

RESEARCH ARTICLE (ORIGINAL) 

Undesirable clinical events related to the administration of vasoactive amines: A cross-sectional study

Eventos clínicos indesejáveis relacionados com a administração de aminas: Estudo transversal

Eventos clínicos indeseables relacionados con la administración de aminas: Estudio transversal

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Abstract

Background: Identifying undesirable clinical events related to the administration of vasoactive amines is essential for patient safety, particularly in intensive care settings.

Objective: The general objective is to analyze the practices related to the administration of vasoactive amines. The specific objectives are to describe the administration of vasoactive amines and analyze the undesirable clinical events related to the administration of these drugs in critically ill patients.

Methodology: Quantitative, observational, cross-sectional study with a sample of 97 patients. The variables related to the administration of vasoactive amines and the records of undesirable clinical events were analyzed. Descriptive and inferential statistical analysis was performed.

Results: The frequency of use of norepinephrine was 70.1%, followed by dobutamine (29.9%). About 47.4% of amines were administered through the proximal lumen of the central venous catheter, while 12.4% were double-checked in the prescription. The undesirable clinical events were three-fold higher in patients monitored every 2 hours.

Conclusion: There is a failure in the monitoring of patients with prescribed amines and in the double checking of these drugs.

Keywords: critical care; nursing care; infusions, intravenous; patient safety; medication errors

Resumo

Enquadramento: Identificação de eventos clínicos indesejáveis relacionados com a administração de aminas é fundamental com vista à segurança dos doentes, particularmente em contexto de cuidados intensivos.

Objetivo: O estudo tem como objetivo geral investigar as práticas relacionadas com a administração de aminas vasoativas e como objetivos específicos descrever a administração de aminas e analisar os eventos clínicos indesejáveis relacionados com a administração destes fármacos em doentes críticos.

Metodologia: Estudo quantitativo observacional, transversal, amostra de 97 doentes. Investigaram-se as variáveis relacionadas com a administração das aminas e com os registos de eventos clínicos indesejáveis. Realizada análise estatística descritiva e inferencial.

Resultados: A noradrenalina obteve uma frequência de uso de (70,1%), seguida da dobutamina (29,9%). Cerca de 47,4% das doses foram administradas no lúmen proximal do cateter venoso central, enquanto que 12,4% foram duplamente confirmadas na prescrição. Evidenciou-se que os eventos clínicos indesejáveis foram três vezes maiores em doentes monitorizados a cada 2 horas.

Conclusão: Verifica-se uma falha na monitorização dos doentes com aminas prescritas, bem como na dupla confirmação destes fármacos.

Palavras-chave: cuidados críticos; cuidados de enfermagem; infusões intravenosas; segurança do paciente; erros de medicação

Resumen

Marco contextual: La identificación de eventos clínicos indeseables relacionados con la administración de aminas es fundamental para la seguridad de los pacientes, especialmente en los entornos de cuidados intensivos.

Objetivo: El estudio pretende investigar las prácticas relacionadas con la administración de aminas vasoactivas y tiene como objetivos específicos describir la administración de aminas y analizar los eventos clínicos indeseables relacionados con la administración de estos fármacos en pacientes críticos.

Metodología: Estudio observacional cuantitativo, transversal, muestra de 97 pacientes. Se investigaron las variables relacionadas con la administración de aminas y con el registro de eventos clínicos indeseables. Se realizó un análisis estadístico descriptivo e inferencial.

Resultados: La frecuencia de uso de la noradrenalina fue del 70,1%, seguida de la dobutamina (29,9%). Alrededor del 47,4% de las dosis se administraron en el lumen proximal del catéter venoso central, mientras que el 12,4% se confirmaron doblemente en la prescripción. Se comprobó que los eventos clínicos indeseables eran tres veces mayores en los pacientes monitorizados cada 2 horas.

Conclusión: Se observa una falta en la monitorización de los pacientes con aminas prescritas, así como en el doble control de estos fármacos.

Palabras clave: cuidados críticos; atención de enfermería; infusiones intravenosas; seguridad del paciente; errores de medicación



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Introduction

The complexity of the care provided to critically ill patients, particularly hemodynamically unstable patients, requires specialized human and material resources to ensure high-quality and safe care. Therefore, it is essential to intervene immediately in case of changes in the clinical status of critically ill patients to prevent adverse events (AEs; Pagnamenta et al., 2012).

In this context, and given the clinical and hemodynamic instability of critically ill patients, it is sometimes necessary to use drugs with peripheral vascular, pulmonary, and/or cardiac effects, such as vasoactive amines, in order to correct cardiovascular changes and/or restore tissue perfusion (Melo et al., 2016; Kastrup et al., 2013).

