to 3.1) after catheterization. Follow-up examination or a phone call 24 to 72 h later was performed to assess late results.

The mean age of the patients was 58 years (range 25 to 91); 166 (58%) were men. Left ventricular ejection fraction was 54 ± 15%. One hundred twenty-seven patients (44%) received intravenous heparin (1,500 to 5,000 U as an intravenous bolus) and 136 (47%) received aspirin.

Major complications included transient ischemic attack (one patient) and ventricular tachycardia requiring cardioversion during ventriculography (two patients). A small hematoma (<5.0 cm) after ablation occurred early (from compression to standing) in 14 patients (5%; 9 received heparin, 8 were taking aspirin) and later (after standing to 72 h) in 9 patients (3%; 2 receiving heparin, 2 taking aspirin). Five patients with a hematoma had studies with a 6F sheath. No patient required surgical intervention for early or late hematoma. Only three patients (1%) needed a 7F or 8F catheter because of suboptimal 5F coronary angiography. Ninety-two percent of patients had a complete study with the 5F catheters.

These results indicate that early ambulation after large lumen 5F femoral left heart catheterization was safe, with minimal postprocedural complications and without compromising angiographic data quality. Early ambulation has the potential to improve outpatient catheterization cost factors by early discharge and increased facility utilization.

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immobilization, the potential for significant arterial bleeding remains a practical concern for most cardiologists. For that reason, earlier ambulation and discharge are not generally attempted.

Bleeding complications are reduced with 5F catheters, but the use of smaller diagnostic catheters has not been widely accepted because of unsatisfactory angiographic results (13). With the use of an innovative, large lumen 5F catheter (Sherwood Medical Company) previous problems related to suboptimal coronary angiography (poor coronary opacification, poor catheter handling and seating) have been overcome. Because early ambulation and early patient discharge may have a significant impact on the practice of outpatient cardiac catheterization, we performed a prospective multicenter clinical pilot trial to assess the safety, complications and cardiac events related to early ambulation after 5F left heart catheterization.

Methods

Study patients. From August 1988 until March 1989, 287 patients underwent diagnostic left heart catheterization and selective coronary arteriography in five medical centers by experienced cardiologists with and without fellows in training (see Appendix 2). Patients underwent investigation for a chest pain syndrome, assessment of the extent and severity of suspected or known coronary artery disease, valvular or myopathic heart disease or cardiac transplantation follow-up examination (Appendix 1). The protocol for early ambulation was approved by appropriate institutional review committees at each institution. No patients were excluded on the basis of gender, age, weight, body condition or clinical presentation. Outpatient catheterization was defined as a procedure performed on the morning of patient admission with discharge on the same day, usually <12 h but always ≥23 h after admission.

Two hundred sixty patients (91%) participated in the early ambulation protocol. Twenty-seven patients were excluded; reasons for exclusion included the requirement for continued heparin and arterial sheath placement before either angioplasty or coronary artery bypass surgery (n = 24) and use of 7F or 8F catheters (n = 3) because of unusually difficult 5F catheter placement or suboptimal angiograms, or both. A 6F sheath was used in 19 patients. Seven procedures used the side arm lumen pressure for hemodynamic studies, and in 12 patients, normal anatomic variations required catheter configurations unavailable in the initial 5F catheter series. These patients were included in the early ambulation protocol.

Techniques for diagnostic left heart catheterization. This procedure was performed according to the established routine at each clinical center using standard Seldinger and Judkins femoral artery techniques in all patients. A 5.2F arterial sheath (either USCI or Cordis) was placed in the femoral artery. Only four 5F catheter configurations were available at the time of study: left 4 cm Judkins curve, right modified Amplatz, Noto right coronary curve and Sherwood open pigtail ventriculography catheter. The order of coronary arteriography and left ventriculography was determined by the attending physician. Room temperature ionic or nonionic contrast medium was used for routine angiography at each laboratory. Coronary angiography was performed by hand injection. Multiple-angled standard views of the left and right coronary arteries and left ventriculography were performed as indicated by the clinical condition. Routine premedications were given per laboratory protocols and included diazepam, diphenhydramine, sublingual nitroglycerin and atropine. Cardiac medications were continued as clinically indicated. The use of heparin was in keeping with the routine laboratory procedures at the particular study center and was not varied for use of the large lumen 5F catheters for the purposes of this evaluation. The average dose of intravenous heparin ranged from 1,500 to 5,000 U, and the need for reversal by protamine sulfate (25 to 50 mg) was determined by the operator at the time of study.

