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Complications of Tenecteplase in pre-hospital care for treatment of acute myocardial infarction

Complicações do uso pré-hospitalar da Tenecteplase para tratamento do Infarto Agudo do Miocárdio com Supradesnivelamento do Segmento ST

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ABSTRACT

The main objective of STEMI treatment is myocardial reperfusion, although FT is a viable and efficient option, it has possible complications like any other medication. The objective of this article to analyze the complications of the pre-hospital use of Tenecteplase for the treatment of Acute Myocardial Infarction. Was performed a study cross-sectional study, carried out in the Mobile Emergency Care Services and Emergency Care Units, with data analyzed by descriptive and inferential statistics. Fifty-three (53) medical records of patients with acute myocardial infarction who used Tenecteplase were analyzed. The use of the medication within 3 hours after the onset of symptoms decreased mortality and provided clinical improvement. Outcomes without clinical improvement were associated with time to onset of use greater than 3 hours. Tenecteplase was an effective therapy when administered within the first 3 hours from the onset of symptoms. However, it was evidenced that hemorrhagic risks are possible, but depended on the dose of fibrinolytic administered, the pharmacological therapy used and the clinical condition of the population studied.

Keywords: ST-segment Elevation Myocardial Infarction; Tenecteplase; Pre-Hospital Care; Fibrinolytic; Emergency Medical Services

RESUMO

O principal objetivo do tratamento do IAMCST é a reperfusão miocárdica, embora o FT seja uma opção viável e eficiente, ele tem possíveis complicações como qualquer outro medicamento. O objetivo deste artigo é analisar as complicações do uso pré-hospitalar de Tenecteplase para o tratamento do Infarto Agudo do Miocárdio. Foi realizado um estudo transversal, nos Serviços de Atendimento Móvel de Emergência e Unidades de Atendimento de Emergência, com dados analisados por estatísticas descritivas e inferenciais. Cinquenta e três (53) prontuários médicos de pacientes com infarto agudo do miocárdio que utilizaram Tenecteplase foram analisados. O uso do medicamento dentro de 3 horas após o início dos sintomas reduziu a mortalidade e proporcionou melhora clínica. Resultados sem melhora clínica foram associados ao tempo de início de uso superior a 3 horas. A Tenecteplase foi uma terapia eficaz quando administrada dentro das primeiras 3 horas do início dos sintomas. No entanto, ficou evidente que os riscos hemorrágicos são possíveis, mas dependem da dose de fibrinolítico administrada, da terapia farmacológica utilizada e da condição clínica da população estudada.

Palavras-chave: Infarto do Miocárdio com Supradesnível do Segmento ST; Tenecteplase; Assistência Pré-Hospitalar; Fibrinolíticos; Serviços Médicos de Urgência.

INTRODUCTION

Coronary Artery Disease (CAD) is defined as the process of accumulation of atherosclerotic plaques in the epicardial arteries and Acute Coronary Syndromes (ACS) are one of the several clinical presentations found in CAD cases. ACS is characterized as episodes that can vary between cardiorespiratory arrest and electrical or hemodynamic instability with cardiogenic shock (KNUUTI et al., 2019; ROFFI et al., 2016). Unlike ACS, Chronic Coronary Syndromes (CCS) include symptomatic and asymptomatic patients with stabilized symptoms, who present angina symptoms and/or dyspnea, patients with onset of heart failure and patients with angina, that is, when these cases are destabilized, the patient progresses to an acute condition of CAD to ACS (KNUUTI et al., 2019). Acute Myocardial Infarction (AMI) is defined as the necrosis of cardiomyocytes accompanied by a consistent condition of acute myocardial ischemia (ROFFI et al., 2016; THYGESEN et al., 2019; COLLET et al., 2021).

Myocardial ischemia occurs due to rupture or fissure of a fibroatheroma, where consequently there is interruption of blood flow in the tissue and consequent muscle tissue necrosis. The extent of the lesion will depend on the time elapsed between the onset of symptoms and the start of treatment. ST-segment elevation acute myocardial infarction (STEMI) is commonly related to the presence of a fully occlusive thrombus, unlike non-ST-segment elevation ACS (NSTE-ACS), which mostly have a partially occlusive thrombus (BAGAI et al., 2014).

