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Original article

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

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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.

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).

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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.

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

after the procedure and according to the manufacturer's instructions. In cases where manual compression was performed, the introducer was removed in the cardiac catheterization laboratory at the end of the procedure and manual pressure was applied to the puncture site for 15 min to 20 min. If needed, a mechanical compression device was used to achieve total occlusion. Subsequently, an inguinal compression bandage was applied for 8 h. According to both the protocol and the clinical practice guidelines, the patients in both groups were not permitted to walk until 12 h to 24 h after the PA procedure.

Definitions and Events

CKD was defined as creatine <60/mL/min as calculated by the Cockcroft-Gault formula: (140–age)×(weight) (×0.85 if female)/(72×serum creatinine) during baseline blood tests at admission. This formula has been validated and accurately predicts the glomerular filtration rate.[10] To identify the spectrum of kidney disease in the study population and its impact on major vascular complications (MVC), the patients with CKD were divided into 2 groups if they presented an estimated creatinine clearance of 30 mL/min to 60 mL/min or <30 mL/min (severe CKD). All patients were examined at admission to assess the presence of complications related to vascular access. Systematic blood analysis was conducted both at admission and between 24 h and 72 h after the procedure. We defined MVC as the composite event of all complications related to vascular access that were fatal or required surgical or endovascular repair or transfusion, or those associated with a fall in hemoglobin ≥3 g/dL. This definition is based on that provided by the Organization to Assess Strategies in Acute Ischemic Syndromes.[11] We also assessed the presence of minor vascular complications, including hematoma, arteriovenous fistula, pseudoaneurysm, bleeding not fulfilling criteria for MVC, and infection at the vascular access site. A VCD failure was defined as aborted implantation or ineffective implantation due to poor occlusion requiring manual or mechanical compression. The analysis was performed with intention-to-treat; thus, in the case of device failure, the patient was included in the VCD group. Thirty-day mortality was also assessed.

Statistical Analysis

The results are presented as mean (1 standard deviation) for normally distributed continuous variables, as median [interquartile range] for non-normally distributed continuous variables, and as percentages for categorical variables. Categorical variables were compared using the χ^2 test or Fisher's exact test. Quantitative variables were analyzed using the *t*-test or Mann-Whitney test, depending on whether the distribution was normal or not. To assess the independent effect of CKD on the incidence of MVC, we constructed a logistic regression model including the variables independently associated with the presence of MVC in our sample (sex and use of VCDs) and other variables that, based on previous studies, clinical experience or asymmetric distribution between groups, were considered potential confounders (age, body surface area, diabetes mellitus, peripheral vascular disease, shock and use of abciximab). The variables were introduced in the model in blocks. Similarly, we constructed a logistic regression model including the same variables to determine the independent effect of using VCDs on MVC in the group of patients with CKD. A *P*-value of <.05 was used as a cutoff for statistical significance. All statistical analysis was performed using the SPSS 15.0 statistical package for Windows (SPSS, Chicago, Illinois, United States).

RESULTS

Between January 1, 2003 and December 31, 2008, 527 patients who fulfilled the inclusion criteria were treated with PA via the femoral artery (32% of all PAs performed during this period). In total, 166 (31.5%) had CKD and of these 23 (13.9%) had a creatinine clearance of <30 mL/min. Of those with CKD, 129 (77.7%) received a VCD and in 37 (22.3%) manual compression was applied. Of the patients with CKD who received a VCD, an Angio-Seal® device was used in 86 (66.7%), a Perclose A-T® device in 25 (19.4%), and a StarClose® device in 18 (13.9%).

Vascular Complications in Patients With Chronic Kidney Disease Treated by Primary Angioplasty Via the Femoral Route

Compared to patients without impaired kidney function, patients with CKD at baseline were significantly older, had a higher prevalence of diabetes mellitus, hypertension, and peripheral artery disease, and were less often treated with abciximab. It should be noted that VCDs were used less frequently in the group of patients with CKD. Table 1 shows the clinical characteristics and procedures applied in the total study population.