Early ambulation protocol. After completion of the diagnostic study, the puncture site was compressed either manually or with a mechanical compression clamp for an average time of 15 min (range 5 to 50). Blood pressure and immediate postcompression puncture site status were recorded by a nurse in the holding area. The target ambulation time was 1.5 h. However, because of logistic difficulties, the physician occasionally could not return to the patient at precisely the target hour. Patients remained at bed rest for an average of 2.6 h (range 1.8 to 3.1), after which with a physician at the bedside, the patient was asked to stand and walk. After early ambulation, the patient’s activities were unlimited. Outpatients were discharged the same evening, inpatients the next morning. A follow-up phone call regarding the presence of hematoma, puncture site pain and other complications was made to outpatients 24 to 72 h after discharge. A sample of the questions asked at the follow-up call is provided in Appendix 1.

Angiographic technique. The radiographic contrast medium used was either ionic or nonionic, in keeping with the laboratory’s standard practices. Coronary injections were performed by hand using 6 to 10 ml of contrast medium. Film framing rates varied from 30/s to 60/s. The rate of contrast injection for ventriculography ranged from 12 to 16 cc/s for total volumes of 36 to 48 cc. A qualitative assessment of coronary angiography, ventriculography, difficulty of catheter positioning and need to change catheters was made for each patient. Angiographic studies were rated by the operating physicians as acceptable or unacceptable in comparison with prior studies in their laboratories using their standard larger (7F or 8F) diameter catheters.

To assess whether angiographic data were comparable with those obtained with 7F or 8F catheters, a two part pilot angiographic study for an additional 63 patients (not part of
Quantitative analysis of normal vessel size using catheter calibrations demonstrated satisfactory linearity (5F, $r = 0.63$, $\text{SEE} = 0.43$; 8F, $r = 0.71$, $\text{SEE} = 0.35$) and interobserver variability. These quantitative comparisons indicated that satisfactory and similar coronary angiograms were obtained for the large lumen 5F catheters in this study.

**Study variables.** Data were collected prospectively. Major complications included stroke, myocardial infarction, death, ventricular arrhythmia requiring cardioversion, vascular injury requiring transfusion, surgical consultation or operation. Minor complications included hematoma or vasovagal event. After catheterization, early hematoma was reported if it occurred from the time of compression to early ambulation; late hematoma occurred from early ambulation to 24 to 72 h. A hematoma was graded as small if <2.5 cm in diameter, moderate if 2.5 to 5 cm in diameter and large if >5.0 cm in diameter. Pain was a subjective finding indicated by the patient.

**Statistical analysis.** Data from the study evaluation forms were sent to the coordinating center and entered into a database (DBASE IV, Aston-Tate Corporation) computer program that tabulated the incidence, average and standard deviation of variables studied. Chi-square analysis and relative risk (odds ratio) were used to determine if various factors were more prevalent in patients who developed a minor hematoma after early ambulation. Statistical significance was accepted with $p$ values <0.05. Results are presented as mean values ± 1 SD.

**Results**

**Patient characteristics.** (Table 1). Patient age, gender, weight (78 ± 17 kg) and height (170 ± 13 cm) distribution among the study centers was similar. Heparin was given to 127 patients (44% of total) and ranged from 17% to 75% of patients at each center. One hundred thirty-six patients (47%) were taking aspirin before catheterization and 22 patients (8%) were also receiving dipyridamole. One hundred seventy-five patients (61%), comprising 16% to 91% of patients at each study center, had studies performed as an inpatient.

**Clinical indications** (Table 1). The majority of patients (n = 231 [80%]) had left heart catheterization performed on an elective basis. One patient had an emergency catheterization, and 38 (13%) had urgent indications for catheterization at the earliest available time.