According to the 2018 Global Burden of Disease Study (GBD), cardiovascular diseases (CVDs) were considered the leading causes of death globally. In 2017, about 17.8 million deaths were recorded worldwide, which corresponds to 330 million years of life lost and 35.6 million years living with disability (GBD, 2018; GBD, 2018).

In Brazil, Chronic Noncommunicable Diseases (CNCDs) resulted in 72% of total deaths in the country, with 30% of these caused by CVD (NASCIMENTO et al., 2018; GBD et al., 2018). According to GBD estimates, among CVD, the leading cause of death in Brazil between 1996 and 2017 was ischemic heart disease (IHD), when in 2017 it was the leading cause of death in all Brazilian states (NASCIMENTO et al., 2018). In the Northeast region of the country, in 2017, CVD accounted for 27.2% of total deaths, with 32.2% caused by IHD. The state of Rio Grande do Norte leads the statistical data in the region, with 38.9% of deaths caused by IHD (OLIVEIRA et al., 2020; DATASUS, 2019).

The main objective of STEMI treatment is myocardial reperfusion, which can be performed through Primary Percutaneous Coronary Intervention (PPCI). This type of procedure is considered the gold standard for these cases because it is associated with better success rates, higher frequency of complete reperfusion, lower incidence of re-infarction, death and recurrent ischemia (OLIVEIRA et al., 2021; PIEGAS et al., 2015; WEAVER et al., 1997). On the other hand, there is the high cost of the procedure and its limited access by a large part of the Brazilian population. Thus, an alternative has been shown to be effective, especially if administered within the first 120 minutes of the onset of symptoms, through the use of fibrinolytic medications. Fibrinolytic Therapy (FT) is recommended in cases where access to PPCI is not possible within the first 2 hours from the diagnosis of STEMI (PINTO et al., 2011; IBANEZ et al., 2018).

FT is indicated within the first 12 hours from the onset of symptoms and targets fibrinolysis of the thrombus responsible for artery occlusion. The role of fibrinolytic in the pre-hospital care of patients with STEMI has been shown to be a key point for the final outcome. When FT was administered during pre-hospital care, it reduced early mortality by about 17% when compared to the beginning of treatment in the in-hospital service (IBANEZ et al., 2018; MORRISON et al., 2000).

Although FT is a viable and efficient option, it has possible complications like any other medication. Among the most common is the risk of hemorrhage, especially intracranial hemorrhage, considered to have the highest morbidity and mortality (BARUZZI; STEFANINI; MANZO, 2018). However, the use of Tenecteplase (TP), which is a type of fibrinolytic that has an affinity for fibrin, is associated with lower rates of blood transfusion and non-brain hemorrhagic complications (KUNADIAN; GIBSON, 2012; DALAL et al., 2013).

The risk of hemorrhage exists, however, it is not exclusively related to the use of FT, since adjuvant pharmacological treatment with antiplatelet and anticoagulant drugs are factors that increase the risk of bleeding. Although they are more frequent after FT, bleeding complications can also occur in patients undergoing PPCI (CÂMARA et al., 2020). A study conducted in 2011, with 199 patients diagnosed with STEMI who used TP, 97% of patients did not develop any type of vascular bleeding and only 3% developed such complications (GOMES JÚNIOR et al., 2012).

Hemorrhagic complications have been the most worrisome type of occurrence involving the treatment of STEMI, especially intracranial hemorrhage. A randomized study consisting of 1892 patients diagnosed with STEMI compared FT and PPCI at 30

days, and demonstrated that, despite being low, the rates of intracranial hemorrhagic stroke and ischemic stroke were more frequent among the fibrinolysis group (ARMSTRONG et al., 2013).

Therefore, the main objective of this article was to analyze the complications of the pre-hospital use of Tenecteplase for the treatment of Acute Myocardial Infarction.

METHODS

This is an individualized epidemiological, observational, descriptive and analytical study, carried out through a cross-sectional design built according to the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) tool, together with mobile pre-hospital services, called the Mobile Emergency Care Service (SAMU) and fixed services represented by three Emergency Care Units (ECU) of the capital of the Brazilian state of Rio Grande do Norte, Natal. In addition to pre-hospital services, data were also collected in eight hospital units referenced as gateways to the pre-hospital units analyzed.

