

# Immediate transfusion incidents reported in children and adolescents

Incidentes transfusionais imediatos notificados em crianças e adolescentes


Reacciones transfusionales inmediatas notificadas en niños y adolescentes

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## Abstract

**Objective:** To analyze the profile of immediate transfusion incidents reported in children and adolescents hospitalized in a high complexity general hospital.

**Methods:** This is a documentary and retrospective study that analyzed 287 notification records, reporting transfusion reactions in children and adolescents from zero to 18 years of age, occurred from January 2007 to May 2021, in a hemovigilance service of a high-complexity philanthropic university hospital in the city of São Paulo.

**Results:** Of the 287 records assessed, 42.5% of reactions were observed in adolescents (between 12 and 18 years), and 83.6% occurred in the first transfusion. Most common clinical manifestations were skin lesions and hyperthermia. About 50% of reactions occurred in patients with leukemia or anemia and the associated blood component was red blood cell concentrate. Most common incidents were nonhemolytic febrile reaction and mostly mild and moderate allergic reactions. Other reactions were 9.8% moderate/severe.

**Conclusion:** The study favored greater knowledge about transfusion incidents in children and adolescents and brings contributions to enhance patient safety and pediatric hemotherapy services.

## Resumo

**Objetivo:** Analisar o perfil dos incidentes transfusionais imediatos notificados em crianças e adolescentes internados em hospital geral de alta complexidade.

**Métodos:** Estudo documental retrospectivo, com análise de 287 Fichas de Notificação, reportando reações transfusionais em crianças e adolescentes de zero a 18 anos de idade, ocorridas no período de janeiro de 2007 e maio de 2021, em um serviço de hemovigilância de um Hospital Universitário, de caráter filantrópico, de alta complexidade, localizado na cidade de São Paulo.

**Resultados:** Das 287 fichas avaliadas, 42,5% das reações foram observadas em adolescentes (entre 12 e 18 anos), 83,6% ocorreram na primeira transfusão. Manifestações clínicas mais comuns foram lesões de pele e hipertermia. Cerca de 50% das reações ocorreram em pacientes com leucemia ou anemias e o hemocomponente associado foi o concentrado de hemácias. Incidentes mais comuns foram: reação febril não hemolítica e reações alérgicas, em sua maioria leves e moderadas. Outras reações foram 9,8% moderadas/graves.

**Conclusão:** O estudo favoreceu maior conhecimento sobre os incidentes transfusionais ocorridos em crianças e adolescentes e traz contribuições para reforçar a segurança do paciente e dos serviços de hemoterapia pediátrica.

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Conflicts of interest: nothing to declare.

## Resumen

**Objetivo:** Analizar el perfil de las reacciones transfusionales inmediatas notificadas en niños y adolescentes internados en un hospital de alta complejidad.

**Métodos:** Estudio documental retrospectivo, con análisis de 287 Fichas de Notificación, donde se reportaron reacciones transfusionales en niños y adolescentes de cero a 18 años, ocurridas en el período de enero de 2007 a mayo de 2021, en un servicio de hemovigilancia de un hospital universitario de carácter filantrópico, de alta complejidad, ubicado en la ciudad de São Paulo.

**Resultados:** De las 287 fichas analizadas, el 42,5 % de las reacciones fue observada en adolescentes (entre 12 y 18 años) y el 83,6 % sucedió en la primera transfusión. Las manifestaciones clínicas más comunes fueron lesiones en la piel e hipertermia. Cerca del 50 % de las reacciones ocurrió en pacientes con leucemia o anemia, y el componente sanguíneo asociado fue el concentrado de eritrocitos. Los incidentes más comunes fueron: reacción febril no hemolítica y reacciones alérgicas, en su mayoría leves y moderadas. Otras reacciones fueron 9,8 % moderadas/graves.

**Conclusión:** El estudio ayudó a tener mayores conocimientos sobre los incidentes transfusionales ocurridos en niños y adolescentes y contribuye para reforzar la seguridad del paciente y de los servicios de hemoterapia pediátrica.