The entire team should be knowledgeable about the pharmacological properties of these drugs. In intensive care units, nurses are one of the main professionals responsible for preparing and/or supervising the preparation and administration of intravenous drugs, especially those with a higher risk of undesirable events such as vasoactive amines (Melo et al., 2016).

The most common undesirable clinical events related to the administration of these drugs include changes in heart rate (HR), blood pressure (BP), respiratory rate, oxygen saturation, fraction of inspired oxygen, tissue perfusion, among others (Melo et al., 2016; Kastrup et al., 2013). Safe medication use is therefore a complex issue in patient safety because it accounts for 30% of hospital errors, being considered the main incident leading to AEs. For example, in 2016, a Brazilian study found that the frequency of adverse drug events was 7%-15.6% (Roque et al., 2016). In another cross-sectional study on the prevalence of AEs in 58 hospitals in five Latin American countries, the authors concluded that 8.2% of patients had at least one adverse drug event. Among these AEs, 28% caused severe harm, and 6% were associated with the patient's death (Aranaz-Andrés et al., 2011). In this context, in 2017, the World Health Organization (WHO) launched the third global patient safety challenge entitled *Medication without harm* (WHO, 2017).

Thus, the general objective of this study is to analyze the practices related to the administration of vasoactive amines. Its specific objectives are to a) describe the administration of vasoactive amines and b) analyze the undesirable clinical events related to the administration of these drugs in critically ill patients.

Background

Vasoactive amines play an important role in intravenous therapy, but, directly or indirectly, they have peripheral vascular, pulmonary, or cardiac effects, acting through receptors located in the vascular endothelium (Rodrigues & Cruz, 2019). Due to their fast and powerful action, one of the criteria for their safe use is the monitoring of the patient's vital signs to strictly control their effects (Biricik et al., 2020). Thus, the good practices related to the administration of vasoactive amines are embedded in

the context and concept of client or patient safety. These good practices integrate a set of measures to prevent or reduce the occurrence of incidents in healthcare services. The concept of undesirable clinical event is used when the patient's vital signs or hemodynamic variables change and are unfavorable (Portaria de Consolidação n.º 2/2017 do Ministério da Saúde, 2017).

The recommendations for evidence-based nursing practice in caring for critically ill patients with prescribed vasoactive amines are as follows: to know drug action, stability, and interaction, being able to intervene in possible interferences; to know if the drug is photosensitive; to administer the drug through an infusion pump, which should be labeled with the name of the drug being administered; to perform aseptic technique for accessing catheters and use a central venous catheter (CVC); to disinfect the CVC hub using the "scrub-the-hub" method and maintain CVC care during infusion; to use a dedicated proximal lumen, properly labeled; to continuously monitor vital signs (BP, HR, respiratory rate, oxygen saturation, and temperature), blood flow, and urine output every hour, being alert to possible variations suggesting the worsening of the patient's hemodynamic status (Silva & Oliveira, 2018; Szpalher & Batalha, 2019).

Research questions

How are vasoactive amines administered to patients admitted to cardiovascular intensive care units?

What is the frequency of undesirable clinical events related to the administration of vasoactive amines in patients admitted to cardiovascular intensive care units?

Methodology

This quantitative, cross-sectional, observational study was conducted at a 10-bed cardiovascular intensive care unit of a university hospital in Rio de Janeiro. The STROBE tool was used to report this study (Malta et al., 2010).

The simple random sample consisted of 97 patients, with a confidence level of 95% and a sampling error of 0.05 ($p = 0.05$), from a population consisting of 265 patients admitted to this unit in 2019. Based on the criteria in the literature, a base percentage of 8% of medication errors was also considered (Aranaz-Andrés et al., 2011). Patients aged 18 years or older with at least one prescribed vasoactive amine were included. Data were collected between June and October 2020 using a form developed with the following variables: characteristics of the infused vasoactive amines, aspects related to their administration, and records of undesirable clinical events in the monitoring of vital signs.

An undesirable clinical event was considered as any situation in which vital signs or hemodynamic variables were altered. The designation of AE was not used because, due to the data collection method, it was not possible to conclude that the analyzed changes caused harm to the patient.

Concerning the characteristics of the amines, the following variables were analyzed: name of the drug, length of use of the vasoactive amine, and prescribed drug dosage.

