Clinical-epidemiological profile of health users who have undergone a Percutaneous Coronary Intervention

Perfil clínico-epidemiológico de usuários de saúde submetidos à Intervenção Coronária Percutânea

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ABSTRACT

Background: Coronary artery disease represents the condition with the highest prevalence worldwide. The treatment of this disease is through Percutaneous Coronary Intervention (PCI). **Aiming:** To outline the clinical epidemiological profile of health users who have undergone PCI, in a Hospital in the state of Rio Grande do Sul. **Methods:** Exploratory research, with a quantitative approach carried out on 188 medical records of health users who were submitted to elective or emergency PCI, with the use of stents or not in the year 2018. Values of p <0.05 represented significant statistical differences. **Results:** Users with a diagnosis of unstable angina (n = 16; 17.8%), diagnostic symptoms of unstable angina (n = 61; 67.8%) and a diagnosis of angina pectoris (n = 52; 57.8%) presented significantly more likely to be submitted to the PCI in elective way (p <0.001). Users diagnosed with Acute Myocardial Infarction - AMI (n = 59; 60.2%) and symptoms with evolution greater than 24 hours (n = 30; 30.6%) and less than 24 hours (n = 24; 24.5%), with dyslipidemia (n = 38; 38.8%) and who underwent catheterization on the same day (n = 87; 88.8%) are significantly more likely to perform emergency surgery (p <0.05). In addition, the data showed that the diagnosis of unstable angina potentiates new cardiomyopathies (n = 9, 47.4%; p <0.001) and restenosis (n = 5; 26.3%; p = 0.002). **Conclusion:** It is necessary to create strategies to strengthen the Health Care Network (HCN) with actions for prevention, promotion and rehabilitation to health, aiming quality in diagnosis, treatment and rehabilitation.

Keywords: Percutaneous coronary intervention, Cardiovascular diseases, Angioplasty.

RESUMO

Introdução: A doença arterial coronariana representa a afecção de maior prevalência mundial. O tratamento desta doença se dá pela intervenção coronária percutânea (ICP). **Objetivo:** Delinear o perfil clínico-epidemiológico dos usuários de saúde submetidos à ICP em um Hospital do estado do Rio Grande do Sul. **Métodos:** Pesquisa exploratória, de abordagem quantitativa realizada em 188 prontuários de usuários de saúde submetidos à ICP eletiva ou de urgência com uso de stent ou não no ano de 2018. Valores de p< 0,05 representaram diferenças estatísticas significativas. **Resultados:** Usuários com diagnóstico de angina instável (n=16; 17,8%), sintomas diagnósticos de angina instável (n= 61; 67,8%) e diagnóstico de angina pectoris (n=52; 57,8%) apresentaram significativamente maior probabilidade de serem submetidos à ICP em caráter eletivo (p<0,001). Usuários com diagnóstico para infarto agudo do miocárdio (n=59; 60,2%) e sintomatologia com evolução maior que 24 horas (n=30; 30,6%) e menor que 24 horas (n=24; 24,5%), com dislipidemia (n=38; 38,8%) e que fizeram cateterismo no mesmo dia (n=87; 88,8%) são significativamente mais propensos a realizar cirurgia de urgência (p<0,05). Além disso, os dados evidenciaram que o diagnóstico de angina instável potencializa novas cardiomiopatias (n=9, 47,4%; p<0,001) e reestenose (n=5; 26,3%; p= 0,002). **Conclusão:** É necessário criar estratégias para fortalecer a Rede de Atenção à Saúde (RAS) com ações de prevenção, promoção e reabilitação à saúde, visando a qualidade no diagnóstico, tratamento e reabilitação.

Palavras-Chave: Intervenção coronária percutânea, Doenças cardiovasculares, Angioplastia.

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BACKGROUND

Cardiovascular diseases (CVD) are the main causes of death, with the Southeast and South regions being responsible for the highest rates nationwide[1,2]. Among the CVD, coronary artery disease (CAD) stands out as the most prevalent disease worldwide[3]. The treatment of CAD is based on optimized clinical treatment and percutaneous or surgical myocardial revascularization[4]. Percutaneous coronary intervention (PCI) is indicated according to the individual's health context, interventionists' expertise, availability of resources and supplies to perform the procedure, as well as aspects such as myocardial feasibility, surgical risk and PCI complexity.