## Introduction

Blood transfusions, when duly prescribed, are able to temporarily correct changes and deficiencies of red blood cells, platelets and coagulation factors. However, some patients require rapid transfusions of one or more blood components.<sup>(1)</sup> It is from the collection of whole blood that blood components and blood products can be obtained, and blood components are extracted from the volume of donated blood at the hemotherapy service, and blood products produced by the pharmaceutical industry through plasma fractionation.<sup>(2)</sup>

Although there are old reports of attempts to treat diseases with blood use, transfusion practice is relatively new and developed in the second half of the 20<sup>th</sup> century and, more recently, in the early 1990s, the first hemovigilance systems appeared. In countries with longer experience in hemovigilance, such as France, studies show that a basal rate of undesirable occurrences is always present for the best and most controlled blood cycle.<sup>(3)</sup>

Although blood transfusions are an effective therapeutic method, transfusion practice involves potential risks of undesirable events.<sup>(4)</sup> These events comprise the signs and symptoms recorded throughout the infusion process and are called transfusion reactions. Data from the Brazilian National Health Regulatory Agency (ANVISA - *Agência Nacional de Vigilância Sanitária*) report, among the 254 services that make up the Sentinel Network, a transfusion reaction (TR) rate in 2017 of 5.29 per 1,000 transfusions performed. For the state of São Paulo, the calculated rate was 4.79 TR/1000, regardless of the age group of blood component recipients.<sup>(5)</sup>

Blood transfusion is a risk factor for mortality in critically ill children, and may cause mediated immunological and non-immunological reactions. TR in children can occur from 0.85% to 3.8% of cases,<sup>(6)</sup> and children older than two years are the most vulnerable. Among 1,548 TR collected from a university hospital in the city of São Paulo, it was observed that 12.4% occurred in children from zero to 17 years of age.<sup>(7)</sup> These data are similar to those reported in a teaching hospital in India, where the authors report 11.6% of TR in children.<sup>(8)</sup> In older cases in Ceará, the authors showed a prevalence of 3.8% of TR in pediatric patients.<sup>(9)</sup>

Recent research shows that transfusion notification and investigation records are not filled out correctly.<sup>(10)</sup> Another study<sup>(11)</sup> reports that in 68.5% of medical records there was no complete identification of patients with TR. Considering the data presented, there is still little notification of transfusion reactions, with underreporting of cases, especially among pediatric patients, with little knowledge about this population group.

Considering the aforementioned and the scarcity of literature on the occurrence of adverse events in pediatric patients receiving blood components, the present study was developed, which aimed to analyze the profile of immediate transfusion incidents reported in children and adolescents hospitalized in a high-complexity general hospital.

## Methods

This is a retrospective documentary study, with descriptive and analytical components, carried

out with the use of secondary data inserted in the Transfusion Incident Notification and Investigation Reports (FNIT - *Fichas de Notificação e Investigação dos incidentes Transfusionais*) received, between January 2007 and May 2021, from the hemovigilance service of a high-complexity philanthropic university hospital in São Paulo, with 86 pediatric beds. Pediatric medical care is arranged as follows: 40 intensive care beds (31 neonatology and nine pediatric scarce), 11 surgical clinic beds, seven isolation beds for infectious and parasitic diseases, 18 clinical and social pediatric beds and 11 Day Hospital beds, which also perform blood transfusions. This hospital is a member of the Brazilian Network of Sentinel Hospitals, and, through the Hospital Sanitary Risk Management, has been carrying out hemovigilance actions since 2002; however, the FNIT analyzed in this study correspond only to those included in the Brazilian National Notification System (NOTIVISA - *Sistema Nacional de Notificação*), created in 2007.

Among the 1,532 hemovigilance notifications, 287 FNIT was obtained, reporting immediate transfusion reactions in children and adolescents treated at the institution, which comprised the study sample. The FNIT were stored in a database worksheet in Excel for further analysis. The transfusion reaction classification regarding diagnosis followed ANVISA recommendations.<sup>(12)</sup>

To carry out this study, we analyzed the criteria for defining and classifying children and adolescents according to the Child and Adolescent Statute (ECA - *Estatuto da Criança e do Adolescente*), which in its Article 2 defines the child as a person from zero to 12 years of age and the adolescent as a person from 12 and 18 years old,<sup>(13)</sup> different from the World Health Organization (WHO), which defines the chronological limits of adolescence between 10 and 19 years old.<sup>(14)</sup>