Patients with CKD had a higher incidence of MVCs than patients without impaired kidney function (8.4% vs 4.2%, *P*=.045). Among those with MVC, there was a greater incidence of femoral bleeding that required transfusion among patients with CKD (6.6% vs 1.9%, *P*=.006). Similarly, patients with CKD had a higher incidence of minor vascular complications (10.2% vs 5.3%, *P*=.035). On the other hand, in the study population, the level of impaired kidney function was also associated with an increased incidence of MVC (4.2% in patients without CKD vs 7% in patients with a creatinine clearance 30 mL/min to 60 mL/min vs 17.4% in patients with severe CKD, *P*=0.017). Thirty-day mortality was significantly higher in patients with CKD than in patients without impaired kidney function (11.4% vs 1.7%, *P*<.001). Table 2 and Figure 1 show the events in the total study population.

In the regression model adjusted for potential confounders, CKD was associated with an increased risk of MVC, although this result was not statistically significant (odds ratio [OR]=2; 95% confidence interval [95%CI], 0.92-4.43; *P*=.081). There was an independent association between severe CKD and MVC (OR=3.4;95%CI, 1.1-11.7; *P*=.043). In this model, in addition to severe CKD, female sex (OR=3.8;95%CI, 1.7-8.3; *P*=.001) and the use of a VCD (OR=0.4; 95%CI, 0.2 to 0.9; *P*=.029) were independently associated with MVC.

Safety and Efficacy of Vascular Closure Devices in Patients With Chronic Kidney Disease Treated With Primary Angioplasty

In the group of patients with CKD, there were no significant differences in baseline characteristics and procedures between patients who received a VCD and those who underwent manual compression (Table 3).

Among patients with CKD treated with PA via the femoral artery, the use of VCDs was associated with a lower incidence of MVC than with the use of manual compression (4.7% vs 1.6%, *P*=.003). The use of VCD in the group of patients with CKD was associated with a decreased need for transfusion (3.9% vs 16.2%, *P*=.016) and a lower incidence of bleeding associated with a fall in hemoglobin ≥3 g/dL (3.1% vs 18.9%, *P*=.003). There were no differences between groups in minor vascular complications in relation to individual components or in combination. Neither were there differences between groups in 30-day mortality. Failure of the VCD in patients with CKD occurred in 8 (6.2%) patients. Among patients with CKD who were implanted with a VCD, device failure

Table 1
Baseline and Procedure Characteristics of the Total Study Population

	Kidney disease (n=166)	Control Group (n=361)	*P*
Age, years	72.3±9.9	60.2±11.7	<.001
Males	121 (72.9)	285 (78.9)	.125
Body surface area (m^2)	1.8±0.2	1.8±0.3	.708
Hypertension	59 (35.5)	78 (21.6)	.001
Dyslipidemia	27 (16.3)	66 (18.3)	.573
Smokers	12 (7.2)	64 (17.7)	.001
Diabetes mellitus	31 (18.7)	33 (9.1)	.002
Peripheral artery disease	16 (9.6)	13 (3.6)	.005
History of AMI	5 (3)	12 (3.3)	.851
History of coronary surgery	2 (0.6)	2 (1.2)	.594
Anterior infarction	71 (43)	163 (45.2)	.650
Cardiogenic shock	14 (8.4)	9 (2.5)	.002
Creatinine clearance (mL/min)	43.7±11.1	91.6±28.3	<.001
Procedure characteristics			
Abciximab	96 (57.8)	258 (71.5)	.002
Clopidogrel	154 (94.5)	344 (96.1)	.407
Symptoms-to-reperfusion time (min)	237 [177-378]	220 [160-322]	.114
Door-to-balloon time (min)	122 [86-173]	111 [80-150]	.031
Angiographic success	160 (97)	355 (98.3)	.333
7 Fr introducer	5 (3)	10 (2.8)	.877
Vascular closure devices	129 (77.7)	307 (85)	.039

AMI, acute myocardial infarction.
Data are expressed as mean±standard deviation for normally distributed variables, as medians [interquartile range] for non-normally distributed variables and as no. (%) for categorical variables.

was associated with greater incidence of MVC than when implantation was successful (25% vs 3.3%, *P*=.036). In table 4 and Figure 2 summary of events in the group of patients with CKD.

