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Original article

Renal Insufficiency and Vascular Complications After Primary Angioplasty Via Femoral Route. Impact of Vascular Closure Devices Use

Oscar Prada-Delgado,* Rodrigo Estévez-Loureiro, Ramón Calviño-Santos, Eduardo Barge-Caballero, Jorge Salgado-Fernández, Pablo Piñón-Esteban, José Manuel Vázquez-Rodríguez, Guillermo Aldama-López, Xacobe Flores-Ríos, María Rita Soler-Martín, Nicolás Vázquez-González, and Alfonso Castro-Beiras

Servicio de Cardiología, Complejo Hospitalario Universitario de A Coruña, A Coruña, Spain

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ABSTRACT

Introduction and objectives: We sought to determine the incidence of vascular complications in patients with chronic kidney disease undergoing primary angioplasty via the femoral route; we also evaluated the safety and efficacy of the use of vascular closure devices in this setting.
Methods: Registry of 527 patients undergoing primary angioplasty via the femoral route from January 2003 to December 2008. Chronic kidney disease was defined as creatinine clearance less than 60 mL/min. The primary endpoint was the presence of major vascular complications.
Results: Baseline chronic kidney disease was observed in 166 (31.5%) patients. Patients with chronic kidney disease experienced higher rates of major vascular complications compared to those without worsening of renal function (8.4% vs 4.2%; *P*=.045), especially those requiring transfusion (6.6% vs 1.9%; *P*=.006). Among patients with chronic kidney disease, 129 (77.7%) received a vascular closure device and manual compression was used in 37 patients (22.3%). The risk of major vascular complications was significantly lower with vascular closure device use compared to manual compression (4.7% vs 21.6%; *P*=.003). Multivariable logistic regression analysis showed that the use of a vascular closure device was independently associated with a decreased risk of major vascular complications in patients with chronic kidney disease undergoing primary angioplasty (odds ratio=0.11; 95% confidence interval, 0.03-0.41; *P*=.001).
Conclusions: Patients with chronic kidney disease undergoing primary angioplasty via the femoral route experience higher rates of major vascular complications. The use of vascular closure devices in this group of patients is safe and is associated with lower rates of major vascular complications compared to manual compression.
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Insuficiencia renal y complicaciones vasculares tras la angioplastia primaria por vía femoral. Impacto del uso de dispositivos de cierre vascular

Palabras clave:
Infarto de miocardio
Angioplastia primaria
Insuficiencia renal crónica
Dispositivos de cierre vascular
Complicaciones vasculares

RESUMEN

Introducción y objetivos: Determinar la incidencia de complicaciones vasculares entre los pacientes con insuficiencia renal crónica tratados con angioplastia primaria por vía femoral, así como evaluar la seguridad y la eficacia del uso de dispositivos de cierre vascular en este contexto.
Métodos: Registro de 527 pacientes sometidos a angioplastia primaria por vía femoral entre enero de 2003 y diciembre de 2008. Se definió insuficiencia renal crónica como aclaramiento de creatinina < 60 ml/min. El objetivo primario fue la presencia de complicaciones vasculares mayores.
Resultados: Un total de 166 (31,5%) pacientes sufrían insuficiencia renal crónica. El grupo de pacientes con insuficiencia renal crónica tuvo mayor incidencia de complicaciones vasculares mayores que los pacientes sin deterioro de la función renal (el 8,4 frente al 4,2%; p = 0,045), especialmente de las que precisaron trasfusión (el 6,6 frente al 1,9%; p = 0,006). Entre los pacientes con insuficiencia renal crónica, 129 (77,7%) recibieron un dispositivo de cierre vascular, mientras que en 37 pacientes (22,3%) se aplicó compresión manual. El riesgo de complicaciones vasculares mayores fue significativamente menor con el uso de dispositivos de cierre vascular que con la compresión manual (el 4,7 frente al 21,6%; p = 0,003). En el análisis multivariable, el uso de dispositivos de cierre vascular entre los pacientes con insuficiencia renal crónica tratados con angioplastia primaria se asoció de forma independiente con menor riesgo de complicaciones vasculares mayores (*odds ratio* = 0,11; intervalo de confianza del 95%, 0,03-0,41; p = 0,001).

* Corresponding author: Servicio de Cardiología, Complejo Hospitalario Universitario de A Coruña, As Xubias 84, 15006 A Coruña, Spain.
E-mail address: Oscar.Prada.Delgado@sergas.es (O. Prada-Delgado).