All FNITs duly completed reporting signs and symptoms of transfusion reaction and which were classified as immediate reactions by the institution's hematologist, observing the chronological age limits of children and adolescents defined for this study. FNITs in which the signs and symptoms recorded were not correlated with an immediate transfusion

incident or those that did not meet the ANVISA case definition criteria were excluded.<sup>(12)</sup>

Based on risk management (RM) hemovigilance service's actions, transfusion reaction occurrences were recorded in the FNIT prepared and validated by the institution itself, containing age, sex, unit of occurrence, clinical manifestations, ABO system and Rh factor, type of blood component and disease indicative of infusion as variables. Reactions, when observed in bed, are recorded in the FNIT by a nurse, who suspends the infusion and requests a medical assessment for managing clinically the reaction. Blood samples are collected from patients and from the bag for counter-proof of immuno-hematological tests by the hemotherapy service. With the results, a hematologist confirms or rules out the reaction and classifies the event according to the case criteria defined by ANVISA.<sup>(12)</sup> All FNITs are forwarded to RM, which stores them in an Excel database, following ascending numerator order. Eligible FNITs, i.e., those qualifying as TR, are entered into ANVISA's National Hemovigilance System (NHS) through NOTIVISA, using the risk manager's e-mail and ID for data entry.

Data stored in Excel spreadsheets between January 2007 and May 2021 were imported and analyzed with the help of Stata Statistical in June 2021, with each line of the spreadsheet (unit of analysis) corresponding to a transfusion in which one or more transfusion reactions. The variables studied were sex, age (in ranges), type of reporting unit (inpatient, outpatient) and detail (which), number of reactions presented in transfusion, if the reaction happened in the first infusion (in the studied service), signs and symptoms, main reason for transfusion, type of blood component, type and severity of transfusion reaction. All these variables were used in their categorical form, presented in table and/or text by absolute (No.) and relative (%) frequency. A study of association between sex and age was carried out to explore the existence of age groups more exposed in each sex; and between the degree of severity and type of transfusion reaction, to understand the potential risk of allergic and febrile non-hemolytic reactions. Pearson's chi-square

test was used in the association studies between such categorical variables, with a significance level of 5%. The outcome of interest was reaction severity, and an association study of mild/moderate and severe reactions was carried out using Pearson's chi-square test, with a significance level of 5%.

This study, after being inserted in *Plataforma Brasil*, was approved by the Research Ethics Committee of the hospital involved, under Opinion 1794086 and CAAE (*Certificado de Apresentação para Apreciação Ética* - Certificate of Presentation for Ethical Consideration) 60855416.5.0000.5505. This study meets all the recommendations and guidelines proposed by Resolution 466/2012 and 510/2016 of the Brazilian National Health Council. In all stages of this study, the ethical criteria established in the ECA were observed.<sup>(13)</sup>

## Results

The hospital reported a total of 1,548 transfusion events, of which 1,532 (98.9%) were eligible as transfusion reactions, and of these, 287 (18.5%) were observed in children and adolescents. Of the total reactions in pediatrics, there was an equivalent arrangement among girls and boys, with 141 (49.2%) and 146 (50.8%) cases, respectively. Table 1 describes sex and age sociodemographic variables. The reactions also occurred in boys and girls, 49.2% and 50.8%, respectively. Regarding age, it is observed that about 10% of TR occurred in children under one year of age, while higher proportions were observed in the age groups between seven and 12 years (18.1%). However, the highest percentage was observed in the age group from 12 to 18 years (42.5%) only in the age group between >12 years and ≤ 18 years. The study of association between sex and age was conducted according to the classification of child and adolescent defined by ECA.<sup>(13)</sup> Among boys, transfusion reactions were less frequent (34%) in adolescents (≥12 years and <18 years). Among girls, the reactions occurred equally in both age groups, resulting in an association and statistically significant ( $X^2 = 9.1098$ ;  $gl=1$ ;  $p=0.003$ ).

