INTERVENTIONAL CARDIOLOGY

Coronary Angiography with 4 F Catheters by the Radial: Minimally Invasive Catheterization

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Introduction and objectives. Experience with 4 F catheters in cardiac catheterization is limited. These devices appear to be more suitable for the radial artery approach than conventional 6 F catheters.

Methods. We analyze our preliminary experience with diagnostic catheterization of the radial artery with 4 F catheters. Angiographic images were evaluated using a predefined scale (1, poor; 2, acceptable; 3, optimal). In a subgroup of patients who underwent coronary angioplasty, the quantitative angiographic data obtained with the 4 F catheter were compared to those obtained with the 6 F guide catheter. In all cases the patients were clinically followed-up at 24 h and 7 days.

Results. Two hundred and six studies performed over a 12-month period were reviewed. In 6 cases (2.9%) the femoral vein had to be used instead and in 4 cases (1.9%) the 4 F catheters were replaced by 6 F catheters. The left coronary angiography was graded as optimal in 83% and as acceptable in 15%. Right coronary artery images were considered optimal in 93% and acceptable in 7%. There was an excellent correlation between the reference diameter obtained by quantitative angiography with the 4 F catheter and values obtained with a 6 F guide catheter (r = 0.92; p < 0.01). No major vascular complications occurred.

Conclusion. 4 F catheters are appropriate for systematic use in diagnostic procedures using the radial access.

Key words: *Angiography. Cardiac catheterization. Catheters.*

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Angiografía coronaria con catéteres de 4 F por la vía radial: el «cateterismo mínimamente invasivo»

Introducción y objetivos. La experiencia con los catéteres de 4 F para el cateterismo cardíaco es limitada. Estos dispositivos parecen más apropiados para el abordaje radial que los catéteres convencionales de 6 F.

Métodos. Análisis de la experiencia preliminar con cateterismos por vía radial con catéteres de 4 F. La evaluación de la calidad de la angiografía se basó en una escala preestablecida (1, pobre; 2, regular; 3, óptima). En un subgrupo de pacientes sometidos a angioplastia, se compararon los datos de angiografía cuantitativa con 4 F y con el catéter-guía de 6 F. Se hizo una revisión clínica sistemática en todos los casos a las 24 h y a los 7 días.

Resultados. Se revisaron 206 cateterismos en un período de 12 meses. En 6 casos (2,9%) se cambió la vía de abordaje a la arteria femoral y en 4 casos (1,9%) se cambió a catéteres de 6 F. En el 83% de los casos se valoró la coronariografía izquierda como óptima y en un 15% de los casos ésta era regular. Las imágenes de la coronaria derecha eran óptimas en el 93% de los casos y regular en el 7%. Se demostró una excelente correlación entre el diámetro de referencia, obtenido por angiografía cuantitativa con catéteres de 4 F, y el conseguido con catéter-guía de 6 F (r = 0,92; p < 0,01). No hubo complicaciones vasculares mayores.

Conclusión. Los catéteres de 4 F son apropiados para uso sistemático en los procedimientos diagnósticos por la vía radial.

Palabras clave: *Angiografía. Cateterismo cardíaco. Catéteres.*

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INTRODUCTION

The use of coronary angiography as a diagnostic tool has increased spectacularly in recent years. In view of recent findings confirming the benefit of coronary interventional procedures in acute coronary syndrome,[1] it can be expected that indications will expand even more. However, elevated cost and a not unappreciable morbidity are important limitations.

Consequently, the development of techniques that make it possible to reduce hospital stays by ensuring early or immediate deambulation, that can potentially reduce hemorrhagic complications, is evidently attractive. The radial approach combines these two advantages.[2-5] However, this technique is less popular than would be expected given the volume of published experience. Undoubtedly, among the factors that explain the relatively limited use of the radial approach is the learning curve, even for operators who are very experienced with the femoral approach, and the general impression that the radial artery is relatively small for the external caliber of the most frequently used introducers (generally 6 F). With respect to the latter factor, although smaller catheters are available (5F and 4F for diagnostic angiography and 5F for interventional procedures), most operators view the utility of these catheters with skepticism. In fact, the first studies made with 4F and 5F catheters suggest that the angiography is of less quality and that there are some difficulties with catheter stability during contrast injection.[6-9]

However, the most recent data obtained with 4F systems are more favorable,[10-13] probably due to progressive technical improvements in catheters and radiographic equipment. Nonetheless, information about the suitability of 4F catheters for radial us is unavailable. The radial approach to coronary angiography has certain particularities that mean that the material used plays a key role in the successful and rapid application of the procedure, especially in the early phases of the learning curve.