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Conclusiones: Los pacientes con insuficiencia renal crónica tratados con angioplastia primaria por vía femoral tienen mayor riesgo de sufrir complicaciones vasculares mayores. El uso de dispositivos de cierre vascular en este grupo de pacientes es seguro y se asocia a reducción del riesgo de complicaciones vasculares mayores, en comparación con la compresión manual.
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Abbreviations

CKD: chronic kidney disease
MVC: major vascular complications
PA: primary angioplasty
PCI: percutaneous coronary intervention
STEACS: ST-segment elevation acute coronary syndrome
VCD: vascular closure device

INTRODUCTION

Chronic kidney disease (CKD) is independently associated with increased cardiovascular morbidity, including the increased risk of acute myocardial infarction.[1] Given the increased prevalence of CKD in the western world, it is unsurprising that patients with impaired kidney function are an increasingly important group among patients admitted to emergency cardiac catheterization laboratories for primary angioplasty (PA) in the treatment of ST-segment elevation acute coronary syndrome (STEACS). Impaired kidney function has been associated with an increased risk of bleeding and complications related to vascular access after percutaneous coronary intervention (PCI).[2] However, in the specific setting of PA, where the risk is particularly high due to the need for intensive anticoagulation and antiplatelet therapy, the actual incidence of complications related to vascular access in the group of patients with CKD remains unknown.

Different strategies have been developed to reduce bleeding complications after PCI, such as the use of new anticoagulants like bivalirudin, or the preferential use of the radial access route.[3,4] The use of vascular closure devices (VCDs) for this purpose remains controversial.[5] Moreover, there is little information on the safety of these devices in patients at high risk of bleeding, such as patients with CKD or those undergoing PA, as these patients have been excluded from most studies that have evaluated the use of VCDs.[6] In the specific case of patients with CKD, recent studies have reported an increased risk of vascular complications with the use of VCDs.[7]

The aim of our study was to analyze the incidence of vascular complications in patients with CKD treated with PA via the femoral artery compared to patients without impaired kidney function and to determine the safety and efficacy of VCDs in patients with CKD treated with PA.

METHODS

Background and Study Population

The Servicio Galego de Saúde (SERGAS; Health Service of Galicia) has launched the PROGALIAM program to ensure access to PA for most of the Galician population. The details of this program have been described previously.[8,9] Briefly, patients with STEACS who are admitted to hospital and are candidates for interventional reperfusion, as defined in the clinical practice guidelines, are treated with urgent PCI. Patients who are first admitted to a noninterventionist hospital are quickly transferred to a hospital with a cardiac catheterization laboratory via the 061 emergency ambulances to receive the same treatment. All patients who presented with typical anginal pain of more than 30 min duration with ST elevation $\geq$1 mm in 2 or more contiguous leads (or with reciprocal depression $\geq$1 mm in leads V_1 or V_2) or left bundle branch block and were eligible for PA within the first 12 h after the onset of symptoms were included in the study if the procedure was performed using the femoral route. Patients who died during the procedure were excluded from the study as well as those who required intraaortic balloon counterpulsation via the same route by which the procedure was performed. Information on their clinical characteristics, cardiovascular risk factors and previous treatments was collected directly from the patient or, if necessary, from medical records.

Primary Angioplasty Protocol

Interventional cardiologists with proven experience performed all the PA according to the clinical practice guidelines. Femoral artery cannulation was performed using the Seldinger technique after the anatomical landmarks were identified. The most frequently used introducers were 6 Fr; only in the case of more complicated interventions were 7 Fr introducers used. All patients received 250 mg of acetylsalicylic acid at the time of diagnosis. A 300-mg loading dose of clopidogrel was administered in the emergency department or during transport by ambulance. If a loading dose had not been received, this was done following angioplasty and before the patient left the cardiac catheterization laboratory. The use of the glycoprotein IIb/IIIa inhibitor abciximab (ReoPro®; 0.25 mg/kg loading dose followed by 0.125 μg/kg/min infusion over 12 h) was strongly recommended in the protocol, although its use was left to the discretion of the physician who initially treated the patient. During catheterization, an intravenous dose of 60 IU/kg unfractionated heparin with abciximab or 100 IU/kg without abciximab was administered. After the procedure a maintenance dose of 75 mg/day of clopidogrel for 1 month was recommended in the case of bare-metal stent implantation or for 12 months in the case of drug-eluting stents.

Occlusion Protocol

In each case, the interventionist chose the femoral artery closure technique. Without exception, when the use of a VCD was considered, femoral angiography was performed prior to implantation. Generally, the device was not used if the puncture site was not located in the common femoral artery, the artery was of small caliber (less than 5 mm), or there was severe peripheral artery disease. A choice of device was available to the operator: Angio-Seal® (St. Jude Medical; St. Paul, Minnesota, United States), StarClose® (Abbott Laboratories; Abbott Park, Illinois, United States) and Perclose A-T® (Abbott Laboratories, Illinois, United States). Device implantation was performed in the cardiac catheterization laboratory directly

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