Comparison of 4 and 6 French Catheters for Coronary Angiography: Real-World Modeling

Ronen Durst MD[1], Chaim Lotan MD[1], Hisham Nassar MD[1], Mervin Gotsman MD[1], Eli Mor MD[1], Boris Varshitzki MD[1], Penko Greganski MD[1], Refat Jabara MD[1], Dan Admon MD[1], David Meerkin MD[2] and Morris Mosseri MD[3]

[1]Department of Cardiology, Hebrew University–Hadassah Medical Center, Jerusalem, Israel
[2]Department of Cardiology, Shaare Zedek Medical Center, Jerusalem, Israel
[3]Deparment of Cardiology, Meir Medical Center, Kfar Saba, Israel

Key words: coronary angiography, cardiovascular diagnostic techniques, angiography complications

Abstract

Background: Femoral artery vascular complications are the most common adverse events following cardiac catheterization. Smaller diameter introducer sheaths and catheters are likely to lower the puncture site complication rate but may hinder visualization.

Objectives: To evaluate the safety and angiographic quality of 4 French catheters.

Methods: The study was designed to simulate real-life operator-based experience. Diagnostic angiography was performed with either 4F or 6F diagnostic catheters; the size of the catheter used in each patient was predetermined by the day of the month. Patients undergoing 4F and 6F diagnostic angiography were ambulated after 4 and 6 hours, respectively. The following technical parameters were recorded by the operator: ease of introducer sheath insertion, ease of coronary intubation, ease of injection, coronary opacification, collateral flow demonstration, and overall assessment. Adverse events were recorded in all patients and included minor bleeding, major bleeding (necessitating blood transfusion), minor hematoma, major hematoma, pseudo-aneurysm formation and arteriovenous fistula.

Results: The study group included 177 patients, of whom 91 were in the 4F arm and 86 in the 6F arm. Demographic and procedural data were similar in both groups. Seventy-seven percent of 6F and 50% of 4F procedures were evaluated as excellent ($P < 0.05$). This difference was attributed to easier intubation of the coronary ostium and contrast material injection, increased opacification of the coronary arteries, and demonstration of collateral flow with 6F catheters. Complications occurred in 22% of patients treated with 6F catheters and in 10% of those treated with 4F catheters ($P = 0.11$). Of the 50 patients who switched from 4F to 6F 12% had complications. In patients undergoing diagnostic angiography, the complication rate was 10% vs. 27% (most of them minor) in the 4F and 6F groups, respectively ($P < 0.05$).

Conclusions: Patients catheterized with 4F have fewer complications compared with 6F diagnostic catheters even when ambulated earlier. Although 4F had a reduced quality compared to 6F angiographies, they were evaluated as satisfactory or excellent in quality 85% of the time. 4F catheters have a potential for reduced hospitalization stay and are a good option for primary catheterization in patients not anticipated to undergo coronary intervention.

IMAJ 2007;9:290–293

Cardiac catheterization has become a routine procedure performed regularly on an ambulatory basis in many centers. For this reason there is a need for increased safety measures that minimize complication rate and patients' discomfort with consequent shorter hospitalization duration. Some of the most common complications associated with cardiac catheterization are due to vascular trauma at the femoral puncture site [1]. Reducing femoral catheter size may minimize the trauma to the femoral artery and reduce complication risk.

Earlier studies using small diameter catheters were discouraging because the quality of angiographic image had declined [2-6]. Newer trials have demonstrated that good quality angiographic imaging using 4F catheters is feasible and may permit early ambulation [7-9].

To evaluate the safety and the angiographic quality of 4F catheters compared to 6F catheters we conducted a prospective comparative study. The study had two endpoints: the first was the quality of the angiographic images as evaluated by the operators, and the second was femoral artery complication rates in 4F and 6F catheters evaluated 24 hours after the procedure. We also compared the duration of the procedure, amount of contrast medium used, and radiation dose between the two catheter groups. The study was designed to imitate real-life performance as much as possible.

Patients and Methods

Included were all patients catheterized for ischemic heart disease who were ≥ 21 years old in January and February 2003. Excluded were patients in whom coronary intervention was planned before starting the procedure (a 6F catheter was used routinely in these patients), with acute myocardial infarction and in whom right heart catheterization was performed (because these patients also undergo venous puncture that might have its own complications and affect the study results).