**Table 1.** Arrangement of immediate transfusion incidents according to sex and chronological age limits of children and adolescents (n=287)

Chronological limits (age) # n(%)	Boys n(%)	Girls n(%)	Total
< 1 year	17(9.9)	12(8.2)	29(10.1)
≥1 year and <2 years	12(8.5)	7(4.8)	19(6.6)
> = 2 years and <5 years	22(15.6)	18(12.3)	40(13.9)
>=5 years and <7 years	16(11.3)	9(6.7)	25(8.7)
>=7 years and <12 years	26(18.4)	26(17.8)	52(18.1)
>=12 years and <=18 years	48(34.2)	74(50.7)	122(42.5)
Total	141(49.2)	146(50.8)	287(100.0)

Table 2 shows variables related to registration site and type of transfusion occurrence. It is observed that the cases reported in the child emergency room were higher, with 26.1% of the total, followed by the clinical and social pediatrics units (19.8%) and Intensive Care Units (14.3%). Although the outpatient oncologic unit has the lowest record (7.3%), it is worth mentioning that, in this health facility, children with oncological diagnosis are hospitalized in different hospital units. Regarding the type of unit, 79.1% of TRs occurred in hospitalized children and 20.9% in outpatient units, both in the Day Hospital and in the outpatient oncology service. In 28.2% (n=77) of the TR studied, it was observed that the reactions were multiple, i.e., they presented more than one sign or symptom. Of the 287 TR, 83.6% corresponded to patients' first transfusion in this hospital.

**Table 2.** Arrangement occurrence site, number of reactions and occurrence in the first transfusion of transfusion incidents observed in children and adolescents (n=287)

Variables	n(%)
Notifying units	
Emergency <sup>1</sup>	75(26.1)
Clinical units <sup>1</sup>	57(19.8)
Intensive Care Unit <sup>1</sup>	41(14.3)
Day Hospital <sup>2</sup>	42(14.6)
Organ transplantation <sup>1</sup>	20(6.9)
Surgical units <sup>1</sup>	31(10.8)
Oncology units <sup>2</sup>	21(7.3)
Type of Unit	
Inpatient <sup>1</sup>	227(79.1)
Outpatient <sup>2</sup>	60(20.9)
Number of reactions	
Single reaction	210(73.1)
Multiple reactions	77(26.9)
Transfusion reaction in the 1st infusion in the health service	
Yes	240(83.6)
No	47(16.4)
Total	287(100.0)

Table 3 presents the most common signs and symptoms observed, the main diseases indicative of transfusion and the type of blood component associated with transfusion reaction. In the analysis of signs and symptoms recorded in the FNIT, it was found that 33.6% reported skin lesions and pruritus, followed by an increase in body temperature with 25.1% of reported cases. In about 10% of cases, cardiac alterations, chills and tremors were observed. Among the clinical manifestations that were classified as other nonspecific, totaling about 10% of cases, gastric alterations and chest or lumbar pain and respiratory problems, including cyosis of extremities, were found.

**Table 3.** Arrangement of signs and symptoms, indicative reasons and type of blood components associated with transfusion reaction observed in children and adolescents (n=287)

Observed signs and symptoms	n(%)
Skin lesions and pruritus	207(33.6)
Increased body temperature	155(25.1)
Cardiac changes	62(10)
Chills and tremors	65(10.5)
Dyspnea and cough	42(6.8)
Nausea with or without vomiting	18(2.9)
Other non-specific	67(10.9)
Total **	616(100.0)
Indicative reasons for transfusion	
Anemias/leukemias*	147(51.2)
Intra and postoperative	35(12.2)
Neoplasms/tumors	25(8.7)
Chronic kidney disease	17(5.9)
Other indicative causes	63(22)
Total	287(100.0)
Type of hemocomponent	
Red blood cell concentrate	251(87.4)
White blood cell concentrate	33(11.5)
Others	4(1.4)
Total	287(100.0)

\*Composition of the anemias/leukemias group: sickle cell disease =106/140 (76%), leukemia=17/140(12%). Other anemias=17/140 (12%); \*\* Total signs and symptoms

Regarding the blood group, it was found that the majority of TR occurred in pediatric patients of blood groups O<sup>(+)</sup> and A<sup>(-)</sup>, while TR associated with Rh factor<sup>(-)</sup> were less present in this study, with only 13.9% of the total reported (data not shown). TR's Rh factor follows the blood donation pattern in our country. Regarding the type of blood component used for transfusion in children and adolescents, it was found that the highest number of reactions was related to the therapeutic use of packed red blood

cells (PRBCs), with 87.4% of the total reactions, against only 11.5% of those reported by the use of platelet concentrate. (Table 3). Among the main diseases indicative of blood transfusion, anemias and leukemias accounted for 51.2% (147/287) of TR, while the recommendation for intraoperative or postoperative blood administration accounted for 12.2% of TR occurrences. In the anemia and leukemia group, sickle cell disease stands out, which represents 75.7% (106/147) of the total TR occurred among patients with anemia. Table 4 shows the reaction severity arrangement according to the reaction classification. Through an analysis, it can be seen that the main ones were febrile nonhemolytic transfusion reactions (FNHTRs), with 51.2% of cases, followed by allergic reaction (ALG), with 14.3%.