**Clinical conditions for patients undergoing diagnostic catheterization included** unstable angina (2 patients [29%]), stable angina (63 patients [22%]), myocardial dysfunction/cardiomypathy (33 patients [11%]), atypical angina chest pain (30 patients [10%]), follow-up coronary angioplasty (26 patients [9%]), congestive heart failure (7 patients [2%]) and angina after coronary artery bypass surgery (6 patients [3%]).

Normal coronary arteriographic findings were present in 95 patients (33%), with a range of 23% to 44% of patients at
The average blood pressure at the time of catheter removal was 130 ± 23/76 ± 11 mm Hg. Patients were ambulated an average of 2.6 ± 1.1 h (range 1.8 to 3.1) after puncture site compression for a mean time of 15.1 ± 12.8 min (range 5.4 to 52). A mechanical puncture site compression clamp was used in 65 (23%) patients.

Major complications. Three patients had a major complication as a result of cardiac catheterization. There were no deaths or myocardial infarctions. One patient, a 78 year old man, had a transient ischemic attack with only transient aphasia during 5F right Noto coronary catheter placement. His left ventricular ejection fraction was 63%. Aphasia was in resolution at follow-up evaluation. Arterial time was 18 min; heparin, but no aspirin, was used. Because of the limited and near complete resolution of symptoms, ambulation at 4 h was uncomplicated.

Two patients had ventricular tachycardia requiring direct current cardioversion during left ventriculography. The first patient was a 64 year old woman with triple vessel coronary artery disease and a left ventricular ejection fraction of 45%. There were no complications after cardioversion, and she participated in the early ambulation protocol without complications. The second patient was a 67 year old man with a left ventricular ejection fraction of 30%. The study required a 6F multipurpose catheter because of anatomic variation. Ventricular tachycardia during ventriculography with the 6F multipurpose catheter occurred with successful direct current cardioversion. The patient had single vessel coronary artery disease. His blood pressure was 148/72 mm Hg at the end of the procedure, and he was ambulated at 4 h after cardiac catheterization without hematoma.

Minor complications (hematoma) (Table 2). Twenty patients had a minor hematoma after early ambulation. Fourteen patients had a hematoma early after cardiac catheterization, nine patients had a late hematoma and two patients had both early and late hematomas. Of the patients who had a hematoma, nine received heparin, eight received aspirin and six received both. Four patients had a 6F sheath used to accommodate the different angiographic catheters needed.

When patients with and without hematoma were compared, no correlations were found for severity of coronary atherosclerosis (triple vessel coronary artery disease, n = 5), depressed left ventricular ejection fraction (<45%, n = 7), elevated systolic pressure (≥130 mm Hg, n = 10) after cardiac catheterization, age >70 years, use of heparin (odds ratio 1.79, range 0.77 to 4.16) or aspirin (odds ratio 1.21, range 0.52 to 2.80), arterial compression time ≥15 min (odds ratio 0.79, range 0.33 to 1.94) or total arterial time ≥30 min (odds ratio 3.0, range 1.29 to 7.10). Chi-square analysis indicated that hematoma occurred in a higher percent of patients receiving both heparin and aspirin (p < 0.01; odds ratio 3.07, range 1.28 to 7.53) and compression time <10 min (p = 0.008; odds ratio 3.0, range 1.29 to 7.10).

Table 1. Results of 5F Left Heart Catheterization

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<tr>
<th>Variables</th>
<th>Total</th>
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<td>No. of patients</td>
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<td>No. with early ambulation</td>
<td>260</td>
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<td>No. of men</td>
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<td>(58)</td>
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Indications

1. Emergency | 1 | (0.3) |
2. Urgent | 38 | (13) |
3. Elective | 231 | (80) |
4. Other/miscellaneous | 17 | (6) |

Conditions

1. Unstable angina | 82 | (9.3) |
2. Cardiogenic shock | 0 | (0) |
3. Stable angina | 63 | (22) |
4. Atypical chest pain | 30 | (10) |
5. Late hematoma (<24-48 h) | 12 | (4) |
6. Myocardial disease | 16 | (6) |
7. Follow-up PTCA | 26 | (9) |
8. Follow-up CABG | 6 | (2) |
9. Congestive heart failure | 7 | (2) |
10. Other/miscellaneous | 33 | (11) |