Allocation

Patient allocation was dependent upon the day of catheterization. Specifically, in the first half of each month (1st to 15th) during the study period 4F catheters were used, and in the second half (16th to 31st) 6F catheters were routinely used by all operators. The catheterization waiting list of elective patients was managed by a secretary who was unaware of the study. Since both 4F and 6F catheters are approved for routine use, we were exempted from collecting patients' informed consent. Moreover, this method has the advantage of allowing for 100% recruitment rate without

dropouts biasing customary randomization trials. This imitates real-life experience better.

All patients underwent coronary angiography via a femoral artery. Patients in the 4F arm who underwent coronary intervention immediately following their diagnostic study had their introducer sheaths upsized to 6F and were analyzed separately with regard to puncture site complications.

Catheterization technique

All coronary angiographic studies were performed by physicians trained and experienced in the procedure. Following local anesthesia, the femoral artery was punctured using the standard Seldinger technique with an 18 gauge needle. A guide wire (0.038") was used to introduce the 4F or 6F hemostatic sheath to the femoral artery. All patients received a bolus injection of 2000 IU heparin upon insertion of the sheath.

The following five views were used in all patients for interrogation of the left coronary, system: anterior-posterior, right anterior oblique cranial, RAO caudal, left anterior oblique cranial and LAO caudal. Additional views (e.g., AP caudal and AP cranial) were used at the operator's discretion. The right coronary artery was interrogated using three standard views (LAO, RAO and AP cranial). Injection of contrast material was performed using the ACIST automated injector (USA). The injector was set to inject up to 8 ml of contrast at a maximal rate of 4 ml/sec to the left coronary system and up to 5 ml at a maximal rate of 3 ml/sec to the right coronary artery. Changing these parameters in specific patients was left to the operator's discretion. The femoral sheath was removed immediately following angiography. Hemostasis was achieved using an external compression device placed by an experienced physician for 1 hour 1–2 cm proximal to the puncture site. After removing the compression device a weight of 2.5 kg was placed on the puncture site for 6 hours in patients undergoing angiography with 6F catheters and for 4 hours in those undergoing angiography with 4F catheters at which point the patients were mobilized. This was done to imitate the anticipated real-life experience where 4F catheterized patients are ambulated early.

Patients' medications before and after catheterization were recorded. To assess procedural performance with 4 and 6F catheters a clinical research form was filled by the operator at the end of each procedure with the following criteria: ease of femoral sheath insertion, ease of coronary ostia intubation, quality of contrast material injection, opacification, collateral flow demonstration, and an overall impression of the catheter performance. For each criterion the operator had to choose from among four quality grades: excellent, satisfactory, unsatisfactory, and not relevant. In addition, the following data were recorded: length of procedure, amount of contrast material delivered, and irradiation dose. On the day following the procedure the following adverse events were recorded when applicable: minor bleeding, major bleeding requiring blood transfusion, minor hematoma involving the insertion site at the groin, major hematoma expanding to the thigh or abdominal wall, pseudo-aneurysm formation, and arteriovenous fistula. For film quality we compared all patients undergoing angiography with either 4F or 6F. However, for complications, we performed two comparisons:

- comparing patients catheterized with 4F or 6F to those who were switched from 4F to 6F for angioplasty. This was done in order to test the possibility that changing catheters is associated with an increased femoral complication rate.
- comparing the complication rate in the 4F and 6F groups in patients who had diagnostic angiography only. This is because in these patients IIb-IIIa antagonists and clopidrogel were not used and thus the results are not biased by non-equal anticoagulation usage.

Statistical methods

Time from angiography to mobilization, duration of procedure, duration of irradiation, and the amount of contrast medium were presented for each group as average ± SD, and comparison was performed between the groups using the Student *t*-test for the comparison of two independent groups. Angiography quality and complication rates were compared between the two or three catheter groups (4F, 6F and change from 4F to 6F) by the chi-square test. All tests applied were two-tailed, and a P value of ≤ 5% was considered statistically significant.