Although these diseases are preventable, mainly through the articulation proposed by the Health Care Network (HCN), it is understood that there is a need to identify the profile of health users undergoing PCI to assist in the implementation of prevention strategies for health problems and health promotion at the three levels of health care.

Therefore, the aim of this study is to outline the clinical and epidemiological profile of health users undergoing percutaneous coronary intervention at a Hospital in the West Frontier of Rio Grande do Sul.

METHODS

It is a documentary, retrospective and exploratory research with a quantitative approach, carried out in the medical records of a Hospital on the West Frontier of Rio Grande do Sul. Until 2018, the Institute of Cardiology had elective and emergency care, open 24 hours a day, linked to the 10th Regional Health Coordination. The service provided assistance via the Unified Health System (SUS), a private and municipal agreement, covering an area of approximately 431 thousand inhabitants.

The sample size was based on the daily record book of interventions identified by the service. Based on the number of procedures performed, the sample calculation was performed, with a tolerable error of 5%, reaching a sample of 188 health users.

The collection took place between the months of May and October 2020 at the Medical Archive and Statistics Service (SAME). The collection instrument developed by the researchers included the variables sociodemographic data; comorbidities and previous symptoms; diagnostic characteristics of coronary angiography and PCI data.

Medical records of health users undergoing elective or emergency PCI with stent implantation or not, from January to December 2018, were included in the sample of coronary angiography.

For analysis, the data were categorized in an Excel spreadsheet and the Statistical Package for Social Sciences (SPSS) version 21.0 for Windows was used. Quantitative variables were described as mean and standard deviation and categorical variables as absolute and relative frequencies. To compare means, Student t-tests or one-way Analysis of Variance (ANOVA) were applied.

To assess the association between categorical variables, Pearson's chi-square test or Fisher's exact test were used. In the case of polytomous variables, the adjusted residual analysis was applied to locate the statistically significant associations. The significance level adopted was 5% ($p < 0.05$).

As for ethical aspects, the research received a favorable opinion from the Research Ethics Committee of the Federal University of Pampa (Certificate of Presentation of Ethical Appreciation nº 32904820.0.0000.5323 and Consubstantiated Opinion nº 4.193.034).

RESULTS

The study sample consisted of 188 health users undergoing PCI, on an elective (n=90; 47.9%) and urgent (n=98; 52.1%) basis. The sample was for males (n=128; 68.1%), with a mean age of 62.5 years-old (SD: 10.79), married marital status (n=78; 41.5%) and white race (n=155; 82.4%). The highest frequency of PCI was in January (n=30; 16.0%) and July (n=33; 17.6%). The sociodemographic characteristics of health users are described in table 1.

Regarding the symptoms and clinical characteristics presented for performing PCI, the typical picture of unstable angina stands out (n=102; 54.3%), followed by acute myocardial infarction with an evolution greater than 24 hours (n=42 ; 22.3%) and acute myocardial infarction with an evolution of less than 24 hours (n=32; 17.0%).

Table 2 shows that healthcare users with International Classification of Diseases (ICD) and diagnostic symptoms of unstable angina and ICD of angina pectoris were significantly more likely to undergo elective interventions.

Table 1. Sociodemographic characteristics of health users undergoing percutaneous coronary intervention in 2018.

Variables	Total PCI (n=188)	Elective PCI (n=90)	Urgency PCI (n=98)	p
Age (years) - average ± SD*	62.5 ± 10.7	62.4 ± 11.4	62.7± 10.1	0.862
Sex				0.385
Male	128 (68.1)	58 (64.4)	70 (71.4)	
Female	60 (31.9)	32 (35.6)	28 (28.6)	
Age group				
34 – 40	4 (2.1)	2 (2.2)	2 (2.0)	
41 – 50	22 (11.7)	13 (14.4)	9 (9.2)	
51 – 60	53 (28.2)	25 (27.8)	28 (28.6)	
61 – 70	68 (36.2)	28 (31.1)	40 (48.8)	
71 or older	41 (21.8)	22 (24.4)	19 (19.4)	
Color or race				0.811
White	155 (82.4)	74 (82.2)	81 (82.7)	
Parda	21 (11.2)	9 (10.0)	12 (12.2)	
Black	9 (4.8)	5 (5.6)	4 (4.1)	
Not registered	3 (1.6)	2 (2.2)	1 (1.0)	

SD = Standard Deviation ; PCI = Percutaneous Coronary Intervention; Source: Authors.