Medications

- Heparin | 127 | (144) |
- Aspirin | 136 | (47) |
- Dipyridamole | 22 | (8) |

CAD

- Normal study | 95 | (33) |
- 1 vessel | 70 | (24) |
- 2 vessel | 64 | (22) |
- ≥3 vessel | 58 | (20) |

Procedure variables

- Systolic pressure (mm Hg) | 130 ± 23 |
- Diastolic pressure (mm Hg) | 76 ± 11 |
- LVEF (%) | 24 ± 13 |
- Hours immobile | 2.81 ± 1.6 |
- Ambulated at (h) | 2.61 ± 1.1 |
- Fluoroscopic time (min) | 6.63 ± 4.7 |
- Arterial time (min) | 25.70 ± 13.1 |
- Compression time (min) | 15.1 ± 12.6 |
- Clamp compression (no.) | 65 | (23) |
- Early hematoma (<4 h) | 14 | (6) |
- Late hematoma (<24-48 h) | 9 | (4) |
- Inpatients | 175 | (61) |
- Major complications | 3 | (1) |

*See Table 2. CABG = coronary artery bypass graft surgery; CAD = coronary artery disease; LVEF = left ventricular ejection fraction; PTCA = percutaneous coronary angiography.
Table 2. Patients With Minor Hematomas After 5F Catheterization

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<th>Late Hematoma</th>
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<th>Con* No.</th>
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<th>Dipy</th>
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<th>LVEF</th>
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*See Appendix 1; †6F sheath used. Values are mean values ± SD. Amb = ambulation; Art Time = arterial time (min); Asp = aspirin; C = clamp; CAD = coronary artery disease (0 = normal study, 1, 2 and 3 = number of involved vessels); CM = both clamp and manual compression; Con = condition; Dia = diastolic pressure in holding area (mm Hg); Dipy = dipyridamole; F = female; Ind = indication; INPT = inpatient; LVEF = left ventricular ejection fraction (%); M = male; MN = manual; Sys = systolic pressure in holding area (mm Hg); + = yes; - = no.
Procedure variables. Ninety-two percent of patients (n = 263) had only the large lumen 5F catheter configurations used during their study. Because of normal anatomic variations, 50 patients (17%) required a change to a different shape catheter unavailable in 5F size at the time of this study (Amplatz, multipurpose; left 3.5, 5 cm Judkins). The different catheter configurations used included 6F left 3.5 cm Judkins (n = 7), left 4 cm Judkins (n = 1), left 5 cm Judkins (n = 4), left 6 cm Judkins (n = 1), 6F right 4 cm Judkins (n = 4), 6F multipurpose (n = 4), 5F modified Amplatz to change from right “Noto” design (n = 22), multipurpose (n = 3) and 5F right 4 cm Judkins (n = 4). Only three patients had angiography with a 7F or 8F catheter.

The average fluoroscopic time was 6.6 ± 4.7 min (range 4.8 to 8.2). The average arterial time from puncture to sheath removal was 25.7 ± 13.1 (range 16.6 to 30.3).

Late clinical events. No patient had a cardiac event, unstable angina after discharge or other reasons for readmission within 24 to 72 h after large lumen 5F cardiac catheterization with early ambulation.

Discussion

The results of this prospective pilot trial indicate that early ambulation (<3 h) after large lumen 5F diagnostic femoral cardiac catheterization can be accomplished safely within minimal complications and without compromise of angiographic data quality.

Comparison with 7F or 8F diagnostic catheters (Table 3). The majority of studies (14–20) reporting complication rates and standards of care have been performed using 7F or 8F diagnostic equipment. In no study was early ambulation attempted. Brown and MacDonald (13) compared complications using both 5F and 7F catheters and reported only two minor groin hematomas after 7 h of bed rest occurring in 100 patients studied with a 5F catheter; this rate was not significantly different from the (low but unspecified) complication rate obtained with 7F catheters in the same institution. However, the postcatheterization recovery time using 5F catheters was reduced only by 1 h from the routine of 8 h of bed rest after diagnostic studies. The investigators indicated that the time to ambulation could probably be reduced further, but early ambulation (that is, <7 h) was not evaluated.

