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Clinical significance of bleeding in patients who underwent percutaneous coronary intervention by radial approach at the CIMEQ

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Acronyms
ACS: acute coronary syndrome
AMI: acute myocardial infarction
DM: diabetes mellitus
HT: hypertension
PCI: percutaneous coronary intervention
PMH: past medical history

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ABSTRACT

Introduction: Bleeding complications after percutaneous coronary intervention are associated with an increased risk of mortality and morbidity. Radial approach is a vas cular access technique that has consistently shown a reduction of these risks. Although it is used in our country, there is still little evidence about its impact regarding the reduction of bleeding and its complications.

Objective: To determine the clinical significance of bleeding in patients undergoing coronary catheterization by radial approach at the CIMEQ hospital.

Method: An observational, descriptive study was conducted with 217 patients who underwent percutaneous coronary intervention by radial approach at the laboratory of hemodynamics of the CIMEQ Cardiology Hospital, from 2009 to 2013. Bleeding was identified and classified, as well as the type of lesion treated. The personal medical history and the presence of complications were explored.

Results: There was a predominance of males (78.3%) with a mean age of 62.2 years. There was a higher incidence of smoking (30.0%) and hypertension (28.0%). There were 6 cases (2.8%) of slight bleeding in the form of hematoma at the access site. Half of the patients with hematoma had type C lesions, with no significant association between these variables (p=0.203). Bleeding was significantly associated only with the loss of radial pulse (p<0.001).

Conclusions: Patients undergoing percutaneous coronary intervention by radial approach at the CIMEQ showed a low incidence of bleeding without serious associated complications.

Key words: Percutaneous coronary intervention, Radial approach, Complications, Hematoma

Importancia clínica del sangrado en pacientes con intervencionismo coronario percutáneo por vía radial en el CIMEQ

RESUMEN

Introducción: Las complicaciones por sangrado después de una intervención coronaria percutánea se asocian con un mayor riesgo de morbilidad y mortalidad. El acceso radial ha demostrado consistentemente la reducción de estos riesgos. A pesar de su uso en nuestro país, aun es escasa la evidencia sobre su repercusión con relación a la disminución del sangrado y sus complicaciones.

Objetivo: Determinar la importancia clínica del sangrado en los pacientes con intervencionismo coronario percutáneo por vía radial en el CIMEQ.

Método: Se realizó un estudio observacional, descriptivo con 217 pacientes, a quienes se les realizó una intervención coronaria percutánea por acceso radial en el laboratorio de hemodinámica del Cardiocentro CIMEQ, entre el 2009 y el 2013. Se determinó y clasificó el sangrado, así como el tipo de lesión tratada, se exploraron los antecedentes patológicos personales y la presencia de complicaciones.

Resultados: Predominó el sexo masculino (78,3 %) y la media de edad fue de 62,2 años. Hubo mayor incidencia de fumadores (62,7 %) e hipertensos (54,4 %) y solo 6 casos (2,8 %) de sangrado leve en forma de hematoma en el sitio de acceso. La mitad de los pacientes con hematoma presentaba lesiones tipo C, sin existir asociación significativa entre estas dos variables (p=0.203). El sangrado solo se asoció significativamente con la pérdida del pulso radial (p<0.001).

Conclusiones: Los pacientes intervenidos por vía radial en el CIMEQ presentaron una baja incidencia de sangrado, sin complicaciones asociadas de gravedad.

Palabras clave: Intervención coronaria percutánea, Acceso radial, Complicaciones, Hematoma

INTRODUCTION

Percutaneous coronary intervention (PCI) has been traditionally performed through the femoral artery. For many years, the femoral artery was the most widely used access route in the world, although there are alternative sites that include the use of brachial, ulnar and radial arteries[1-3].

The risk associated with the transfemoral PCI involves vascular lesions at the site of puncture, such as hematomas and bleeding, with an incidence rate ranging from 0.5 to 37.0%, depending on the complexity of the procedure. In acute coronary syndrome (ACS), up to 23.0% of patients have complications associated with bleeding; therefore, additional treatments are needed, including blood transfusion or surgery[4,5].

Although the definition of bleeding and the characteristics of patients vary, it is known that there is an increase in mortality in patients who have suffered major bleeding, suggesting that major femoral bleeding should not be underestimated as a trivial complication in PCI[6].

The CathPCI Registry, from the Northern New England Cardiovascular Disease Study Group, the Mayo Clinic Registry and that of the Wake Forest University showed that major bleeding complications in patients undergoing PCI had declined, which was attributable to the use of bivalirudin and radial access[7].

The transradial cardiac catheterization and PCI have a lower risk of hematoma and bleeding at the access site, even in the ACS, which favors early ambulation, a shorter hospital stay and lower costs[7-9].