**Table 4.** Severity degree arrangement according to type of transfusion reaction in children and adolescents, São Paulo, 2007-2021 (n=287)

Type of reaction n(%)	Mild n(%)	Moderate/severe n(%)	Total
Febrile nonhemolytic transfusion reaction	139(94.6)	8(5.4)	147(100.0)
Allergic reaction	112(90.3)	12(9.7)	124(100.0)
Other reactions	8(50)	8(50)	16(100.0)
Total	259(90.2)	28(9.8)	287(100.0)

$\chi^2 = 26.2004$ ; gl-5;  $p < 0.001$

As can be seen in Table 4, the majority of transfusion reactions in children and adolescents were mild (90.2%). In the studied sample, 5.4% (8/139) of FNHTR and 9.7% (12/112) of ALG were moderate or severe. In reactions not classified in these two groups that accounted for 5.5% (16/287) of reported reactions, about half were moderate or severe (8/16). The association between the degree of severity and type of reaction was statistically significant ( $p=0.001$ ).

## Discussion

During the study period, RM analyzed 287 transfusion reactions observed in 236 children and adolescents from zero to 18 years old who were hospitalized in inpatient and outpatient units performing blood transfusions in the hospital institution under study.

Regarding sex, no differences were observed between boys and girls, data that corroborate the study conducted in Ceará, with 53.1% of TR among boys and 46.9% in girls.<sup>(15)</sup> In India, of 411 TR, the authors reported 60.6% of occurrences for males and 39.4% for females.<sup>(8)</sup>

In the age groups analyzed, TR was more pronounced between  $\geq 2$  years and  $< 5$  years and between  $\geq 7$  and  $< 12$  years, with 13.9% and 18.1% of the total TR, respectively. In a previous study, it was reported that the proportion of TR for the age group from zero to seventeen years corresponded to 12.4% of the total TR.<sup>(7)</sup> In the findings of a study conducted in Ceará,<sup>(9)</sup> of the 57 TR analyzed in 46 pediatric patients, none were reported in children up to 30 days of age, data that differ from this study, which reveals 26 (9.5%) TR in children under 29 days of life.

When we analyzed the pediatric inpatient units where TRs were registered, it appears that the highest number of notifications occurred in emergency units (26.1%), followed by clinical units (19.8%) and Neonatal Intensive Care Units (14.3%); however, other authors report that the highest number of TR was reported in oncology units.<sup>(15)</sup> In a prospective study on alloimmunization in patients treated in emergencies, the authors report that the greater the number of transfusions performed, the more sensitive the organism becomes to the production of alloantibodies, thus justifying the greater occurrence of TR,<sup>(16)</sup> and the same was observed in children with sickle cell anemia.<sup>(17)</sup>

The main clinical manifestations of TR in children and adolescents include hyperthermia, chills, nausea, vomiting, flushing, diarrhea, itching, hives, bronchial wheezing, headache, dyspnea, hypertension, chest and back pain, circulatory collapse, respiratory failure, and shock.<sup>(18)</sup> In our series, clinical manifestations point mainly to skin lesions and itching, followed by temperature increase. Our data support the findings in oncological children, who report urticaria with 51.2%, erythema with 30.9% and hyperthermia in 30.9% of reported cases as the most common clinical manifestations.<sup>(15)</sup>

Some studies report a higher probability of TR occurrence in patients with transfusion history without however citing disease indicative of

blood transfusion.<sup>(18)</sup> In another study conducted at a hospital that assists children from zero to 18 years, in Ceará,<sup>(9)</sup> the authors showed that 5.6% of TRs occurred in children with no previous history of transfusion, which corroborates the findings of this study, with 83.8% of TRs in the first transfusion. However, of the cases in which there was TR, among the pediatric patients analyzed in Ceará, 94.4% involved polytransfused patients, of which 62.3% were observed in children with a history of previous reaction,<sup>(15)</sup> contradicting our findings with only 26.9% (n=77) of FNITs reporting multiple TR in pediatric patients. In a study conducted in India, the authors showed that of the 411 TR studied, only 35 had reports of a previous history of transfusions that presented TR.<sup>(8)</sup>