Results

Altogether, 177 consecutive patients participated in the trial, 91 in the 4F arm and 86 in the 6F arm. Percutaneous coronary intervention was performed in 97 patients (55%). There was no difference in age, gender, procedure duration, amount of contrast used and radiation exposure between the 4F and 6F groups [Table 1].

Performance analysis

In general, 4F received lower scorings than 6F catheters [Figure 1]. In the overall scores, 77% of the 6F procedures and only 50% of the 4F were evaluated as excellent ($P < 0.01$), whereas 23.0% of 6F and 34.8% of 4F catheters were considered satisfactory ($P < 0.05$). For specific parameters, excellent scores for 4F and 6F were as follows: 48% vs. 72% for ease of coronary artery intubation, 59% vs. 76% for ease of injection, 56% vs. 74% for opacification, and 59% vs. 77% for collateral demonstration, respectively ($P < 0.05$ for all). The percent of 4F procedures evaluated as

Table 1. Comparison of age, gender, duration of coronary catheterization, radiation dose and amount of contrast material in the two groups

	4F (n=91)	6F (n=86)	*P*
Age (yrs)	62.24 ± 10.72	64.24 ± 12.04	0.29
Percent female	23.3%	32.6%	0.183
Duration of procedure (min)	46.3 ± 29.73	44.17 ± 26.98	0.632
Radiation dose (Gy)	124.29	123.12	0.961
Contrast amount (ml)	149.62	148.15	0.913

RAO = right anterior oblique
LAO = left anterior oblique
AP = anteroposterior

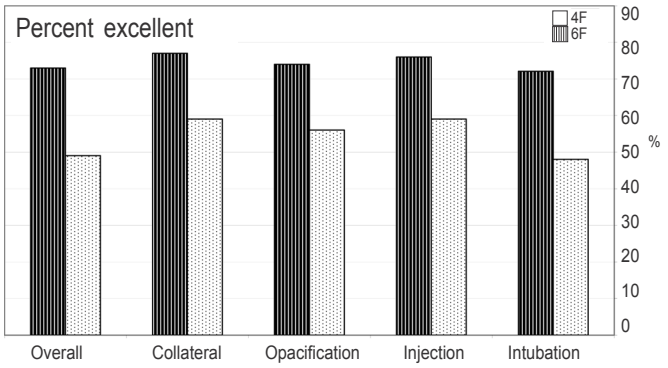

Figure 1. Percent of catheterization (of 177 patients) with excellent scores in the following parameters: ease of introducer sheath insertion, ease of coronary intubation, ease of injection, coronary opacification, collateral flow demonstration and overall assessment. The lined bars represent 6F catheters and the dotted bar 4F catheters.

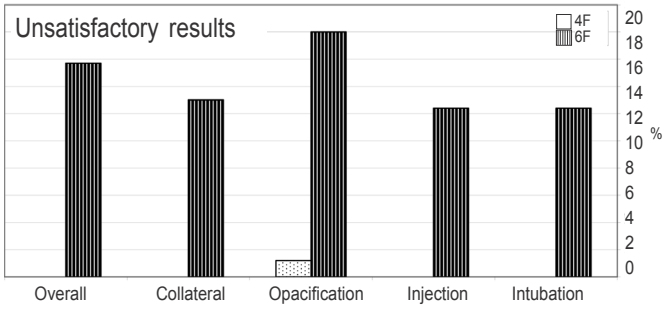

Figure 2. Percent of catheterization (of 177 patients) with unsatisfactory scores in the following parameters: ease of introducer sheath insertion, ease of coronary intubation, ease of injection, coronary opacification, collateral flow demonstration and overall assessment. The lined bars represent 4F catheters and the dotted bar 6F catheters.

satisfactory was 34.8% vs. 26.7% of the 6F catheters ($P < 0.05$). Specific parameter scorings were as follows: 28.1% vs. 23.3% for ease of coronary artery intubation, 25.8% vs. 24.4% for ease of injection, and 26.4% vs. 22.6% for opacification and collateral demonstration in the 6F and 4F groups, respectively (P = NS). Fourteen of the 4F patients (15.7%) and none in the 6F group had unsatisfactory results ($P < 0.05$) [Figure 2].