In a preliminary study, Klinke et al. (8) compared the time to hemostasis using 5F and 7F or 8F catheters. Fifty-two patients with similar age, body weight and blood pressure were randomized to 5F or 7F left heart catheterization. Fifteen of 26 patients in the 5F group (compared with 0 of 26 in the 8F group) demonstrated poor catheter torque control and 4 (compared with 0 patients) 1J unsatisfactory angiograms. The time to hemostasis, however, was reduced significantly to 19 ± 6 from 28 ± 11 min. Puncture site hematomas occurred in 18% and 1% of both 5F and 8F groups, respectively. Late postcatheterization bleeding did not occur in any patient in the 5F group, but occurred in 3 (12%) of 26 patients in the 8F group. There was no difference in procedure (25 ± 11 min) or fluoroscopic (4.4 ± 2.6 min) times. In this unique comparison study, although the 5F catheters reduced the time to hemostasis, the advantage was offset by the frequent need to change to larger catheters, poor torque control or poor quality of cineangiograms. With the use of the newer large lumen 5F catheters in our study, these disadvantages were eliminated and, as demonstrated, the advantage in hemostasis realized.

Complications associated with outpatient cardiac catheterization. Complications of outpatient cardiac catheterization have been reported by Block et al. (7) (outpatient versus inpatient) as follows: hematoma (12% versus 8%), numbness or weakness of limb (0.5% versus 1.6%), cold or blue limb (1.6% versus 1.1%) and acute myocardial infarction (1.6% versus...
0.05%) (all p = NS). In the current study with 39% outpatients, major and minor complications were less than the earlier reported rates. Small hematomas in this study were listed as minor complications, but in many centers would not be reported or considered important. This study and other large trials (14) indicate that elective outpatient catheterization for selected patients is feasible and safe (3), with a small increase in complication rates using standard 7F or 8F catheters.

Vascular complication rates. The incidence of major arterial injury (requiring transfusion or surgery) in patients undergoing diagnostic cardiac catheterization from several large series (10,11,15-20) has been reported to range from 0.35% to 5%. In a study of outpatient cardiac catheterization, Pink et al. (9) reported a 1.5% incidence rate of femoral artery bleeding after an 8F catheter study that required hospitalization. In the earlier Coronary Artery Surgery Study (CASS) (10.17), vascular complications in 17,165 patients were reported in 152 or 8.4/1,000 patients; arterial thrombosis in 101 patients, arterial dissection or rupture in 35 patients, hematoma (size unspecified) in 21 patients; pseudoaneurysm in 3 patients and thrombophlebitis in 2 patients; all of these rates are higher than those observed in our study. With procedures performed in earlier decades, vascular complications most often included thrombosis and distal embolism. No patient in the early ambulation portion of this study had arterial complications requiring surgery for decompression, repair or thromboembolism. The currently reported (12,19) low vascular complication rates of <0.5% reflects improved equipment, use of heparin and extensive operator experience.

Late (>3 weeks) sequelae such as pseudoaneurysm formation or arteriovenous fistula after femoral artery catheterization have been rarely reported (22) and would not be identified in the current study with a follow-up period of only 24 to 48 h. The incidence of this late complication is <0.01% (13-15,21).

Limitations. This study was a clinical pilot safety trial of early ambulation with large lumen 5F catheters. For direct comparison to larger catheters, two approaches could have been attempted: a 7F or 8F catheter placed in the contralateral artery in the same patient or a randomized design of early ambulation with 5F or 8F catheters. The first approach would be generally unacceptable (and potentially unethical) to most patients. We were concerned with safety problems with <3 h ambulation with 8F catheter (8-13). Because of these methodologic limitations, only direct comparisons of angiography but not early ambulation with 8F catheters were performed. Therefore, comparative rates of hematoma and vascular complications from previous studies in >200,000 cases (10,12,17,19) using standard 7F or 8F catheters were utilized. The published complication rates and incidence of hematoma formation are currently very low and achieved with bedrest under standard protocols of approximately 8 h.