About half of the sample of this study obtained the therapeutic recommendation of blood transfusion for leukemias and anemias, including sickle cell anemia (SCA) in this group. Half of patients with SCA will receive transfusion at some point in their lives and, of these, 5% to 10% will become chronic recipients of this blood component,<sup>(17)</sup> a fact that may explain the prevalence of TR in polytransfused patients, due to alloimmunization and the frequency of late FNHTR in these patients. In India, among the children who presented TR, the main indications for blood transfusion were for the correction of anemia and thalassemia.<sup>(8)</sup> However, 53% of children who received PRBC had underlying hematological or oncological diagnosis, of which 33% were in general pediatric wards.<sup>(18)</sup>

Pediatric data report that 8% of PRBC prescriptions are for newborns, 14% for children between one month and one year of life and 78% for those older than one year, with a median of five years.<sup>(18)</sup> Regarding the type of blood component in adults, we found that the highest number of TRs is related to the therapeutic use of PRBCs, results corroborated by the literature, which points out PRBC as the most used for both adult and pediatric patients.<sup>(5,7,19)</sup> In a study conducted in the United Kingdom of 1,302 transfusions in children admitted to 160 pediatric hospitals, 74% received a single PRBC.<sup>(18)</sup> Other studies show that PRBC is present in 88% of blood transfusions of adults and children.<sup>(7,20)</sup>

Data on the classification of TR may vary from study to study, a fact that can be explained due to differences in the reaction report or in the recording of symptoms by the nursing staff, use of premedication in patients and even in the alloimmunization of polytransfused patients. The data presented corroborate the national<sup>(5,7,15,19)</sup> and international<sup>(6,21)</sup> literature that report similar results of higher frequency of FNHTR and ALG. However, when we analyzed TR in children, it was verified that the data indicate 77.2% and 69.8% for ALG and 14% and 27.2% for FNHTR in cancer<sup>(15)</sup> and pediatric patient studies,<sup>(9)</sup> respectively.

TR according to severity can be classified as mild and moderate when they do not present risk of death, but subject to systemic changes of rapid recovery within 24 hours. Severe reactions may present with long-term morbidity or imminent risk of death. The TR presented in this study were basically mild, without offering risk of death to patients. These data support the findings of Pedrosa<sup>(9)</sup>, which reports 77.2% of TR classified as mild, moderate and severe ALG and 14% of the FNHTR type. Although poorly represented (7/46.7%), severe reactions require extreme care in clinical management to avoid complications and risk of death.<sup>(11)</sup> However, we observed that the correct choice of the PRBC subtype contributes to reducing TR, that the correct choice of the PRBC subtype contributes to reducing TR in children; however, we still observed that pediatricians have insufficient knowledge about prescribing PRBC and do not know how to recognize TR.<sup>(22)</sup>

This study made it possible to quantify the immediate transfusion reactions and their degree of severity in children and adolescents during hemotherapy treatment received at a university hospital, from the analysis of the FNITs collected routinely for about 14 years. However, the sample obtained was not sufficient to allow more detailed analysis to identify groups more exposed to more severe reactions.

## Conclusion

The critical analysis of this study showed that transfusion reactions occur more frequently

among adolescents aged 12 to 18 years, and are usually reported in the first blood transfusion. Immediate TR in the most frequent children and adolescents were FNHTR and ALG in its almost all mild grade and associated with sickle cell disease. It is expected that the data can contribute to the knowledge of transfusion incidents in children and adolescents and contribute significantly to the understanding of hemotherapy in this population group. Although children are more susceptible to allergic and respiratory processes, future studies to assess the risk factors for these events should be encouraged, with the aim of improving the quality of processes and increasing the safety of children and adolescents who receive blood components.

## Collaborations

Grandi JL, Oliveira CS, Kasinski S, Areco KCN, Chiba A and Barros MMO declare that they contributed to the study design, data analysis and interpretation, article writing, relevant critical review of intellectual content and approval of the final version to be published.

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