The study population was composed of the medical records of patients treated by pre-hospital services with a medical diagnosis of STEMI, whose sample was extracted in a census among those who used FT as a therapeutic modality, specifically using the drug Tenecteplase.

We included patients of both sexes, aged ≥18 years and who used TP during pre-hospital care at the sites selected by the study and excluded those who did not have their records located, or those, when located, were incomplete or did not provide sufficient information to meet the objectives of this study.

The collection was carried out in two moments, the first with the extraction of information from the records or medical records of the consultations carried out by the SAMU or ECU listed for the study. In a second moment, the data were collected in the medical records of the hospital services doors of entry of the care.

The clinical outcomes of: clinical improvement and no clinical improvement were considered for this study. When improvement of the clinical picture or reversal of the signs and symptoms present on admission before the use of TP was identified, it was characterized as clinical improvement; when an AMI occurred up to 28 days after the care performed by the SAMU or ECU team and when there was registration by the medical or nursing team of death, it was considered as without clinical improvement.

Data were organized in spreadsheets using Microsoft Excel® software, imported for analysis using the Statistical Package for Social Sciences - SPSS® software version 20.0. To describe the variables and their distribution patterns, frequencies and measures of central tendency and dispersion were calculated using Fisher's Exact Test to compare patient characteristics with final outcomes. For all tests, a significance level of 0.05 was considered.

This study had its research protocol previously approved in its ethical and methodological aspects by the Research Ethics Committee of the Federal University of Rio Grande do Norte (UFRN) in accordance with Resolution number 466/12 of the National Health Council (NHC) of the Ministry of Health of Brazil (CAAE: 59963416.5.0000.5537).

RESULTS

In the period studied, a total of 96 records of care of patients with STEMI using TP were found in fixed and mobile pre-hospital care services. When searching the medical records of the patients treated and applying the inclusion and exclusion criteria, 53 cases were located, resulting in part from the limitation of the filing system, mainly in the ECUs.

All patients analyzed received TP as FT in pre-hospital care. In addition, drugs such as aspirin (96.2%), clopidogrel (88.7%), low molecular weight heparin - LMWH (69.8%), morphine (60.4%), isordil (50.9%), captopril (24.5%), among others, were used as pharmacological treatment in the first visit, in addition to the use of oxygen (47.2%).

As comorbidities or lifestyle habits, 36 (67.9%) were hypertensive, 21 (39.6%) diabetic, 20 (37.7%) smokers, 17 (26.4%) sedentary, 10 (18.9%) alcoholics, 10 (18.9%) had coronary heart disease and eight (15.1%) dyslipidemias, among other conditions. The main symptoms at admission were chest pain in 44 (83%) cases, sweating in 19 (35.8%), dyspnea in 15 (28.3%) and hypertension in 10 (18.9%).

Among patients who received TP in pre-hospital services (n=53), 30 (56.6%) were referred and received treatment in hemodynamic services and 21 (39.6%) received only pre-hospital TP.

Table 1. Final outcome *versus* the main general characteristics of patients treated with ST Segment Elevation Acute Myocardial Infarction treated with Tenecteplase. Natal/RN, 2021 (n=47)

Variables	Clinical improvement n (%)	No clinical improvement n (%)	Total n (%)	$p^{\dagger}$
Sex				
Male	25(75.7)	08(24.2)	33(100)	0.956
Female	10(71.4)	04(28.5)	14(100)	
Age				
≤ 75 years	32(76.2)	10(23.8)	42(100)	0.808
> 75 years	03(60)	02(40)	05(100)	
Pre-hospital service				
SAMU	02(66.7)	01(33.3)	03(100)	0.937
ECU Esperança	18(75)	06(25)	24(100)	
ECU Potengi	04(66.6)	02(33.3)	06(100)	
ECU Pajuçara	11(78.6)	03(21.4)	14(100)	
Time symptom-gate*				
≤ 2 h	08(72.7)	03(27.2)	11(100)	0.736
> 2 h	15(71.4)	06(28.5)	21(100)	
Symptom-reperfusion time*				
< 3 h	04(100)	-	04(100)	0.449
3 - 6 h	07(70)	03(30)	10(100)	
> 6 h	07(70)	03(30)	10(100)	
Door-to-needle time*				
≤ 30 min.	03(75)	01(25)	04(100)	0.600
> 30min	24(77.4)	07(22.5)	31(100)	
Post-FT complication*				
No	25(92.6)	02(7.4)	27(100)	0.003
Yes	09(50)	09(50)	18(100)	

Key:*Some medical records did not present complete data records; † Fisher's Exact Test.