Side effects analysis

Of the 177 patients participating in the trial 29 (16%) had complications, the majority of which were mild hematoma involving the insertion site at the groin (71%) and minor bleeding (28%) not requiring blood transfusion. Only one patient had a serious adverse event. This patient had severe retroperitoneal hematoma and died. He was catheterized with a 4F catheter that was changed to 6F for PCI and received IIb-IIIa antagonist.

For comparison of side effects between 4F and 6F catheters two analyses were performed. In the first one the study cohort was divided into three groups:

- 41 patients (23%) who were randomized to the 4F arm and underwent diagnostic catheterization only.
- 86 patients (49%) who were randomized to the 6F arm.
- 50 patients (28%) whose 4F catheters were changed to 6F catheters for PCI or because of inadequate angiography. This was done because changing catheters from 4F to 6F might be associated with an increased femoral complication rate

In this analysis, 19 (22%) of the patients who were catheterized with the 6F catheter; 4 (10%) of the 4F patients and 6 (12.2%) of those who were switched from 4F to 6F suffered complications (P = 0.11). Treatment with aspirin, clopidogrel and heparin was not associated with increased complication rate (13% vs. 5%, P = 0.45; 10% vs. 16%, P = 0.20; and 10% vs. 17%, P = 0.35, for patients treated or not treated with each medication, respectively). Of the patients catheterized with 6F catheters, 45 patients were treated with IIb-IIIa antagonists. Of these, 13 (27.3%) had complications compared to 5 (12%) who were not treated with these medications (P = 0.053)

Since patients undergoing angioplasty receive more anticoagulation as well as clopidogrel and IIb-IIIa antagonists which might increase the complication rate, we also analyzed separately patients who underwent diagnostic angiography without angioplasty. In this analysis 41 patients in the 4F arm and 37 in the 6F arm were included. Complication rates were 10% (4 patients) and 27% (10 patients) in the 4F and 6F groups, respectively ($P < 0.05$).

Discussion

In the trial comparing the safety and efficacy of 4F and 6F catheters, we did not find any difference in procedure time, contrast material volume delivered, or amount of radiation between the 4F and the 6F groups. Others have demonstrated that 4F catheters are associated with significantly less use of contrast [8,9]. This discrepancy is probably because we used an automatic injector with fixed maximal contrast amount and injection rate [10]. The velocity of a fixed amount of dye streaming out of a narrow catheter diameter is higher by the square of the diameter. A high velocity jet of contrast medium set by the operator to overcome the small diameter might push the catheter back out of the coronary orifice and cause some of the reported difficulties in intubating the coronary ostia.

We found that 4F catheters slightly compromise the quality of angiography compared to 6F catheters. However, in the majority of procedures (85%), the scoring of the 4F catheters was either satisfactory or excellent. The quality of 4F angiography may improve following a learning curve. For instance, the opacification and intubation quality can improve after the operators learn to avoid high contrast velocity jets. It may explain why others found similar angiographic quality in 4F and 6F catheters [7-9]. The scoring of the catheter visualization performance was done by the operator and not by a core laboratory. Although this method is more prone to personal bias, it does give an impression of real-world outcomes.

PCI = percutaneous coronary intervention

Groin complications following coronary angiography have been shown to be related to catheter size [11–13]. It was thus expected that small diameter catheters would reduce the puncture site complication rate. In our trial we found a reduced groin complication rate (mostly minor) with 4F catheters (10% vs. 27% with 6F catheters). This reduced complication rate occurred despite shortened bed stay and local pressure time with the 4F catheters. It is important to note that although minor hematoma and bleeding have no clinical implications, there is a financial implication in that they might require additional monitoring which will postpone the patient's discharge from the hospital. Other investigators have also demonstrated that early mobilization with 4F catheters is possible and safe [8,9]. Thus, it can be deduced that hospitalization stay may be diminished with the use of 4F introducer and catheters.

In the present study, scheduling patients to specific days in the month was done by personnel who were not aware of the study. Logistically, it made the study simpler to perform because we compared two catheters approved for clinical use and thus there was no need for patients' informed consent. Furthermore, this method saves a screening phase without dropout of patients (their own choice). Another advantage is the participation of all our operators in the study. Therefore, this method more closely models real-world conditions and overcomes some inherent drawbacks of other randomization methods. Previous studies comparing 4F and 6F catheters were more selective in recruitment and therefore less accurately modeled the real world [2,3,6-9].