The aim of this study is to analyze the preliminary experience of a single center with a radial strategy using 4F catheters, focusing on the practical utility and safety of the technique.

METHODS

Patients

A review was made of all patients who had undergone cardiac catheterization in our unit, in which the initial route of access was a radial artery and the first alternative used was a 4F catheters, in the period between September 2000 and August 2001. After the first 3 months of this phase, a consensus decision was developed among all the operators of the unit to progressively change the routine access route for diagnostic catheterization from the femoral to the radial artery. In this period, 2434 diagnostic procedures were performed, in which at least a 4F catheter was used in 823 cases, and in 233 cases the approach was initially radial. Altogether, 206 diagnostic procedures were performed by way of the radial approach with 4F catheters, which represent the study group. The choice of access route and catheters was made by the operator based on the presence of a broad radial pulse, a positive Allen test, the presence or absence of intermittent claudication, and the availability of appropriate material.

Procedures

Before arterial puncture, midazolam, 2 mg, was administered intravenously unless the level of consciousness was already lowered. After local anesthesia with 2% mepivacaine (0.5-1 mL) using an insulin needle, the radial artery was punctured using the Seldinger technique with a 21G trocar or Abocath-20G, and an 11-cm 4F radial introducer (Cordis Corporation, Miami, FL, U.S.) or 9-cm introducer (William Cook Europe ApS, Bjaeverskov, Denmark) was inserted. Before introducing the catheters, a combination of 3 mg of verapamil and 5000 U of heparin, dissolved in a total of 20 ml of 0.9% saline solution was instilled through the arterial introducer. In the first 12 cases, the dose of heparin used was 3000 U. To advance and exchange catheters, conventional 0.025 or 0.035 J guides of 260 cm were used. The catheters chosen in most cases to probe the left coronary were 3.5-cm left Judkins type catheters, and for the right coronary, the right 4-cm Judkins (Infinity™, Cordis Corporation, Miami, FL, U.S.). The procedure time was defined as the interval between the administration of local anesthetic for arterial puncture and the removal of the introducer. It includes, therefore, the time used to obtain a satisfactory arterial access and the complete angiographic study. In the case of interventional procedures, this time was not considered in the analysis.

After catheterization, the introducer was withdrawn in the hemodynamics room by manual compression, followed immediately by the placement of a compressive bandage composed of a gauze roll and three Medipore bands (3M, Borken, Germany) measuring about 14 cm long. This compressive bandage was kept in place for a minimum of 2 h in cases of diagnostic catheterization and for 4 h in the case of percutaneous coronary interventions. The patients studied as ambulatory cases were released 3-4 h after diagnostic catheterization in the absence of complications. Patients referred from other hospitals were transferred within 2-4 h of the diagnostic procedure. In the case of combined diagnostic and angioplasty procedures, the patient remained hospitalized until the next morning.

All patients were reviewed in the outpatient clinic 7-10 days after the procedure. The presence of local hematoma, radial pulse, and ischemia, at rest or induced,

in the hand on the same side as the puncture was assessed specifically.

Coronary angiography

Manual injection was used in all cases. The contrast medium was of low osmolarity (Omnitrast 300). The angiography was recorded on a conventional CD in DICOM format at a rate of 12.5 images/s for off line analysis by a single observer who did not know the patient's clinical data or the details of catheterization (M.S.). The first three sequences of the left coronary and the two first of the right coronary, as long as the catheter was correctly located in the coronary ostium, were used for qualitative assessment. The angiography was evaluated in accordance with the following classification: grade 1, poor quality (equivalent to non-diagnostic), with incomplete filling of the coronaries; grade 2, regular quality, with sufficient filling of the coronary tree, but more than one photogram is needed for complete visualization; grade 3, optimal quality, in which filling was complete in a single photogram in diastole.

Quantitative angiography

Patients who underwent diagnostic coronariography with a 4F catheter and had a recent angiography (<2 months) with a 6F catheter were included in a substudy of quantitative angiographic assessment with 4F catheters. The Gemnet (Medical GE Systems, Milwaukee, Wisconsin) system of quantitative angiography was used. The criteria for inclusion in this substudy were: *a)* availability of an angiography of good quality (grade 3) with both the 4F catheter and the 6F catheter, before carrying out an angioplasty and passing an angioplasty guide; *b)* good visualization of the catheter without contrast in the center of the angiographic image; *c)* previous nitroglycerin administration (150-200 μg by the intracoronary route). Following these criteria, a total of 18 angiographies were used in the analysis. The reference diameter measured with both catheters was compared, using the 6F catheter as the reference scale. It was decided not to estimate the variation in the determination of other data, such as length of the lesion, percentage stenosis, and minimum luminal diameter, because 4F and 6F angiography views with identical angling in the were not available.