Among the medical records that contained information (n=47) on the general clinical outcome of the care of patients with STEMI who used TP, 35 (74.4%) presented clinical improvement and 12 (25.5%) did not obtain clinical improvement.

Of the sample analyzed, 38 (71.7%) patients were male, 38 (71.7%) were up to 65 years of age, with a mean age of 57.3 (±12.78) years and a median of 55 years of age. Most of them, 47 (88.7%) were attended in the ECU, with 6 (11.3%) of services provided by SAMU.

The mean time between the onset of pain and the administration of TP was 443.59 minutes (equivalent to approximately seven hours) and the mean time between the activation of the pre-hospital service and the administration of TP was 244.15 minutes (equivalent to four hours).

The main justifications in the medical records in which there were records for choosing the use of TP were the lack of vacancies in hemodynamics services in 06 (58.6%) cases, lack of vacancies in Intensive Care Units in 06 (58.6%), hemodynamics service without physician in 04 (19%), no contact with hemodynamics service in 02 (9.5%), among others.

Table 1 shows the relationships between the final outcomes. It was observed that when the symptom-reperfusion time was less than 3 hours, all patients showed clinical improvement.

Table 2. Characterization of the outcome clinical improvement of cases of patients with Acute Myocardial Infarction with ST-segment elevation using Tenecteplase. Natal/RN, 2021 (n=35).

Variables	n (%)
Reversal of precordial pain	24(68.6)
Sweating reversal	07(20)
Reversal of ST segment elevation	05(14.3)
Reversal of dyspnea	03(8.6)
Reversal of hypotension	02(5.7)
Reversal of nausea/emesis	02(5.7)
Reversal of hypertension	01(2.9)
Improvement of precordial pain	01(2.9)
Improvement of level of consciousness	01(2.9)

Legend:*Item admitted more than one answer.

In the pre-hospital, after fibrinolysis, data contained in 45 medical records indicated clinical improvement in 35 (77.8%) cases, electrocardiographic alteration in 08 (17.8%), death in 07 (15.6%), worsening of the clinical condition in 04 (8.9%), refractory AMI in 02 (4.4%) and maintenance of precordial pain in 01 (2.2%).

As the effectiveness of FT for this study was related to the final outcome, Table 2 presents the characterization of the outcome of clinical improvement after the use of TP.

The final outcome death was observed in 19.1% of patients, when 77.7% of these occurred in the pre-hospital environment. However, 57.1% of patients have already been admitted with signs of hemodynamic instability before the use of TP, with respiratory distress recorded in all of them.

Death was higher in women (28.5%) than in men (15.1%) or in the total population (19.1%). There was a higher frequency of deaths in women with Diabetes

Mellitus (DM) (53.3%) and Arterial Hypertension (80%) compared to men (34.2%) and (63.2%), respectively.

The death outcome was related to the delay in FT with a rate of 38.2% in the population with more than 3 hours between chest discomfort and FT. All patients in this study who were treated with TP in the period less than 3 hours reached the outcome of clinical improvement, which decreased proportionally when this interval was 3 to 6 hours and greater than 6 hours, with rates of 70% and 63.6%, respectively.

Table 3. Complications after use of Tenecteplase for treatment of Acute Myocardial Infarction with ST-Segment Elevation (n=53) *versus* adverse effects of Tenecteplase for treatment of Acute Myocardial Infarction with ST-Segment Elevation. Natal/RN, 2021 (n=18).