Table 2. Comorbidities and diagnostic symptoms of health users undergoing percutaneous coronary intervention in 2018.

Variables	Total PCI (%) (n=188)	Elective PCI (%) (n=90)	Urgency PCI (%) (n=98)	P
Previous comorbidities				
SAH	118 (62.8)	61 (67.8)	57 (58.2)	0.285
Previous AMI	54 (28.7)	28 (31.1)	26 (26.5)	0.595
DM	52 (27.7)	27 (30.0)	25 (25.5)	0.600
Cardiomyopathy	13 (6.9)	10 (11.1)	3 (3.1)	0.059
CHF	5 (2.7)	2 (2.2)	3 (3.1)	1.000
COPD	3 (1.6)	1 (1.1)	2 (2.0)	1.000
Dyslipidemia	57 (30.3)	19 (21.1)	38 (38.8)	0.013
Symptoms that led to coronary angiography				<0.001
Asymptomatic	8 (4.3)	6 (6.7)	2 (2.0)	
Unstable angina	102 (54.3)	61 (67.8)*	41 (41.8)	
Stable Angina	4 (2.1)	3 (3.3)	1 (1.0)	
AMI with evolution >24h	42 (22.3)	12 (13.3)	30 (30.6)*	
AMI with evolution <24h	32 (17.0)	8 (8.9)	24 (24.5)*	
ICD				<0.001
Unstable angina	19 (10.1)	16 (17.8)*	3 (3.1)	
AMI, not specified	78 (41.5)	19 (21.1)	59 (60.2)*	
Chronic ischemic heart disease	3 (1.6)	3 (3.3)	-	
Angina pectoris, unspecified	88 (46.8)	52 (57.8)*	36 (36.7)	
Coronary angiography				0.665
Single arterial	152 (80.9)	70 (77.8)	83 (84.7)	
Double arterial	24 (12.8)	14 (15.6)	10 (10.2)	
Triple arterial	6 (3.2)	3 (3.3)	3 (3.1)	
Total obstruction of the left coronary trunk	6 (3.2)	4 (4.4)	2 (2.0)	
Coronary angiography followed by PCI	126 (67.0)	39 (43.3)	87 (88.8%)	<0.001
Biased arteries				0.200
Anterior Descending Artery	103 (54.8)	49 (54.4)	54 (55.1)	
Right Coronary Artery	50 (26.6)	19 (21.1)	31 (31.6)	
Circumflex Artery	25 (13.3)	16 (17.8)	9 (9.2)	
Marginal Artery	5 (2.7)	2 (2.2)	3 (3.1)	
Diagonal Artery	2 (1.1)	2 (2.2)	-	
Left Coronary Trunk (LCT)	3 (1.6)	2 (2.2)	1 (1.0)	
Restenose	13 (6.9)	8 (8.9)	5 (5.1)	0.463
Type of stent				0.479
Pharmacological	130 (64.9)	60 (66.7)	70 (71.4)	
Conventional	53 (28.2)	28 (31.1)	25 (25.5)	

* Statistically significant association by the residual test adjusted to 5% significance; PCI = Percutaneous Coronary Intervention, AMI = Acute Myocardial Infarction; SAH=Systolic Arterial Hypertension; DM=Diabetes Mellitus; CVA =Cerebral Vascular Accident; ICC= Congestive Heart Failure; COPD=Chronic Obstructive Pulmonary Disease; ICD=International Classification of Diseases, available at: https://www.cid10.com.br/code. Source: Authors.

However, healthcare users with unspecified ICD of AMI, who have dyslipidemia, with diagnostic symptoms of AMI and who underwent catheterization on the same day are significantly more likely to undergo emergency surgery, which corresponds to a time of less than 24 hours after diagnosis. More than half of healthcare users underwent cardiac catheterization as a diagnostic intervention on the same day, followed by angioplasty as a method of clinical treatment.

Table 3 identifies that the use of three stents or balloon had significantly more total left coronary artery trunk (LCAT) obstruction and major arteries involved.

The associations of the study variables and the diagnostic ICD are shown in table 4. It is observed that healthcare users diagnosed with unstable angina have significantly more ischemic cardiomyopathy and restenosis.