Statistics

Continuous variables are expressed as mean±standard deviation (SD). For comparison of continuous va-

riables, the Student t test was used. The reference diameters obtained by means of quantitative angiography with 4F catheters were analyzed using the values obtained with the 6F catheter as reference. Accuracy (mean of the differences, including sign), precision (mean of the SD of these differences), and coefficient of variation (relation between SD and the mean) were calculated, in addition to calculating the correlation coefficient. The SPSS 9.0 program for Windows for statistical analysis was used.

RESULTS

Patients

The study population was composed by 204 patients, out of a total of 206 catheterizations. The clinical data appear in Table 1. Most of the selected patients were referred for study due to the suspicion of, or need for, re-evaluating coronary disease.

Procedures

In Table 2 are listed the main diagnoses obtained by catheterization. In 59 cases (28.6%), catheterization demonstrated the absence of significant coronary stenoses. In 43 cases, the procedure was continued with an *ad hoc* coronary intervention. In 137 cases, ventriculography was performed in addition to coronariography, and in 4 patients an aortography was also carried out. The mean

TABLE 1. **General data of the population**

Age, years	63±12
BMI, kg/m²	27.8±4.2
Female sex	30 (14.6%)
Indication of catheterization	
Ischemic heart disease	190 (92.2%)
Aortic cardiac valve disease	8 (3.9%)
Dilated cardiomyopathy	3 (1.5%)
Programmed angiographic control	4 (1.9%)
Peripheral vascular disease	30 (14.6%)
Previous coronary surgery	11 (5.3%)

BMI indicates body mass index.

TABLE 2. **Main diagnosis obtained with catheterization**

Diagnosis	Total (%)
Coronary artery disease	133 (64.1)
Aortic stenosis	6 (2.9)
Aortic insufficiency	3 (1.5)
Dilated cardiomyopathy	3 (1.5)
Aneurysm of the thoracic aorta	1 (0.5)
Normal coronary arteries	59 (28.6)

TABLE 3. **Difficulties during catheterization**

	Total (%)	Switch to the femoral route (% total)
Acute spasm	6 (2.9%)	1 (0.5%)
Loop in the radial artery	4 (1.9%)	1 (0.5%)
Tortuosity of the subclavian artery	2 (1.0%)	2 (1.0%)
Failed puncture	1 (0.5%)	1 (0.5%)
Failed placement of the introducer	1 (0.5%)	1 (0.5%)

total procedure time was 25.4±13.0 min (maximum 90 and minimum 4 min) and the fluoroscopy time was 8.8±5.7 min (maximum 41.8 and minimum 2.0 min). The contrast volume was 121.7±45.6 mL. In order to evaluate the possible effect of the learning curve on procedure times, the sample was divided into two groups of the same size (103 catheterization procedures in each group). There were no statistically significant differences with respect to fluoroscopy time between the first and last halves of the series (9.6±6.4 versus 8.0±4.8 min; P=.094), although the procedure time varied (28.8±17.8 versus 21.6±9.8 min; P=.001).

In Table 3 are listed the main difficulties encountered with the procedure, excluding difficulty with selective probing of coronary arteries. In 6 cases (2.9%), the approach had to be changed to the femoral artery for different reasons (Table 3). In 4 cases (1.9%), the 4F catheter was not used because of poor visualization of the coronary arteries (n=3) or difficulty in advancing the catheter due to the tortuous path of the subclavian artery (n=1).

Angiography quality

In the graph in Figure 1, the angiographic scores are shown. The most important finding was that 187 of 192 angiographies of the left coronary yielded a score of 2 or 3, that is, a diagnostically acceptable point of view. Of these, 83% were considered optimal (grade 3). For the right coronary, all the angiographies analyzed were considered diagnostic (score of 2 or 3), and 92% were classified as grade 3.