Complications after FT administration*	n (%)
None	31(60.78)
Lowering of the level of consciousness	08(15.7)
Respiratory failure	05(9.8)
Cardiorespiratory arrest	04(7.8)
Bradycardia	03(5.9)
Hypotension	03(5.9)
Acute lung edema	02(3.9)
Hematoma	02(3.9)
Oral bleeding	02(3.9)
Arrhythmia	01(1.9)
Cardiogenic shock	01(1.9)
Septic shock	01(1.9)
Hemoglobin decrease	01(1.9)
Dyspnea	01(1.9)
Epigastric pain	01(1.9)
Epistaxis	01(1.9)
Ecchymosis	01(1.9)
Hematuria	01(1.9)
Hemoptysis	01(1.9)
Hypoxia	01(1.9)
Need for blood transfusion	01(1.9)
Urethral bleeding	01(1.9)
Ventricular tachycardia	01(1.9)
Occurrences in hospital records*	**n (%)**
None	08(50)
Lowering of the level of consciousness	02(12.5)
Hematuria	01(6.2)
Cardiogenic shock	01(6.2)
Bradycardia	01(6.2)
Respiratory failure	01(6.2)
Septic shock	01(6.2)
Cardiorespiratory arrest	01(6.2)

Ecchymosis	01(6.2)
Urethral bleeding	01(6.2)
Acute edema	01(6.2)

Legend:*Item admitted more than one answer; some medical records (n=4) did not present complete data records.

Of the total number of patients who used TP, 60.78% did not have any type of complication and 15.7% presented alteration with lowering of the level of consciousness, however, the latter datum is only data suggestive of intracranial hemorrhage, since it cannot be affirmed that there was bleeding due to the absence of records of imaging tests that confirmed it (Table 3).

Hemorrhagic occurrences, although low, were identified. The hemorrhagic complications recorded after the administration of TP corresponded to 15.09% of the total complications, where according to the records 02 (13.25%) presented oral bleeding, 1 (6.62%) epistaxis, 1 (6.62%) ecchymosis, 1 (6.62%) hematuria, 1 (6.62%) hemoptysis, 1 (6.62%) required blood transfusion and 1 (6.62%) presented urethral bleeding. It is noteworthy that the item admitted more than one answer.

The analysis of occurrences in hospital records showed that 16.66% of occurrences were related to some type of bleeding, where 1 (6%) presented hematuria, 1 (6%) ecchymosis and 1 (6%) urethral bleeding, this item admitted more than one response.

When analyzing the complete medical records in relation to hospitalization, it was also possible to describe the complications and outcomes of the use of TP recorded in the hospital, according to table 3.

DISCUSSION

As a treatment modality, studies have shown that the use of fibrinolytic in patients with STEMI decreased early deaths by up to 17% if administered still in pre-hospital care, when compared to in-hospital care (MORRISON et al., 2000). The STrategic Reperfusion Early After Myocardial infarction (STREAM) study demonstrated that fibrinolysis performed during pre-hospital care followed by early PPCI obtained a similar result to the transfer to a primary PPCI in patients with STEMI who presented within 3 hours between the onset of symptoms, where it was not possible to perform primary PPCI within 1 hour (SINNAEVE et al., 2014; MADAN et al., 2015).

According to The GUSTO Investigators (1993), the fibrinolytic of choice should be that specific to fibrin, with emphasis on Tenecteplase as the safest in relation to the prevention of non-cerebral bleeding and blood transfusion, in addition to being more easily administered during pre-hospital care (VAN DE WERF et al., 1999).

According to the data, the number of records of care performed by the SAMU was lower than the number recorded by the ECU, this can be explained by the fact that the mobile service team usually waited for the patient to arrive at the hospital service for the administration of the fibrinolytic.

The shorter the time to STEMI treatment, the better the chances of myocardial recovery, with the time proportional to the extent of the myocardial injury, which can lead to a better clinical outcome when started in the first hours from the onset of symptoms (GIBSON, 2001).

Based on the data collected in this study, all patients received Tenecteplase associated with antiplatelet agents such as aspirin and clopidogrel, anticoagulant such as low molecular weight heparin - LMWH and analgesic such as morphine, among others, in addition to the use of oxygen. A study pointed to the adoption of the measures presented in this research, where TP was administered concomitantly with the use of antiplatelet agents, anticoagulants and analgesics for the treatment of AMI. Because it is selective and specific to fibrin, Tenecteplase allows a rapid effect and a longer action time, which allows it to be administered as a single bolus (PIEGAS et al., 2015).

Based on the sample analyzed, patients had a median symptom-door time of 180 minutes and an interval of 30 to 1,560 minutes. The symptom-perfusion time was 300 minutes, with an interval of 90 to 1,685 minutes and the door-to-needle time between the patient's first contact with the service and the TP was 160 minutes.