The following variables related to the administration of amines were used: dedicated route or concurrent infusion, route identification with the name of the amine, administration through a proximal lumen, label of the infusion pump with the name of the amine, record in the patient's prescription system (checking of the drug by the team, double-checking, solution expiration date). Concerning the clinical effects of vasoactive amines, the following variables were assessed: monitoring of vital signs (namely systemic BP and HR) every 2 hours and every 4 hours and record of any undesirable clinical events (systolic BP \geq 200 mmHg or \leq 50mmHg, HR \geq 150 bpm or \leq 50 bpm). These events were particularly analyzed because the cardiovascular effects of vasoactive amines are dose-dependent, which means that even small dose changes cause sudden changes in systemic BP and HR (Melo et al., 2016; Roque et al., 2016; Kastrup et al., 2013). The information on vital signs was collected from the information recorded in the patient's file. The measurements and the frequency of monitoring/recording were recorded in the 24-hour retrospective record. The variables related to the administration were collected from direct observation of infusion administration. It should be noted that the professionals involved in direct patient care were not observed.

Data were organized using Microsoft Excel® software, 2016 version. Data on the characteristics of the administration of vasoactive amines, the frequency of the types of amines, the routes of administration, the infusion characteristics, and the prescription records were presented in absolute and relative frequencies. As for undesirable clinical events, prevalence and prevalence ratio were estimated and later compared with the Chi-square test that assessed the frequency of assessment every 2 and 4 hours. A *p*-value less than or equal to 0.05 was considered for confirmation of statistical significance. All association tests were performed on a free, web-based platform (www.openepi.com®).

In compliance with Resolution no. 466/2012, the study was submitted to and approved by the Research Ethics Committee, under opinion no. 2.970.036, obtaining the Certificate of Submission for Ethical Appreciation (CAAE) number 16581119.0.0000.5258.

Results

Concerning the administration of vasoactive amines in critically ill patients, Table 1 shows that noradrenaline was the most frequently administered amine (70.1%), followed by dobutamine hydrochloride (29.9%). The simultaneous administration of more than one type of vasoactive amine was not identified in any patient.

Table 1

Characteristics of the administration of vasoactive amines in critically ill patients admitted to the cardiovascular intensive care unit of a university hospital

Characteristics	<i>n</i>	%
Type of vasoactive amine		
Noradrenaline	68	70.1
Dobutamine	29	29.9
Administration route		
Dedicated route	97	100
Labeled route	85	87.6
Administered through proximal lumen	46	47.4
Perfusion		
Labeled infusion pump	97	100
Solutions within the expiration date	97	100
Prescription records		
Checked prescription	97	100
Double-checking	12	12.4

All types of amines were administered through a dedicated route, and the infusion pumps were correctly identified with the name of the amine. Regarding route identification, 87.6% were correctly identified, and 47.4% were administered through a proximal lumen.

The records show that 100% of the administered vasoac-

tive amines were checked in the prescription and within the 24-hour expiration period. However, only 12.4% of the drugs were double-checked.

The analysis of the variables related to the evaluation of the vasoactive amines showed that the overall prevalence of undesirable clinical events was 27.8%. Table 2 shows

that the most significant event was the increase in HR (23.7%), followed by the increase in BP (4.1%). There were no records of HR \leq 50 bpm or BP \leq 50 mmHg during the study.

Table 2

Record of undesirable clinical events in patients with amines according to the interval of vital signs monitoring

Monitoring interval	Undesirable clinical events	<i>n</i>	%
Vital signs every 2h	Blood pressure \geq 200 mmHg	4	4.12
	Heart rate \geq 150 bpm	17	17.53
	No record	31	31.96
Vital signs every 4h	Blood pressure \geq 200 mmHg	0	0
	Heart rate \geq 150 bpm	6	6.19
	No record	39	40.21
Total		97	100

Table 3 shows the association between the undesirable clinical events and the interval of vital signs monitoring. The prevalence of events was 40.38% when vital signs were assessed every 2 hours and 13.33% every 4 hours. Based on these results, a prevalence ratio ($PR = 3.029$) was

obtained, that is, during the administration of vasoactive amines, the occurrence of unfavorable clinical events was three times higher in patients who were monitored every 2 hours, suggesting that some events went unnoticed in patients who were monitored every 4 hours.

Table 3

Prevalence (P) and Prevalence Ratio (PR) of undesirable clinical events during vasoactive amine use according to the frequency of vital signs monitoring

Vital Signs Monitoring	<i>N</i>	<i>P</i> ¹ (%)	<i>p</i> -value*	<i>PR</i> ² (95%CI)
Interval every 2h	52	40.38%	0.003032	3.029
Interval every 4h	45	13.33%		(1.341-6.841)

Note. *P*¹ = Prevalence; *PR*² = Prevalance Ratio; *CI*³ = Confidence interval.