Quantitative angiography

The coefficient of correlation between the reference diameters obtained with 4F diagnostic catheters and those obtained with 6F guide catheters was 0.93 (P<.01). The difference between these diameters is represented in the graph in Figure 2. The average difference between measurements (accuracy) was –0.03 mm. The SD between differences (precision) was 0.22 mm. The coefficient of variation was 7.4%.

Complications

No pseudoaneurysms were observed and there was no need for transfusions or vascular surgery. Six patients (3%) presented hematomas less than 3 cm in diameter. Four patients presented local bleeding of the puncture site some hours after the procedure, which was easily controlled by pressure. The absence of a radial pulse was documented in 6 patients (3%) 7-10 days after the procedure. In none of these cases was there ischemia at rest or inducible ischemia. One patient with absence of the radial pulse had undergone an interventional procedure with a 6F system. One patient experienced clear recovery of the radial pulse one month after the procedure. Three of the six patients with loss of the radial pulse were catheterized in the first 2 months of this series (first 12 patients), a period in which only 3000 U of heparin were administered.

DISCUSSION

The present study analyzed the results obtained with systematic use of 4F catheters by a radial approach
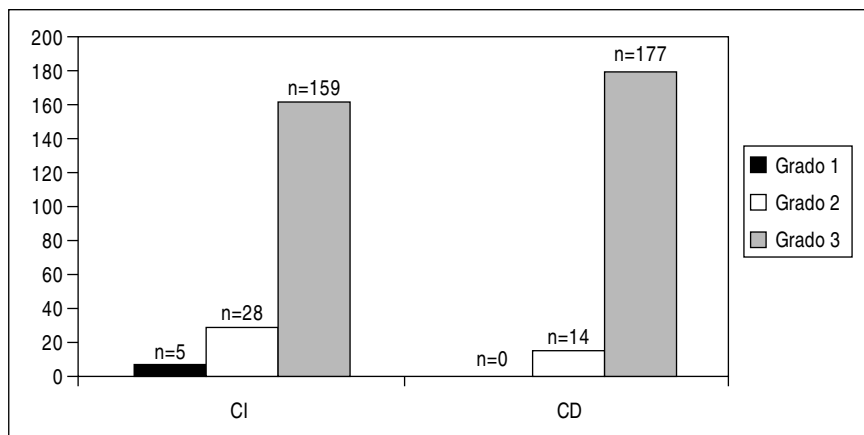
Fig. 1. Angiographic evaluation of the quality of the images obtained. LC indicates left coronary; RC, right coronary.
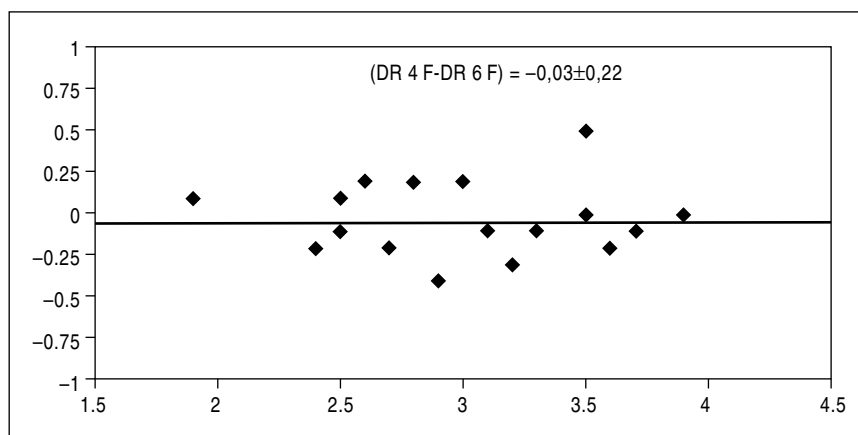
Fig. 2. Difference between the measurements obtained with the 4F diagnostic catheters and 6F guide catheters. RD indicates reference diameter.

with regard to obtaining an angiography of sufficient quality. These catheters are not conventionally used in hemodynamics laboratories in our country because most operators feel that they involve certain difficulties in handling and obtaining of high quality angiographic images. However, some more recent studies suggest that a similar angiographic quality can be obtained with a significant reduction in the volume of contrast administered.[10-13] Based on our own experience, in which these catheters are frequently used by the femoral route, we find that comparative difficulties with 6F catheters — particularly less stability, less torque, and more resistance to contrast injection — are easily resolved with a small learning curve. Some maneuvers incorporated into routine practice, such as the use of warm, low-osmolarity contrast media, injection with two hands, and the application of a progressive injection force can keep the catheter from moving and increase the comfort of the procedure for the operator.