When dealing with the use of TP, the time factor is essential, it is known that the longer the time interval between the onset of symptoms and the administration of fibrinolytic agents, the greater the area of extension of the myocardial injury. With the establishment of the STEMI diagnosis, the administration of fibrinolytic agents within 10 minutes is recommended, which is determined based on the median time from randomization to the bolus recorded by the STREAM study, which was 9 minutes (ARMSTRONG et al., 2013).

Successful fibrinolysis does not rule out the performance of PPCI, since in these cases the patient must be transferred to a hemodynamic center for early PPCI, preferably between 2 to 24 hours after fibrinolysis (MADAN et al., 2015). In situations

where hemodynamic and electrical instability, chest pain and ischemia persist even after fibrinolytic administration, rescue PPCI is indicated (ARMSTRONG et al., 2013; GERSHLICK et al., 2005).

For this, it is essential that the mobile emergency team has the necessary resources to identify the STEMI and that it has at least one person from the team trained in advanced life support. Mobile emergency services are not only a means of transport, but a system that should be used to improve diagnosis, screening and treatment, with the possibility of early identification and treatment of STEMI (TERKELSEN et al., 2010; HUBER et al., 2005).

Hemorrhagic occurrences are the major concern when talking about FT, as they are the most frequent and severe secondary complications. However, FT is usually associated with drugs such as antiplatelet agents and anticoagulants, which makes the risk of bleeding a complication not exclusive to the use of fibrinolytic agents, but of the interaction of FT with other drugs used for the treatment of STEMI (CÂMARA et al., 2020).

Three systematic review studies compared the risks of bleeding between FT and PPCI, obtaining similar values between the bleeding rates of the two forms of treatment; However, with fibrinolysis, there were greater chances of intracranial bleeding (CÂMARA et al., 2020; BUNDHUN; JANOO; CHEN, 2016; ROULE et al., 2016).

According to the STREAM study, intracranial hemorrhage was more recurrent in patients over 75 years of age, which brought the need to reduce the dose of tenecteplase in that subgroup, which resulted in the absence of hemorrhagic occurrences in the study patients and reduced mortality (ARMSTRONG et al., 2013).

Complications such as respiratory failure, bradycardia, acute pulmonary edema, hypoxia, arrhythmia and septic shock may be observed. Patients with STEMI are considered severe and potentially severe and have risks of complications depending on the extent of the ischemia area, time between the onset of FT and the comorbidities presented, regardless of the use of fibrinolytic agents (CÂMARA et al., 2020). It is noteworthy that although these complications were present in the study, they are not exclusively related to the use of FT.

One patient in this study presented with cardiogenic shock at an interval of approximately 24 hours after fibrinolytic administration and progressed to death. Cardiogenic shock is still the most common cause of mortality in patients with STEMI regardless of the therapy used for treatment (HENRY et al., 2021).

When FT is initiated in the pre-hospital environment, there is a reduction in the chances of developing cardiogenic shock compared to PPCI. Based on the CAPTIM study, cardiogenic shock occurred in all cases when the patient underwent PPCI, which indicates that delayed initiation of treatment may increase the risks of complications (BONNEFOY et al., 2002). According to a systematic review of the literature, the risks of cardiogenic shock in patients undergoing PPCI are higher when compared to patients undergoing fibrinolysis (ROULE et al., 2016).

The limitation of this study is the lack of important data such as the patient's clinical condition, diagnosis, signs and symptoms of myocardial reperfusion, details about the clinical condition in the outcome of the unit, especially in the pre-hospital unit, and the absence of imaging tests to investigate the 15% of patients who had a lower level of consciousness.

CONCLUSION

Thus, this study followed the patients and their clinical outcomes, which made it possible to analyze that more than half of the patients did not present complications related to the use of FT, even without being in an Intensive Care Unit (ICU) with materials and resources to assist them.

It was demonstrated that patients aged ≤ 75 years had higher failure rates with the use of TP compared to individuals ≥ 75 years. In addition, the female group had a higher mortality rate compared to male individuals.

Therefore, it was possible to identify that in cases of STEMI, TP, when administered in a timely manner, can significantly decrease the chances of mortality. Although there is a risk of bleeding complications, this condition will also depend on the clinical picture presented by the patient and the pharmacological therapy chosen, which should be carefully analyzed with respect to the risk-benefit for each particular case.

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