Conclusions

Our trial adds to the increasing evidence that 4F catheters can achieve an acceptable rate of good quality diagnostic angiography. Added to the reduced groin complication rate and the potential for reduced hospitalization stay and patient discomfort, 4F catheters are a viable alternative for coronary angiography, especially in patients not expected to undergo coronary intervention.

References

1. Skillman JJ, Kim D, Baim DS. Vascular complications of percutaneous femoral cardiac intervention: incidence and operative repair. *Arch Surg* 1988;123:1207–12.
2. Molajo AO, Ward C, Bray CL, et al. Comparison of the performance of superflow (5F) and conventional 8F catheter for cardiac catheterization by the femoral route. *Cath Cardiovasc Diagn* 1987;13: 275–6.
3. Hui WK, Klinke WP, Kubac G, et al. Comparison of 5F and 7/8 catheters for the left ventricular and coronary angiography. *Cath Cardiovasc Diagn* 1990;19:84–6.
4. Brown EF, Hartnell GG, Morris K, et al. Limitations in the use of five French coronary catheters. *Int J Cardiol Imaging* 1991;7:43–5.
5. Pande AK, Meier B, Urban P, et al. Coronary angiography with four French catheters. *Am J Cardiol* 1992;70:1085–6.
6. Lefevre T, Morice MC, Bonan R, et al. Coronary angiography using 4 or 6 French diagnostic catheters: a prospective, randomized study. *J Invasive Cardiol* 2001;13:674–7.
7. Todd DM, Hubner PJ, Hudson N, et al. Multi-center, prospective, randomized trial of 4 vs. 6 French catheters in 410 patients undergoing coronary angiography. *Cath Cardiovasc Interv* 2001;54:269–75.
8. Khoukaz S, Kern MJ, Bitar SR, et al. Coronary angiography using 4 Fr catheters with assisted power injection: a randomized comparison to 6 Fr manual technique and early ambulation. *Cath Cardiovasc Interv* 2001;52:393–8.
9. Mehta H, Chatterjee T, Windecker S, et al. Four French catheters for diagnostic coronary angiography. *Cath Cardiovasc Interv* 2003;58: 275–80.
10. Arora P, Naik N, Bahl VK, et al. Coronary angiography using 4 French catheters with power injection: a randomized comparison with 6 French catheters. *Indian Heart J* 2002;54:184–8.
11. Noto TJJ, Johnson LW, Krone R, et al. Cardiac catheterization 1990: a report of the Registry of the Society for Cardiac Angiography and Intervention (SCA&I). *Cath Cardiovasc Diagn* 1991; 24:75–83.
12. Baum RA, Gantt DS. Safety of decreasing bed rest after coronary angiography. *Cath Cardiovasc Diagn* 1996;39:230–3.
13. Meyer P, Gervais A, Touati C. Systematic use of 4 French catheters for left heart catheterization and coronary angiographies. *Arch Mal Coeur Vaiss* 1997;90:35–40.

Correspondence: Dr. M. Mosseri, Head of Cardiology Division, Meir Medical Center,
Kfar Saba 44281, Israel.
Phone: (972-9) 747-2587; Fax: (972-9) 741-0704
email: mosseri@cc.huji.ac.il

Capsule

Human kin detection

Evolved mechanisms for assessing genetic relatedness have been found in many species, but their existence in humans has been a matter of controversy. Liberman and associates report three converging lines of evidence, drawn from siblings, that support the hypothesis that kin detection mechanisms exist in humans. These operate by computing, for each familiar individual, a unitary regulatory variable (the kinship index) that corresponds to a pair-wise estimate of genetic relatedness between self and other. The cues that the system uses were identified by quantitatively matching individual exposure to potential cues of relatedness to variation in three outputs relevant to the system's evolved functions: sibling altruism, aversion to personally engaging in sibling incest, and moral opposition to third-party sibling incest. As predicted, the kin detection system uses two distinct, ancestrally valid cues to compute relatedness: the familiar other's perinatal association with the individual's biological mother, and duration of sibling co-residence.

Nature 2007;445:727

Eitan Israeli