In a meta-analysis of 23 randomized trials with 7.020 patients[10], the incidence of major bleeding was 0.05% in the transradial group compared with 2.3% in the femoral group (p<0.001).

The adoption of the radial approach to improve the safety of PCI is a reasonable goal. However, according to the study RIVAL[7], the improvement of traditional effectiveness indicators, such as death and acute myocardial infarction (AMI), has not been proven with the radial approach.

Although the technique is currently well established, it is used in less than 2% of cases in the US and accounts for less than 12% of total PCI worldwide[8,11].

Our country has also gained experience with the use of radial access in some centers, and there are publications showing encouraging results that support the feasibility and safety of this approach[12,13]. However, there is still little evidence of such results and the impact of this technique in the incidence of bleed-

ing and its association with complications. For this reason, it was decided to conduct this study in order to determine the behavior of bleeding in the access site in patients who underwent PCI by radial approach at the CIMEQ.

METHOD

An observational, descriptive, prospective study was conducted with 217 patients who underwent coronary angiography and PCI by radial access at the Hemodynamics Laboratory of the CIMEQ Cardiology Hospital. All patients in whom this technique was used from 2009 to 2013, and who agreed to participate in the study, were included.

Coronary angiography was performed by cannulation of the radial artery by the Seldinger technique, without Allen test, and sodium heparin was used as anticoagulant in doses of 50 mg for diagnostic procedures and 75 mg for PCI. Patients who were implanted with bare metal stents, received 600 mg of clopidogrel as loading dose, and 75 mg daily during a period of 4 weeks; Moreover, those patients who were implanted with a drug-eluting stent received the same initial and maintenance dose over a period of 18 months.

The introducer sheath was withdrawn immediately after the procedure ended. A compression bandage was applied to the puncture site for 4 hours and the patient was told to keep the wrist motionless for 6 hours. Patients were kept in observation for 4 hours. Their vital signs, radial pulse, temperature and color of the hand were assessed every hour, as well as the occurrence of bleeding and the presence of clinical alterations or other manifestation suggestive of complications. At the end of four-hour period without the presence of symptoms suggestive of myocardial or upper limb ischemia, or other complications, the patients were discharged (to their home or hospital of origin).

The variables used included: a) past medical history (PMH), such as smoking, a history of myocardial infarction, hypertension (HT), dyslipidemia, and type 2 diabetes mellitus (DM); b) the incidence of bleeding, according to the GUSTO study classification (mild, moderate or severe); c) the presence of complications (AMI, death, emergency revascularization of the treated lesion, cerebrovascular accident, blood transfusion, loss of radial pulse, hand ischemia); and d) type of angiographic lesion (A, B_1, B_2, C), according to the American College of Cardiology and the American Heart Association, as modified by Ellis.

The collected data were reflected in a data collection sheet devised for the study. A database was created in the SPSS program version 11.5 and the information was organized in tables for easy interpretation. Frequency distributions, mean, confidence intervals and percentage calculations were used.

RESULTS

A predominance of males was observed, with 78.3% of all cases. The mean age of all patients was 62.2 years, while in women it was 61.4 years and 62.5 years in men (**Table 1**).

A higher incidence of smoking was found in men 44.0%, compared to 18.0% in women. The second most frequent PMH condition was the HT, for an incidence rate of 35.5% in men and 18.9% in women; a history of MI, dyslipidemia and diabetes were less commonly found (**Table 2**).

Only 6 cases of mild bleeding, in the form of hematoma in the access site, were found, which accounted for 2.8% of all patients included in the study, 5 of the 170 men (2.9%) and only one (2.1%) of the 47 women

Table 1. Distribution of patients by sex and age.

Age groups (years)	Sex				Total	
	Female		Male			
	№	%	№	%	№	%
36 - 40	1	0.5	2	0.9	3	1.4
41 - 45	2	0.9	4	1.8	6	2.7
46 - 50	2	0.9	9	4.1	11	5.0
51 - 55	5	2.3	19	8.7	24	11.0
56 - 60	8	3.7	37	17.0	45	20.7
61 - 65	14	6.5	40	18.4	54	24.9
66 - 70	10	4.6	24	10.0	34	14.6
71 - 75	3	1.4	21	11.0	24	12.4
76 - 80	2	0.9	12	5.5	14	6.4
81 and over	0	0.0	2	0.9	2	0.9
Total	47	21.7	170	78.3	217	100

Table 2. Distribution by sex and past medical history (n=217).

Past medical history	Sex				Total	
	Female		Male			
	Nº	%	Nº	%	Nº	%
Smoking	39	18.0	97	44.7	136	62.7
History of AMI	24	11.0	41	18.9	65	29.9
HT	41	18.9	77	35.5	118	54.4
Dyslipidemia	30	13.8	35	16.1	65	29.9
Diabetes mellitus type 2	23	10.6	19	8.7	42	13.4

Table 3. Incidence of bleeding by sex.