Healthcare users with unspecified AMI have significantly more dyslipidemia and underwent catheterization on the same day as angioplasty.

Table 3. Stent implantation related to coronary angiography in users undergoing percutaneous coronary intervention in 2018.

Variables	One stent (n=175)	Three stent (n=8)	Baloon (n=5)	p
Coronary angiography – n (%)				0.013
Single arterial	143 (81.7)	6 (75.0)	4 (80.0)	
Double arterial	24 (13.7)	-	-	
Triple arterial	6 (3.4)	1 (12.5)	-	
Total Obstruction of the Left Coronary Trunk	2 (1.1)	1 (12.5)*	1 (20.0)*	
Compromised arteries – n (%)				<0.008
Left Coronary Trunk	1 (0.6)	1 (12.5)*	1 (20.0)*	
Circumflex Artery	25 (14.3)	-	-	
Anterior Descending Artery	98 (56.0)	4 (50.0)	1 (20.0)	
Right Coronary Artery	44 (25.1)	3 (37.5)	3 (60.0)	
Diagonal Artery	2 (1.1)	-	-	
Marginal Artery	5 (2.9)	-	-	

* Statistically significant association by the residual test adjusted to 5% significance.
Source: Autores.

Table 4. Association of variables with diagnostic ICD.

Variables	Unstable Angina (n=19)	AMI NS (n=78)	Ischemic Disease (n=3)	Angina pectoris NS (n=88)	p
Age (years) – average ± SD	66.8 ± 11.0	61.3 ± 11.6	68.0 ± 7.0	62.5 ± 9.7	0.193
Comorbidades prévias					
AMI	2 (10.5)	24 (30.8)	2 (66.7)	26 (29.5)	0.147
SAH	14 (73.7)	49 (62.8)	3 (100)	53 (60.2)	0.394
DM	8 (42.1)	22 (28.2)	1 (33.3)	21 (23.9)	0.444
CVA	-	1 (1.3)	-	-	0.701
CHF	1 (5.3)	3 (3.8)	-	1 (1.1)	0.617
Ischemic Cardiomyopathy	9 (47.4)*	2 (2.6)	-	2 (2.3)	<0.001
COPD	0 (0.0)	3 (3.8)	-	0 (0.0)	0.231
Obesity	1 (5.3)	2 (2.6)	-	2 (2.3)	0.889
Dyslipidemia	1 (5.3)	43 (55.1)*	-	13 (14.8)	<0.001
Coronary angiography followed by PCI – n (%)	10 (52.6)	71 (91.0)*	-	45 (51.1)	<0.001
Restenosis – n (%)	5 (26.3)*	1 (1.3)	-	7 (8.0)	0.002

* Statistically significant association by the residual test adjusted to 5% significance; NE= Not Specified; PCI = Percutaneous Coronary Intervention, AMI = Acute Myocardial Infarction; SAH=Systolic Arterial Hypertension; DM=Diabetes Mellitus; CVA =Cerebral Vascular Accident; CHF= Congestive Heart Failure; COPD=Chronic Obstructive Pulmonary Disease; ICD =International Classification of Diseases, available at: https://www.cid10.com.br/code.
Source: Authors.

DISCUSSION

The clinical and epidemiological characteristics of health users undergoing PCI in this study are in line with another survey conducted in the state of Rio Grande do Sul (RS) which identified a prevalence of males (n=142; 71.0%), with average age of 65.2 years-old (SD: 10.10), with a prevalence of comorbidities such as SAH (n=162; 81.0%) and DM (n=62; 31.0%) [4].

Such similarity was found in another study carried out in the Northeast region of the country, in a referral hospital for cardiac emergencies with 222 health users undergoing PCI. The characteristics identified were men (n= 145; 65.3%), with a mean age of 62.7 years-old, married (n=142; 64%), diagnosed with SAH (n= 178; 80.2%), Previous AMI (n=91; 41.0%) and DM (n=85; 38.3%)[5]. Regarding the prevalence of dyslipidemia, a study on the survival of health users undergoing PCI in a sample of 169, 69.8% had this comorbidity[6].

The similarity between the studies demonstrates that regardless of the flow of care to referral hospitals for cardiovascular treatment, the characteristics of these health users demand lines of care and referral and counter-referral with regard to promotion, prevention, treatment and rehabilitation. Therefore, despite different territorial and epidemiological contexts, the studies trace the same line of predominant variables in relation to clinical and epidemiological characteristics.

