Safety of Diagnostic Transradial Catheterization in Patients Undergoing Long-Term Anticoagulation With Coumarin Derivatives

Marcelo Sanmartín, Begoña Pereira, Rosana Rúa, Sofía Vázquez, Filiberto Hervert, José A. Baz, and Andrés Íñiguez

Unidad de Cardiología Intervencionista, Medtec, Hospital Meixoeiro, Vigo, Pontevedra, Spain

The aim of this study was to evaluate the safety of transradial catheterization without prior withdrawal of oral anticoagulation. In total, 183 patients on long-term acenocoumarol treatment who underwent transradial catheterization were included in a prospective study. In 135 patients, the coumarin derivative was continued without interruption before and during catheterization and, in 48, the drug was stopped 48 hours in advance. No severe thromboembolic or hemorrhagic complications occurred. At 7-day follow-up, the rate of occurrence of hematomas >3 cm in size was 5.5% in the group that continued anticoagulant treatment, and 10.4% in the group that stopped oral anticoagulation (P=.31). The transradial approach appears to be a safe option for patients receiving long-term coumarin treatment and could be the technique of choice because it avoids the drawbacks and complications associated with the withdrawal of oral anticoagulation.

Key words: Cardiac catheterization. Oral anticoagulation. Coumarin derivatives.

Seguridad del cateterismo diagnóstico transradial en pacientes anticoagulados de forma crónica con dicumarínicos

El objetivo de este estudio es evaluar la seguridad de una estrategia de cateterismo transradial sin la retirada previa del tratamiento anticoagulante oral. Se incluyó a 183 pacientes en tratamiento crónico con acenocumarol en los que se realizó un cateterismo transradial en un registro prospectivo. En 135 casos el dicumarínico se mantuvo sin interrupción antes y después del cateterismo, y en 48 casos se había suspendido el fármaco 48 h antes. No se observaron complicaciones tromboembólicas o hemorrágicas graves. A los 7 días de seguimiento, la tasa de hematomas > 3 cm era del 5,5% en el grupo de pacientes sin retirada del anticoagulante y del 10,4% cuando el anticoagulante oral se suspendía previamente (p = 0,31). Se concluye que la vía transradial en pacientes tratados con dicumarínicos de forma continua es una alternativa segura y puede representar la técnica de elección porque evita los inconvenientes y las complicaciones relacionados con la suspensión de los anticoagulantes orales.

Palabras clave: Cateterismo cardiaco. Anticoagulación oral. Dicumarínicos.

INTRODUCTION

Oral anticoagulation (OA) is a drawback for invasive surgical procedures. The additional risk of hemorrhagic complications requires discontinuation of anticoagulant therapy sufficiently in advance of performing a diagnostic

Correspondence: Dr. M. Sanmartín-Fernández. Unidad de Cardiología Intervencionista. Hospital Meixoeiro. Meixoeiro, s/n. Vigo. Pontevedra. España. E-mail: msanfer@telefonica.net

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technique involving arterial puncture, such as cardiac catheterization. However, interruption of anticoagulant therapy can imply an increased risk of thromboembolic complications, as well as hemorrhagic events when anticoagulants are replaced with low-molecular-weight or unfractionated heparin.^{1,2} Traditionally, patients under oral anticoagulant therapy requiring catheterization are instructed to discontinue the oral drug and are placed on unfractionated or low-molecular-weight heparin. The use of transradial catheterization may change this strategy. Since hemostasis following procedures involving a radial approach is simpler and safer than hemostasis with transfemoral access,³⁻⁶ diagnostic catheterization without prior discontinuation of anticoagulation can be considered with this technique.

METHODS

Study Population

Based on the favorable results obtained with the transradial technique, particularly the low rate of hemorrhagic complications.^{6,7} in February 2004 we switched from the conventional strategy of discontinuing OA at least 48 hours before catheterization to scheduling these procedures without withdrawing coumarin and without administering low-molecular-weight or unfractionated heparin. In light of this change, a prospective study was designed to assess the rate of associated complications occurring with this strategy. The inclusion criteria were: a) ambulatory patients scheduled for diagnostic catheterization, and b) intent to perform the procedure by radial access. Patients scheduled for coronary angioplasty, urgent procedures, or concomitant percutaneous mitral valvuloplasty were excluded.

Cardiac Catheterization and Hemostasis

In all cases, a 5 Fr introducer was used. Through the arterial introducer, a spasmolytic solution was administered containing 2.5 mg of verapamil and 1000 U of unfractionated heparin. Once the diagnostic procedure had been completed, the arterial introducer was immediately withdrawn. Hemostasis was performed with a compression bandage consisting of a gauze swab and 3 strips of adhesive elastic bandage for a minimum of 2 h. Following this period, the puncture site was checked and if there was no continuous bleeding, the patient was discharged.

TABLE 1. Baseline Clinical Characteristics*

	OA Continued (n=135)	OA Discontinued (n=48)	P
Age, mean (SD), years	69.5 (9.2)	70.2 (8.7)	.66
Women	53 (39%)	27 (56%)	.04
BMI	28.6 (4.7)	25.8 (4.1)	.9
Diabetes	27 (20%)	14 (29.2%)	.22
Hypertension	69 (51%)	28 (58%)	.4
Smoker	24 (18%)	3 (6%)	.06
Hypercholesterolemia	36 (27%)	12 (25%)	1
Indication catheterization			
Ischemic heart disease	45 (33%)	17 (35%)	.86
Hypertensive heart disease	3 (2%)	2 (4%)	.61
Valvular heart disease	57 (42%)	18 (37%)	.61
Dilated cardiomyopathy	13 (9.6%)	2 (4%)	.36
Others	17 (13%)	9 (19%)	.38
Prior treatment			
Aspirin	16 (12%)	7 (15%)	.61
Clopidogrel	5 (4%)	4 (8%)	.24
LMWH	3 (2%)	28 (58%)	.001

*OA indicates oral anticoagulation; LMWH, low-molecular-weight heparin.