Sex	Nº	%*	%**
Female	1	2.1	0.5
Male	5	2.9	2.3
Total	6	-	2.8

* Regarding the total of each sex (n=47, n=170)
** Regarding the total number of patients (n=217)

Table 4. Bleeding by type of lesion.

Type of lesion	Nº	%	Bleeding		p	95% CI	
			Nº	%		From	To
A	23	9.8	1	0.4	0.624	6.0	13.6
B_1	61	26.0	0	0.0	0.120	20.2	31.8
B_2	91	39.0	2	0.8	0.665	32.5	45.5
C	59	25.2	3	1.3	0.203	19.4	31.0
Total	234	100	6	2.5	-	-	-

IC: Confidence Interval

Table 5. Bleeding by other complications.

Other complications	Nº	%	Bleeding		p	Total	
			Nº	%		Nº	%
Myocardial infarction	2	0.9	0	0.0	0.811	2	0.9
Loss of radial pulse	9	4.1	2	0.9	<0.001	11	5.0
None	200	92.2	4	1.8	<0.001	204	94.0
Total	211	97.2	6	2.8	-	217	100

(**Table 3**).

A total of 234 lesions were treated. Type B_2 were the most frequent ones (39.0%); however, there was a higher frequency of bleeding in type C lesions (**Table 4**), with an incidence of 1.3%. The chi-square test, with a 95% confidence interval, established that the bleeding was not related to the type of lesion.

There were 2 cases of nonfatal AMI and 9 cases with loss of radial pulse without causing hand ischemia (**Table 5**). There was no incidence of other complications (death, emergency revascularization of the treated lesion, cerebrovascular accident, or need for blood transfusion). There was a statistical significance (p<0.001) when bleeding was related with the absence of complications and the loss of radial pulse.

DISCUSSION

The average age in our study behaved similarly to that observed in the literature reviewed, which ranges from 63.2 years to 65.0 years[2,5,8,14].

With regard to sex, various publications report a percentage of women between 17.0 and 33.0%[2,4,8]. In a study assessing the use of heparin vs. bivalirudin for ACS, 80.0% of patients who were treated with radial approach were men[9]. It is possible that the low incidence of women in these studies is influenced by the fact that they tend to have smaller arteries, making it difficult to proceed through this way[4].

With respect to PMH, an Italian study shows a higher prevalence of smokers and hypertensive patients[9]. A report from the National Cardiovascular Data Registry of New York and a Canadian study show that the PMH conditions more commonly found were HT

and dislipidemia[8,15]. Also, a Mexican study shows a predominance of smoking and DM, with 60.0% respectively, followed by HT with a 50.0% prevalence[2]. Rao *et al*[14], in the United States, also found a prevalence of hypertension in 78.0% of cases.

There is consensus in general literature when considering that the incidence of bleeding associated with the PCI is reduced with the use of the radial approach, hence it is the access site where this complication is most commonly seen[16]. Even in ACS, the persistence of complications as bleeding varies from local superficial hematomas (<5.0%) to compartment syndrome (0.01%)[17]. Because angiographic results are comparable to those of the femoral approach, some authors have suggested that the radial approach should be the most suitable access route for PCI[18]. In a publication from the Hermanos Ameijeiras Hospital, the center that pioneered this approach in Cuba, the absence of major bleeding in the group of patients with radial access was confirmed[12]. Meanwhile the incidence of hematoma at the access site was limited to 0.58% of those studied by the Brueck *et al*[5], without any case of major bleeding. Chow *et al*[19] did not found either major bleeding in their selection of patients with ACS.

Complex lesions may be associated with increased risk of bleeding due to the possible use of larger catheters and the need for more anticoagulation. However, the evidence regarding the effectiveness and safety of the radial approach in these lesions is still scarce[20,21]. Roberts *et al*[22], presented in their sample more than 80.0% of cases with type B_2 and type C lesions without reporting significant incidence of bleeding. Rathore *et al*[20] and Wu *et al*[21], did not report any association between bleeding and the treatment of lesions with total occlusion; the same as Almeida *et al*[12].

It is universally accepted that the presence of major bleeding (moderate or severe, according to GUSTO[23]) is associated with an increased risk of death and morbidity[5,6,9,14,16]. It is considered that the absence of major bleeding in our study was the cause of the low incidence of associated cardiovascular complications. Radial pulse loss in patients with bleeding is justified by a possible larger damage to the vessel, as well as the vascular compromise produced by the hematoma, with a current incidence of 9.0% according to some authors[24].

CONCLUSIONS

Patients who underwent coronary catheterization by radial approach at the CIMEQ showed a low incidence of hematoma at the site of access and a favorable clinical outcome, without serious associated complications. The results of our study are consistent with the trend shown by the current evidence, which supports the radial approach as an effective and safe technique for patients who undergo PCI.

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