In the logistic regression analysis adjusted for potential confounders, the use of VCDs in patients with CKD treated with PA was independently associated with a decreased risk of MVC (OR=0.11; 95%CI, 0.03-0.41, *P*=.001). In addition to the use of VCDs, only body surface area was independently associated with MVC in patients with CKD (OR=0.02; 95%CI, 0.01-0.7; *P*=.033)

Table 2
Summary of Events in the Total Study Population

	Chronic kidney disease (n=166)	Control group (n=361)	*P*
MVC	14 (8.4)	15 (4.2)	.045
Transfusion	11 (6.6)	7 (1.9)	.006
Decrease in hemoglobin ≥3 g/dL	11 (6.6)	13 (3.6)	.118
Need for intervention	4 (1.1)	1 (0.6)	.942
Retroperitoneal hemorrhage	2 (1.2)	4 (1.1)	.923
Minor vascular complications	17 (10.2)	19 (5.3)	.035
Pseudoaneurysm	1 (0.6)	1 (0.3)	.531
Arteriovenous fistula	2 (1.2)	2 (0.6)	.594
Minor bleeding/hematoma	13 (7.8)	16 (4.4)	.112
Infection	1 (0.6)	0 (0)	.315
Death at 30 days			
Total	19 (11.4)	6 (1.7)	<.001
Vascular	1 (0.6)	1 (0.3)	.531

MVC, major vascular complications.
Data are expressed as no. (%).

DISCUSSION

This is the first study to assess the incidence of complications related to vascular access in patients with CKD treated with PA via the femoral artery in the setting of STEACS, as well as the safety and efficacy of VCDs in this group of patients.

Vascular Complications in the Group of Patients With Chronic Kidney Disease Treated With Primary Angioplasty Via the Femoral Route

Several studies have found a strong association between impaired kidney function and bleeding complications following

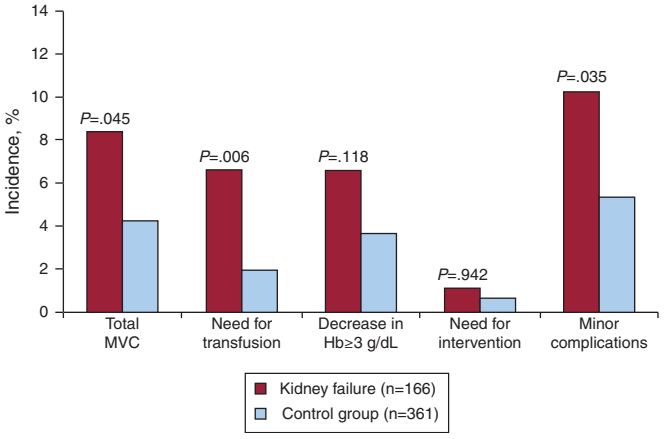

Figure 1. Bar graph showing the incidence of vascular complications in the total population in relation to chronic kidney disease. Hb, hemoglobin; MVC, major vascular complications.

Table 3
Baseline and Procedure Characteristics of the Patients With Chronic Kidney Disease

	Vascular closure devices (n=129)	Manual compression (n=37)	*P*
Age, years	72.8±9.6	70.9±10.7	.322
Males	95 (73.6)	26 (70.3)	.684
Body surface area (m^2)	1.8±0.3	1.8±0.1	.953
Hypertension	44 (34.1)	15 (40.5)	.471
Dyslipidemia	22 (17.1)	5 (13.5)	.607
Smokers	12 (9.3)	0	.070
Diabetes mellitus	22 (17.1)	9 (24.3)	.317
Peripheral artery disease	11 (8.5)	5 (13.5)	.355
History of AMI	3 (2.3)	2 (5.4)	.312
History of coronary surgery	2 (1.6)	0	.987
Anterior infarction	57 (44.5)	14 (37.8)	.469
Cardiogenic shock	9 (7)	5 (13.5)	.310
Creatinine clearance (mL/min)	42.7±13.7	47±10.3	.085
Procedure characteristics			
Abciximab	74 (57.4)	22 (59.5)	.820
Clopidogrel	121 (96)	33 (89.2)	.119
Symptoms-reperfusion time (min)	254 [190-389]	212 [153-294]	.131
Door-to-balloon time (min)	126 [87-189]	120 [78-157]	.248
7 Fr introducer	4 (3.1)	1 (2.7)	.899
Angiographic success	126 (98.4)	34 (91.9)	.075