The prevalence of men who require cardiac intervention is even more relevant when it is observed that more than half were submitted to emergency intervention, compared to females. The number of elective interventions among women may be linked to the protection provided by the hormone estradiol until menopause[5,7]. Another protective factor is the preventive and continuous health maintenance carried out by the female population in relation to the male population.

The higher prevalence of PCI in the months of January and July can be explained, in part, by the extreme temperature of the city, where the study was carried out. Patients with Acute Coronary Syndrome (ACS) have a higher number of hospitalizations, worse angiographic results and risk of cardiac mortality when admitted during the winter[8].

Very low or very high temperatures are potential risk factors for cardiovascular mortality, given the body temperature regulating mechanism that promotes vasoconstriction and peripheral vasodilation, respectively.

Other mechanisms that give rise to these changes during temperature extremes involve the increase in systemic blood pressure, increased blood viscosity and cholesterol levels, as well as the exacerbation of the cardiovascular system due to respiratory infections[9].

PCI is primarily used in the treatment of coronary lesions due to effective clearance through dilation or a percutaneous device. Its effectiveness is linked to the indications for performing the procedure, which include treatment of the left coronary artery trunk (LCAT), complete revascularization in patients with multi-vessel involvement, and PCI immediately after the coronary angiography.

Furthermore, the implantation of drug-eluting or conventional stents reduces the acute and late complications of PCI for the treatment of simple to complex coronary lesions[10] when it is compared to the use of balloon catheters, even in the treatment of restenosis lesions[11].

The high percentage of stent implants at the site of this study confirms that it is an accurate and highly effective technique in the treatment, mainly because it identifies a low percentage of complications arising from the use of stents, such as restenosis. However, it should be noted that the quality of service provision can be associated, in part, with professional qualification, provision and organization of materials and supplies.

The door-to-balloon time is defined by the period between the arrival of healthcare users at the hospital until the beginning of the angioplasty procedure[11], which must be less than 90 minutes or up to 120 minutes when there is a need for transfer to the hemodynamic service[12]. For its implementation in clinical practice, researchers instituted a protocol that reduced the door-to-balloon time from 142 ± 78 minutes in the first 10 health users, followed by 150 ± 50 minutes, 131 ± 37 minutes and, finally, 116 ± 29 minutes[13]. Such improvements to the health of the population prove that the implementation of a care and institutional protocol is necessary to reduce cardiac ischemia rates.

In the meantime, it is necessary to implement a care protocol articulated with the Health Care Network (HCN) that respects the door-to-balloon time in order to minimize the delay in clinical diagnosis, failures in the articulation between the various points of the HCN and reduction of time lost due to distance from the reference hemodynamics service to the region. The allusion to implementation in the city, where the study was conducted, is linked to the identification that of the 30 health users who underwent urgent PCI due to a diagnosis of AMI with an evolution greater than 24 hours, only 12 lived in the city of the hemodynamic service.

A cohort study, comparing transferred healthcare users and healthcare users admitted by spontaneous demand for PCI, showed that transferred healthcare users have increased ischemia time and late initiation of coronary artery bypass graft treatment[14]. Early treatment indicates better structures with regard to referral and counter-referral, accessibility to health, reduction of bureaucracy by the regulation center and effectiveness of services.

A high percentage of urgent interventions for catheterization followed by PCI and elective coronary angiography followed by PCI were identified. The performance of diagnostic cardiac catheterization and PCI in the same procedure (ad hoc PCI) has shown advantages such as reduced hospital costs, patient safety, reduction of vascular complications and radiation rate. Ad hoc PCI is as safe and effective as staged PCI in patients with stable angina, and is associated with a significantly lower rate of bleeding complications related to vascular access [15]. However, it can still be justified that decision-making is related to the service's referral to the Unified Health System (SUS) with the 10th Regional Health Coordination.

The identification of an angina association, whether unstable or unspecified, demonstrates that its symptoms are unspecific to guide decision-making, whether urgent or elective intervention. Thus, it is inferred that its symptoms can be quickly controlled by drugs and its prognosis taken electively, as shown in the study. In contrast, there was the use of three stents for angina pectoris, which was significant for the treatment of LCAT and the use of a balloon catheter.