Discussion

WHO identified six goals for patient safety, an attribute of high-quality care that aims to prevent harm to patients during care provision (WHO, 2017).

The third goal is focused on improving safety in the prescription, preparation, and administration of the drug. Concerning the safety of care, medication use is a particularly complex issue worldwide and one of the main risk factors for AEs in critically ill patients (Sousa et al., 2018).

In this study, the most commonly used amines in intensive care and critically ill patients were noradrenaline and dobutamine hydrochloride. Noradrenaline, a precursor of adrenaline, was infused in 70.1% of the patients in this study. It is known to act on cardiac output, with direct action on BP regulation, and is usually used as a first-choice agent in cases of low BP, except for those related to hypovolemia, resulting in increased venous return because it is an important systemic vasoconstrictor (Biricik et al., 2020).

Dobutamine hydrochloride was used in 29.9% of patients. It is a synthetic drug that mimics the effects of the sympa-

thetic nervous system and has hemodynamic benefits in cases of low cardiac output with low BP associated with myocardial contractility. It improves ventricular function through its positive inotropic effect, with mild peripheral vascular effect (Biricik et al., 2020). These data converge with the results of another descriptive retrospective study conducted with 85 patients admitted to an intensive care unit, which found that 67.1% of patients were given noradrenaline and 35.3% were given dobutamine (Melo et al., 2016).

Although these drugs are first-choice agents and frequently used to treat life-threatening low BP, it should be noted that AEs related to their administration could lead to both short-term acute clinical events and potentially fatal complications (Trentine, 2014).

Thus, the care related to their administration and the evaluation of cardiovascular effects is essential. Among the critical care for safe medication administration, the study showed that all solutions were infused through a dedicated and correctly labeled route, reflecting good practices based on a proactive culture of safety in the unit under analysis (Fassarella, 2021). The evidence-based practice recommends the administration of vasoactive

amines through a dedicated route with a label containing the solution's name, dose, and dilution. This measure is efficient in reducing errors, such as drug incompatibility due to the administration, in the same route, of drugs that are not compatible (such as sodium nitroprusside and dobutamine, vasodilator and anesthetic), and preventing the occurrence of adverse drug events (ADEs; Instituto de Práticas Seguras de Medicação, 2019; Cortes & Silvino, 2019).

Another important factor related to using the dedicated route is the prevention of inadvertent bolus administration due to the administration of other drugs in the same route, which increases the concentration of vasoactive amine in the blood to the point of causing harm to the patient. Thus, the proximal lumen should include the name of the amine, signaling the prohibition of administration of other drugs in this route or the lateral injector, contributing to medication safety (Instituto de Práticas Seguras de Medicação, 2019).

In addition to these data, special attention should be drawn to the fact that only 47.4% of amines were administered through the proximal lumen of the CVC. When using a multi-lumen CVC, one of the good practices is to use the proximal lumen for amines because it has a small gauge than the distal lumen, making it easier for the solution to be infused alone. Another recommendation is to use larger-gauge lumens for other solutions and medications, reducing the risk of inadvertent bolus administration of amines, combination of solutions, and other administration-related AEs (Paim et al., 2017).

The infusion pump used for intravenous medications that require flow and volume control is a hard technology resource that increases safety during the infusion therapy of vasoactive amines. In this study, 100% of infusion pumps were properly labeled with the name of the medication being administered. This measure facilitates the work process because it reduces the occurrence of errors by allowing the identification of the medication delivered by continuous infusion (Paim et al., 2017).

It should be noted that the infusion pump alarm indicates priority in care because it identifies unsafe circumstances such as the end of the infusion, air in the pump, or occlusion of the route. In the case of vasoactive amines, which act to optimize cardiac output, the unexpected and unplanned pause of the infusion brings high risks and has a negative impact on the patient's hemodynamic status (Franco et al., 2018).

Another good practice that promotes medication safety is the nursing team's double-checking of the medication, at different times. This study showed that all vasoactive drugs were checked in the prescription, but only 12.4% were double-checked. In the double-checking process, the medication is checked by two professionals before its administration, reducing errors and ensuring beneficial therapeutic outcomes (Paim et al., 2017).