AMI, acute myocardial infarction.
Data are expressed as mean±standard deviation for normally distributed variables, as medians [interquartile range] for non-normally distributed variables and as no. (%) for categorical variables.

PCI and in the setting of PA itself.[12,13] However, the specific incidence of bleeding complications related to vascular access in patients with CKD treated with PA via the femoral artery has not been previously published. Our results show a higher incidence of femoral vascular complications in patients with CKD than in patients without impaired kidney function; the risk of MVC is also higher the greater the deterioration in renal function. It should be highlighted that there was an increased risk of femoral bleeding requiring blood transfusion in patients with CKD.

Several mechanisms may explain the increase risk of bleeding complications in patients with CKD following PCI. First, there is a high prevalence of associated comorbidities in this population that may partly explain the increased risk of bleeding.[13] Second, it has been suggested that impaired kidney function itself has a direct effect on the risk of bleeding, mediated by the endothelial and platelet dysfunction that occurs in uremia.[14] Thus, in the present study, patients with CKD were older and had a higher prevalence of diabetes mellitus and peripheral artery disease; after adjustment, the analysis showed that severe CKD alone was independently associated with MVC.

In the study population, and consistent with the results reported in previous studies, CKD was associated with increased mortality following PA.[13] It remains to be determined to what degree this increase in mortality is explained by the greater incidence of bleeding complications in patients with CKD.

Table 4
Summary of Events in the Group of Patients With Chronic Kidney Disease

	Vascular closure devices (n=129)	Manual compression (n=37)	*P*
MVC	6 (4.7)	8 (21.6)	.003
Transfusion	5 (3.9)	6 (16.2)	.016
Decrease in hemoglobin≥3 g/dL	4 (3.1)	7 (18.9)	.003
Need for intervention	0	1 (2.7)	.223
Retroperitoneal hemorrhage	1 (0.8)	1 (2.7)	.397
Minor vascular complications	13 (10.1)	4 (10.8)	.945
Pseudoaneurysm	0	1 (2.7)	.223
Arteriovenous fistula	2 (1.6)	0	.603
Minor bleeding/hematoma	10 (7.8)	3 (8.1)	.944
Infection	1 (0.8)	0	.777
Death at 30 days			
Total	13 (10.1)	6 (16.2)	.378
Vascular	0	1 (2.7)	.223

MVC, major vascular complications.
Data are expressed as no. (%).

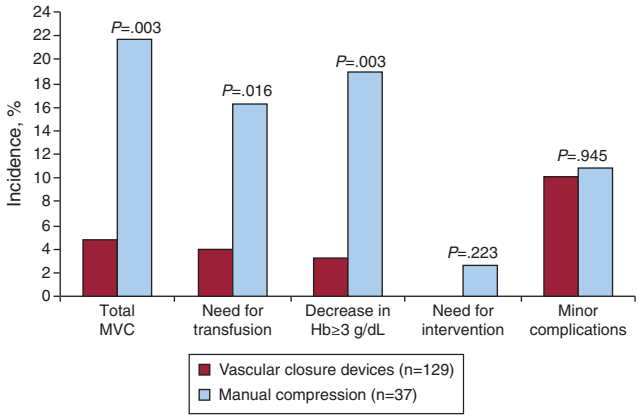

Figure 2. Bar graph showing the incidence of vascular complications in the group of patients with chronic kidney disease in relation to the use of vascular closure devices. Hb, hemoglobin; MVC, major vascular complications.