This data demonstrates that angina pectoris can be a serious disease, and it is up to health professionals to value its symptoms, even if treated electively. The association between the use of two to three stents, or the use of balloons to treat total obstruction of LCAT stands out, corroborating another study that identifies complex anatomical patterns[16] in lesions of the left coronary artery trunk, with an average of 2.4 stents per patient[17].

Another inference about decision-making based on a clinical diagnosis of angina is the flow of care needed to manage the disease. The diagnosis of angina can be previously identified through tests available in the HCN and treated by professionals in primary health care. Thus, it is important to emphasize that the decision-making of professionals to treat angina electively is linked to the user's symptoms and the diagnostic flow in the HCN.

Corroborating this, the study identified that angina can be diagnosed in a timely manner for an elective intervention. However, the presence of preexisting cardiomyopathies in healthcare users enhances new cardiac events, which may partially explain the correlation with unstable angina.

Chronic ischemic diseases significantly identified in asymptomatic healthcare users may correspond to the presence of collateral coronary circulation, which leads to silent occlusions. A study demonstrates that the presence of collateral circulation coexisting with coronary circulation results in myocardial tissue perfusion acceptable to muscle demand, highlighting the fundamental role of collateral circulation in the survival of these users[18]. Such evidence can support the average age of health users.

AMI has symptoms that destabilize the clinical condition of health users, who must be led to urgent interventions as identified in the study. Its treatment requires emergency actions to reduce necrotic ischemic tissue damage, leading to severe complications of myocardial contractility[18]. This corroborates the absence of urgent interventions for chronic ischemic heart disease.

The sudden picture caused by AMI with a significant association with dyslipidemia is justified. Atherosclerosis is a chronic inflammatory disease of multifactorial origin, which occurs in response to endothelial aggression, mainly affecting the intima layer of the arteries due to several risk factors, such as dyslipidemia and arterial hypertension[20]. Related to the atherosclerotic event, previous comorbidities are significantly associated with myocardial infarction. This confirms that the healthcare user diagnosed with dyslipidemia associated with at least one risk factor is statistically predisposed to AMI and to performing urgent PCI.

The study identified a significant relationship between the diagnosis of unstable angina and a high percentage of restenosis. This fact is due to the pattern of obstruction of these stents, since the atheromatous plaque reduces myocardial blood flow, leading to anginal pain[21]. This corroborates the finding of the study in which the procedure is performed electively, as the health user notices the recurrence of symptoms and has sufficient time to seek medical help.

As for the diagnostic symptoms, the study proved the accuracy of the identification of signs and symptoms through correct medical diagnosis, justifying that the service is prepared to receive health users urgently or not with regard to cardiovascular manifestations.

This study has limitations because it is documentary, carried out in a single center and has a limited sample of health users. It was also evidenced a large amount of incomplete and/or non-existent information from the data in the medical records for the analysis of the clinical and epidemiological characteristics, which would be crucial to reach more detailed objectives.

The findings of this research have the potential to contribute to the development of guidelines that can direct care and promote the development of care protocols. Therefore, we note the importance of continuing to analyze the clinical and epidemiological characteristics of health users undergoing PCI, thus contributing to the quality of care provided.

The results of this study made it possible to identify the main clinical and epidemiological characteristics associated with coronary diseases that require PCI, in addition to contributing to a reflection on the importance of the care provided by the multidisciplinary team in the HCN, especially the multidisciplinary team, in the prevention and control of health problems.

Data demonstrate that preexisting diseases such as dyslipidemia are risk factors for unspecified AMI, which require urgent interventions, while angina increases complications such as restenosis and recurrence of new ischemic heart diseases. However, it is evident that angina, pectoris or unstable, can be diagnosed and stabilized to be later treated in an elective intervention.

The study can contribute to subsidize the care and management practice of the service, but mainly in the creation of strategies to strengthen the HCN, providing prevention, promotion and health rehabilitation actions, aiming at quality in diagnosis, treatment and rehabilitation.

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1. Contribuição substancial no esboço do estudo ou na interpretação dos dados: JPSA, DAE, LDL e AKSRT

2. Participação na redação da versão preliminar: JPSA, LDL, PEBF e LGO

3. Participação na revisão e aprovação da versão final: AKSRT, LDL e PEBF

4. Conformidade em ser responsável pela exatidão ou integridade de qualquer parte do estudo: LDL e JPSA

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