The recommendation of the Brazilian Ministry of Health for the administration of potentially dangerous drugs, such as amines, is that the doses should be double-checked during their preparation and dispensing. This good practice aims to identify any errors in the steps before

nurses' administration, improving safety in the medication therapy process (Portaria de Consolidação n.º 2/2017 do Ministério da Saúde, 2017). This measure is a complementary barrier to facilitating the identification of details unnoticed by other professionals involved in the process, such as dose, schedule, patients, route, and expiration date of the solution. In Brazil, double-checking is usually performed by a nurse and a nursing technician, but it is still poorly implemented in institutions due to the high number of patients for each professional. Therefore, team overload can interfere with the quality of health services, especially with medication safety (Roque et al., 2016). As for the risks related to amine administration, it is assumed that their use is positively associated with the occurrence of AEs because their actions are focused on the regulation of cardiac output that, in small doses, already produce rapid responses and have a dose-dependent effect. Thus, minimal changes in the infused dose can rapidly change BP and HR, impacting the maintenance of cardiac output. It should be noted that the main preventable AEs related to amines include cardiac arrhythmias, hypotension/hypertension, bradycardia/tachycardia, and altered urine output (Roque et al., 2016).

In this study, the undesirable clinical events identified were increased HR (23.7%) and increased BP (4.1%), both of which reflect situations that need to be promptly reversed to avoid potential harm to patients, especially critically ill patients.

It is known that tachycardia decreases the efficiency of blood flow to the heart, which reduces the ejected systolic volume, and increases myocardial oxygen demand, posing a high risk for acute myocardial infarction (AMI), heart failure (HF), stroke, kidney failure, arrhythmias, and thromboembolism (Issa et al., 2021).

BP higher than 200 mmHg overloads the cardiovascular system because high BP on the wall of coronary arteries increases afterload, leading to greater resistance to blood flow and, consequently, reducing the effectiveness of oxygenation, thus weakening the heart muscle and other systems (Issa et al., 2021).

In the analysis of the association between the interval of vital signs monitoring and the prevalence of clinical events, the measurement of the prevalence ratio showed that undesirable clinical events were three times more common in amine patients monitored every 2 hours than in those monitored every 4 hours.

It is believed that monitoring vital signs at shorter intervals increases the likelihood that nurses will recognize hemodynamic changes early. Many circumstances can interfere with the identification of these events, namely the high demand/workload, low staffing levels, the lack of direct patient observation by the team, the patient's inability to ask for help, the inadequate setting of alarms, and the alarm fatigue phenomenon (Franco et al., 2018). Thus, the interval of vital signs monitoring is important to ensure a standard of surveillance of a patient's vital signs. Thus, given the pharmacological effects of vasoactive amines, such as their rapid and potent action on hemodynamics, the patient's vital signs, namely BP and HR, should be assessed continuously and recorded

every hour. This intervention reduced the occurrence of undesirable events because it identifies early changes in vital signs that reflect the worsening/deterioration of clinical status, allowing immediate correction to prevent sequential AEs (Trentine, 2014).

The following good practices related to the administration of vasoactive amines were discussed in this study: infusion in a dedicated route, administration in proximal lumen and infusion pump, infusion of solution within the expiration date and double-checked, monitoring and time recording of vital signs, and sufficient knowledge about the medication. These measures promote patient safety during medication administration.

Based on scientific knowledge, intensive nurses are responsible for assisting in the administration of vasoactive amines in collaboration with the medical team. Therefore, their contribution should consist of the systematization of the nursing process and care, as well as the development and implementation of best practice protocols to guide the multidisciplinary team (Trentine, 2014).

Even though the study was conducted at a local level, its contributions allow substantiating, assessing, and proposing strategies for improving nursing care and preventing errors and AEs related to the use of vasoactive amines in intensive care settings. Data showed that monitoring with shorter intervals is associated with better clinical outcomes and fewer undesirable events.

A limitation of this study was the collection of data in a single setting, limiting the analysis of different hospital realities. Other limitations were the lack of observation of alarm settings and the team's response time to alarms, as well as the impossibility of checking the duration of high BP and tachycardia in patients. These limitations show that the theme is not exhausted and that further studies should be conducted to analyze new variables.

Conclusion

The characterization of the administration of vasoactive amines showed that there are still gaps in patient monitoring and in the double-checking of these drugs, making critically ill patients more vulnerable to undesirable clinical events. The analysis of the administration of vasoactive amines identified improvement opportunities for the unit under analysis through interventions for preventing AEs. Therefore, the following interventions for preventing AEs are suggested: the use of a route identification system to avoid administration of other drugs and administration of bolus doses of amines; the preferential use of the catheter's proximal route for amine administration; the reference to the need for double-checking of these drugs in the prescription; the monitoring of vital signs every hour, or at least every 2 hours, for patients receiving amines to facilitate the identification and immediate correction of hemodynamic events.

Author contributions

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