A randomized study with large diameter catheters with ambulation earlier than 6 to 8 h would be needed to answer the safety issue demonstrated with 5F catheters.

Patients were not selected on the basis of clinical presentation, although some operator bias may have been introduced because of knowledge regarding the nature of previously known peripheral vascular or coronary artery disease, bypass surgery, hypertension, complex valvular disease or critically ill, unstable patients. Although small in number, in the subset of high risk patients (older, hypertensive, aortic insufficiency, peripheral vascular disease), the use of the large lumen 5F catheters for diagnostic studies was found to be adequate. Significant hypertension (systolic pressure >160 mm Hg), although considered a problem in early ambulation, was not present in most patients studied in this protocol. We believe caution should still be used in patients with uncontrolled hypertension, aortic insufficiency or coagulopathy after any diagnostic catheterization.

The 5F large lumen catheter did not perform perfectly. Streaming of contrast medium because of a short left main coronary artery and seating of the NYU shape was a problem in a few patients. In the current study, the large lumen 5F catheters were used successfully without requiring catheter change to 6F or larger catheters in 263 patients (92%). With increased experience and the addition of alternative catheter configurations, this number could be higher.

Clinical significance. Early ambulation appears safe after large lumen 5F diagnostic left heart catheterization. Patients and families commented favorably on the comfort and increased activity level after the procedure. The rate of minor hematoma formation and other complications using this system was low. The angiographic data quality was uncompromised, a feature that offsets disadvantages currently limiting the widespread clinical use of small diameter catheters. Although we did not compute the direct cost savings of increasing patient turnover projected for an outpatient facility, it is apparent that the fixed costs will be reduced by higher patient volume. Early discharge after early ambulation has the potential to improve outpatient catheterization cost factors by increasing facility utilization.

We thank the J. C. Mudd Cardiac Catheterization Laboratory team, Mary Glosemeyer, RN and Neal G. Keller of Sherwood Medical Company. We also thank Donna Sander for manuscript preparation.

Appendix 1

Code for Indications
Code definitions

1. Emergency catheterization performed for critical illness that could not be deferred because of shock, refractory pain or hemodynamic compromise

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2. Urgent catheterization performed in a timely fashion, usually the same day, for unstable conditions potentially necessitating intervention.

3. Elective catheterizations performed at prearranged time or patients with stable clinical conditions including angina, congestive heart failure, atypical angina pectoris or valvular heart disease.

4. Other/miscellaneous (for example, preoperative evaluation, stable but needing urgent study)

**Codes for Conditions**

1. Unstable angina
2. Cardiogenic shock
3. Stable angina
4. Atypical anginal chest pain
5. Acute or recent myocardial infarction
6. Myocardial disease
7. Follow-up percutaneous transluminal coronary angiography
8. Follow-up coronary artery bypass graft surgery
9. Congestive heart failure
10. Other/miscellaneous (for example, postinfarction angina/hypotension)

**Early Ambulation Follow-Up Questionnaire**

1. Did you experience any discomfort around the catheterization site last night?
2. Did you notice any bleeding from the site?
3. Did you experience any numbness, tingling or weakness in any arm, leg or part of the face?
4. Did you have any chest discomfort or chest pain throughout the night?
4a. How long did your chest pain last? Did you take any medications to relieve the pain?
5. Were you able to walk without pain or discomfort in the leg of the procedure?
6. Have you noticed any swelling or an increase in swelling around the catheterization site?
7. Have you noticed a change in color or increased discoloration around the catheterization site?

*Definitions from reference 24.

**Appendix 2**

The following is a list of participating clinical centers, collaborating investigators and technical assistants.

- University of Louisville, Louisville, Kentucky: J. David Talley, MD (principal investigator), Joel Kapersmith, MD, Chief of Division, Abraham Joseph, MD, Joseph Kowalski, MD, Glenn Friedman, MD, Charles Prince, MD, Igor Singer, MD, Joe Ann Yussman, RN.
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**References**

Early Ambulation After 5 French Catheterization