All cases were reassessed at 7 to 10 days to investigate the presence of hematoma, ecchymosis, or thromboembolic complications.

Study Groups and Statistics

Despite generic recommendations to referral physicians advocating against discontinuation of coumarin before catheterization, some centers choose to maintain the "old" strategy of using a bridge therapy of low-molecularweight heparin. This situation allowed the population to be divided into 2 study groups: OA discontinued and OA continued.

The numerical values are expressed as the mean (standard deviation). Comparison between numerical values was done with Student's *t* test for independent samples, and comparison between percentages with Fisher's exact test. Statistical calculations were performed with SPSS 11.5.

RESULTS

A total of 183 consecutive patients were included between March 2004 and December 2005. In 135 patients, anticoagulant treatment was maintained without interruption before catheterization and in 48, anticoagulants were discontinued at least 48 hours before the procedure. The baseline characteristics of the patients are summarized in Table 1. There were no significant differences in baseline demographic data with the exception of female sex, which was more frequent in the OA discontinued group (56% vs 39%; P=.04).

Procedure Data

Overall, left catheterization alone was performed for left coronary angiography and ventriculography in 170 patients (93%). Ten patients (5.5%) additionally underwent right catheterization, which was carried out through venous accesses: puncture of a vein in the anterior fold of the elbow in 2 patients and the femoral vein in 8 patients. In 3 patients (1.6%) coronary angioplasty with stent placement was undertaken immediately after the diagnostic procedure. All 3 patients were in the group with continued AO. In 8 patients (4.4%) femoral artery puncture was required because transradial catheterization had failed. A closure device was used in these patients to achieve hemostasis.

The international normalized ratio (INR) was 2.4 (0.7) in the OA continued group, and 1.4 (0.5) in the OA discontinued group (P<.001).

COMPLICATIONS

Overall, among the 183 patients included, 12 (7%) hematomas >3 cm were observed at the time of discharge. An area of ecchymosis following the procedure was

TABLE 2. Hemorrhagic Complications*

	OA Continued (n=135)	OA Discontinued (n=48)	Р
At discharge			
Ecchymosis	2 (1.5%)	1 (2.1%)	1.0
Bleeding	11 (8.1%)	3 (6.3%)	1.0
Hematoma (>3 cm)	7 (5.2%)	5 (10.4%)	.31
Severe hemorrhage+	0 (0%)	0 (%)	1
At 7 days			
Ecchymosis	9 (7.1%)	8 (17.8%)	.07
Occlusion	1 (0.8%)	0	1.0
Mild hematoma‡	7 (5.5%)	5 (10.4%)	.3
Severe hemorrhage+	0	0	1.0
Thromboembolic event	0	0	1.0

*OA indicates oral anticoagulation.

+Severe hemorrhage: requires surgery, blood product transfusion, or lengthy hospitalization.

‡Mild hematoma: any hematoma >3 cm in diameter.

observed in 3 patients (2%). The compression bandage had to be continued or repeated in 14 patients (8%) due to bleeding.

There were no significant differences between the study groups with regard to complications at discharge or at 7 days (Table 2), although there seemed to be a trend toward a higher rate of mild hematomas in the group treated with prior OA discontinuation (5.2% vs 10.4%; P=.3).

Comparison of the 7-day complication rate between the group catheterized without prior withdrawal of coumarin derivatives and a control population of 795 patients with transradial catheterization and protocolled clinical follow-up in our center in 2001 and 2002 showed very similar values for mild hematoma (5.2% in the group treated with OA and 5.0% for the control population; P=.82).

DISCUSSION

The present study indicates that transradial cardiac catheterization is a safe technique for patients under treatment with coumarin derivatives and allows the procedure to be undertaken without discontinuing the drug. Our findings in this line corroborate previously published data from 2 similar studies,^{8,9} and extend these observations to a larger number of patients in a prospective study with protocolled follow-up at 7 days. Moreover, our study compares the evolution of patients with continued OA and an INR in the "therapeutic" range to a control population in which coumarin had been withdrawn 48 hours before catheterization. In this context, our data indicate that the conventional strategy of withdrawing coumarin and applying a replacement therapy with low-molecular-weight heparin may be unnecessary, in addition to contributing to the

development of a few additional cases of mild hematoma at the puncture site.

The main limitation of this study is its observational nature. The absence of randomization between the groups might have introduced some selection bias, and this fact precludes extending the results to the entire population of patients with long-term OA and an indication for catheterization. There were no relevant differences in the baseline clinical characteristics, however, and because the decision to discontinue coumarin was made by the referral physicians, an inclusion bias on behalf of the interventionalist is improbable. Additionally, the small number of hemorrhagic complications observed with the use of the radial approach makes it difficult to design a randomized study with large enough sample size to demonstrate noninferiority or superiority of transradial cardiac catheterization without discontinuing coumarin.

To apply this strategy, it is important for interventional cardiologist to have sufficient experience with the transradial technique in order to minimize the number of conversions to a transfermoral approach.¹⁰

In conclusion, transradial cardiac catheterization in patients receiving coumarin can avoid the disadvantages of interrupting anticoagulant treatment and may be the therapy of choice for this subgroup of patients.

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