On the other hand, if the difference in the external diameter of 4F and 6F introducers is proportionally small in the common femoral artery, which usually measures 5 to 6 mm, the change in caliber is notable in a smaller artery like the radial, which has a diameter of approximately 2.2 to 2.5 mm.[14] When radial procedures are systematically followed up by echo-Doppler, the caliber of the introducer is an independent factor of complications after catheterization.[14]

The present study confirms the findings of some previous studies,[10-13] suggesting that the quality of coronariographies obtained with 4F catheters is adequate, including in procedures carried out by the radial route. Although no randomized comparison was made with larger caliber catheters, we consider this type of comparison to be unnecessary once the diagnostic sufficiency of the smaller devices is demonstrated.

As for the utility of 4F catheters in assessing the reference diameter by means of quantitative angio-

graphy, we found that they were highly accurate (mean difference between measurements, –0.03 mm) and precise (SD of difference, 0.22 mm) when 6F guide catheters were used as a reference scale. These findings are of a similar magnitude to the interobserver variation obtained with conventional systems of automated quantitative angiography.[15-17] Nonetheless, although the present analysis suggests that 4F catheters can be used at least to estimate the reference size of the vessel, some limitations must be considered. In the first place, the sample size is relatively small (18 cases), which makes exact assessment of the differences difficult. Secondly, due to the retrospective character of this analysis, in some cases the angiographic views were not exactly the same, which limits the assessment to calculating the reference diameter. Therefore, the possible variation in estimates of the percentage stenosis, minimum luminal diameter, or lesion length, which are other important data systematically collected with quantitative angiography, is not known. Finally, since intracoronary nitroglycerin administration was not required for inclusion in this study, differences in vasomotor tone between the compared angiographies cannot be excluded. An integral appreciation of the usefulness of 4F catheters in quantitative angiography can only be evaluated by studies specifically designed for this purpose.

The procedure times reported are relatively prolonged compared with routine practice using the femoral route. However, this series represents the initial experience of a single center embarking on a radial strategy, so it reflects the initial phase of the learning curve of four different operators. In fact, a significant reduction in procedural time is observed between the first and second half of the series, with a tendency toward a shorter fluoroscopy time. On the other hand, the failure rate of the technique is fairly low (approximately 3%) compared with other series,[18] which is su-

rely related with the careful selection of cases in this preliminary phase. In this context, the study population is made up of patients considered «good candidates» for the radial technique. The inclusion of patients with a low body surface, multiple aortocoronary bridges, or those who need concomitant venous puncture for right catheterization (valvular disease) was avoided.

Study limitations

In addition to the limitations mentioned in relation to automated quantitative analysis of lesions, this study had other limitations. The selection of cases means that a high percentage of patients with angiographically normal coronary arteries exists, which tended to favor images of good quality. The angiographic score used to assess the quality of coronariography has been simplified into three levels to facilitate evaluation and reduce the subjectivity of analysis. However, this classification does take into consideration possible differences between the degrees of contrast filling, which can be relevant for the analysis of some lesions. In this sense, the quality defined as «optimal» can include angiographies in which adequate filling exists in diastole, but not throughout the cardiac cycle. The analysis is descriptive and no comparisons were made between the quality of the angiography and complications of the procedure with other approaches or with conventional 6F catheters. Any comparative study should be randomized. In the case of the femoral approach, the available evidence suggests equivalence in terms of the quality of the angiography, with a tendency towards a reduction in contrast volume.[11,13] Carrying out a randomized study using the radial approach, after demonstrating the effectiveness and safety of the smaller catheters, as in the present study, would not be justified.

CLINICAL IMPLICATIONS

This study has implications for routine practice in interventional cardiology units. The radial approach allows immediate deambulation without using a special closure device and makes hospital discharge within a few hours of catheterization possible, in addition to producing a reduction, as demonstrated in other studies, of the rate of bleeding complications.[2,5] The experience described in this paper suggests that the strategy of gradually replacing the femoral technique with a radial approach is positive and can be made while maintaining a good quality of angiography, even with catheters of very small caliber, by selecting favorable cases in the earliest phase of the learning curve.

Although there is no evidence based on randomized studies, it seems reasonable to assume that the systematic use of smaller arterial introducers would tend to reduce certain difficulties with the radial approach, such as spasm or pain that sometimes occurs during positioning of the introducer or exchange of catheters. Given a similar diagnostic yield, the operator should choose the «least aggressive» material and technique.

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