Impact of the Use of Vascular Closure Devices in the Group of Patients With Chronic Kidney Disease Treated With Primary Angioplasty

The use of VCDs for the prevention of bleeding complications following PCI remains controversial.[15] Up to the present, several studies have shown a decrease in vascular complications with the use of VCDs.[16] In contrast, other studies have noted an increase in local complications with the use of VCDs compared to manual compression.[17] Finally, the majority of randomized studies have reported no effect.[6] A recent metaanalysis,[5] which assessed 31 clinical trials that included 7528 patients undergoing diagnostic and therapeutic coronary interventions, showed that although the use of VCD was associated with shorter occlusion times, this did not significantly decrease local bleeding complications compared to manual compression.

However, certain aspects should be kept in mind when interpreting these results. First, the available information on the use of VCDs in patients at increased risk of bleeding, such as those undergoing an emergency procedure or with severely impaired kidney function, is very scarce given that these patients have been routinely excluded from studies assessing VCD use. In this sense, the ACUITY study[18] showed that in patients with acute coronary syndrome without ST elevation undergoing early PCI the use of VCDs was associated with a significant decrease in major bleeding complications. In the setting of STEACS treated with PA via the femoral route, the results obtained from our total study population showed that the use of VCDs was independently associated with a lower incidence of MVC compared to manual compression.[19]

There is even less information available on the safety and efficacy of using VCDs in patients with CKD. In a recent study, Aziz et al.[7] reported a high risk of vascular complications with the use of VCDs in patients with CKD undergoing PCI. However, any conclusions that can be drawn from this study are limited due to the lack of a manual compression control group. The present study is the first to specifically assess the use of VCDs in patients with CKD in a setting in which there is a particularly high risk of bleeding, such as that of PA. Our results show that the use of VCDs in this population is safe and is associated with a low incidence of vascular complications, lower than in the manual compression group and very similar to that of patients without CKD. These results are consistent with what has been reported for the total study population.[19]

The second point to note is that the results of clinical trials do not appear to reflect actual clinical practice, in which strict occlusion protocols may not always be established. Thus, consistent with our results, several recently published registries that have assessed the use of VCDs in clinical practice have described favorable outcomes in the prevention of bleeding complications.[3,16,20,21] In a registry of more than 1.5 million patients who underwent PCI, Marso et al.[3] found that the use of VCDs was associated with a lower incidence of major bleeding complications, particularly in patients at higher risk of bleeding, including patients undergoing urgent procedures or those with CKD. Paradoxically, the register shows that patients at a higher risk of bleeding receive a VCD less frequently. Similarly, in our study population, the use of VCDs was lower among patients with CKD compared to patients without impaired kidney function.

Finally, in a recent review of strategies for the prevention of bleeding complications following PCI, Dauerman et al.[22] concluded that there is now sufficient evidence to support the use of VCDs for this purpose. This conclusion appears to be very solid, particularly regarding patients at a higher risk of bleeding. In this line, the results of our study have the advantage of being directly applicable in clinical practice in a setting in which conducting randomized trials is difficult, and thus it seems reasonable to consider the use of VCDs in patients with CKD treated with PA via the femoral artery.

Limitations

This study has several limitations that should be considered when interpreting the results. First, the nonrandomized observational design of the study could have introduced a selection bias that remained uncontrolled during the statistical analysis. In this regard, the number of patients with CKD who received a VCD was significantly different to the number of those receiving manual compression because the technique used to close the femoral artery was left to the discretion of the interventional cardiologist. Thus, it is possible that patients selected for manual compression were a group at increased risk of bleeding, with worse anatomical distribution or unfavorable femoral puncture sites. Second, our cardiac catheterization laboratory does not systematically measure activated clotting time, thus the relationship between the level of anticoagulation administration and the occurrence of bleeding complications could not be assessed.

CONCLUSIONS

Patients with CKD treated with PA via the femoral artery in the setting of STEACS are at greater risk of MVC than patients without impaired kidney function. The use of VCDs in patients with CKD undergoing PA is safe and is associated with a decrease in MVC compared to manual compression.

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CONFLICTS OF INTEREST

None declared.

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