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Medication safety incidents: characterization of voluntary reports in an oncology hospital in Porto Alegre

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Abstract

Objective: To characterize and quantify the medication security incidents reported in a specialized hospital in oncology, located in Porto Alegre, in addition to identifying the profile of the patients most affected by them. **Methods:** Cross-sectional study with retrospective data collection. Spontaneous notifications of pharmacovigilance, related to drug incidents from 2018 to 2020, were analyzed through an active search in the institutional system, through documents previously prepared by the pharmacy service and electronic medical records. Duplicate notifications were excluded. The collected data were grouped in variables related to notificated incidents and patient characteristics, with a descriptive analysis and the Chi-square test being performed to check whether there was an association between observed frequencies of the years of the study (categories) and the classification of notifications of security incidents. **Results:** 861 notifications were analyzed, 313 refering to 2020, 327 refering to 2019 and 221 to 2018. Incidents with damage were the prevalent classification, corresponding to 87.3% (n=752) of the reported occurrences. Among them, adverse drug reactions (ADRs) were the type associated with the years 2018 and 2019, often related to the use of antineoplasic agents. The classification of incidents varied according to the years of study, with statistically significant difference. There was a significant difference between the occurrences of drug-related incidents over the years. The mean age of the patients observed was 57.3 years (± 14.1), with a predominance of females and digestive system neoplasms as the main diagnosis. Antineoplasic agents were the most reported drugs, especially paclitaxel. **Conclusions:** The occurrence of incidents with damage in oncology centers, especially ADRs, is similar to findings in the literature. The results obtained allow an overview of safety issues and serve as a basis for directing pharmacovigilance actions within health services.

Keywords: pharmacovigilance; oncology service; risk management; drug-related side effects and adverse reactions; adverse drug reaction reporting systems; pharmacy service, hospital.

Incidentes de segurança envolvendo medicamentos: caracterização das notificações em um hospital oncológico de Porto Alegre

Resumo

Objetivo: Caracterizar e quantificar os incidentes de segurança relacionados a medicamentos notificados em um hospital especializado em oncologia, localizado em Porto Alegre, além de identificar o perfil dos pacientes mais acometidos por eles. **Métodos:** Estudo transversal, com coleta de dados retrospectiva. Foram analisadas notificações espontâneas de farmacovigilância, relacionadas a incidentes com medicamentos de 2018 a 2020, através de busca ativa no sistema institucional, por meio de documentos previamente confeccionados pelo serviço de farmácia e por prontuários eletrônicos. Foram excluídas as notificações que constavam em duplicidade. Os dados coletados foram agrupados em variáveis relacionadas aos incidentes notificados e às características do paciente, sendo realizada análise descritiva e realizado o teste de Qui-quadrado para verificar se existia associação entre frequências observadas dos anos do estudo (categorias) e a classificação das notificações de incidentes de segurança. **Resultados:** Foram analisadas 861 notificações, sendo 313, 327 e 221 referentes a 2020, 2019 2018, respectivamente. Incidentes com dano foram prevalentes, correspondendo a 87,3% (n=752) das ocorrências reportadas. As reações adversas a medicamentos (RAMs) associadas aos anos 2018 e 2019, relacionaram-se majoritariamente aos antineoplásicos. Houve uma diferença significativa entre as ocorrências dos incidentes relacionados a medicamentos ao longo dos anos. Quanto aos pacientes, a média de idade observada foi de 57,3 anos (± 14,1), com predomínio do sexo feminino e de neoplasias do sistema digestivo como o diagnóstico principal. Os antineoplásicos foram os medicamentos mais notificados, especialmente o paclitaxel. **Conclusões:** A ocorrência de incidentes com dano em centros de oncologia, especialmente RAMs é similar aos achados na literatura. Os resultados obtidos permitiram a descrição de problemas de segurança em um hospital brasileiro e poderão colaborar com o direcionamento de ações de farmacovigilância em serviços de saúde.

Palavras-chave: farmacovigilância; serviço hospitalar de oncologia; segurança do paciente; efeitos colaterais e reações adversas relacionados a medicamentos; sistemas de notificação de reações adversas a medicamentos; serviço de farmácia hospitalar.

Introduction

Cancer is a multifactorial disease and is currently considered the biggest public health problem in the world and one of the four potential causes of early death. It is estimated that, for each year of the 2020-2022 triennium, 625,000 new cases of the disease will appear in Brazil, with non-melanoma skin, breast and prostate cancers having the highest incidence.[1] It is estimated that the number of new cases of all cancers worldwide, in both genders and all ages, will increase from 19.3 million in 2020 to 21.9 million in 2025.[2] Although much research is carried out in the Oncology area, the antineoplastic medications used in therapies have a considerable cytotoxic effect and a narrow therapeutic window, which turns them into potential causes of adverse effects.[3]

In addition to the weaknesses generated in the body by the disease itself, cancer patients, especially older ones, are at an increased risk of developing intolerance to the treatments proposed, such as chemotherapy and radiotherapy, surgeries and adjuvant medications.[4] In addition, the polypharmacy observed in the treatment of cancer patients, which includes medications for the management of symptoms and those used in combinations of already established protocols, can exert an impact on the occurrence of adverse events or other incidents when there are interactions between them.[5]

In 2017, while promoting the third Global Patient Safety Challenge, the World Health Organization (WHO) launched the "Medication Without Harm" goal, which aimed at reducing, in the following five years, 50% of the preventable serious harms related to medications.[6] In 2009, it proposed the classification of four key concepts related to safety incidents, namely: reportable occurrence, incident without harm, incident with harm (or adverse event) and near miss. The first relates to a situation in which there was significant potential for harm but no incident occurred and the second relates to an event that affected the patient but did not cause harm, while the third caused harm to the patient; and the last was identified prior to its occurrence and, therefore, did not harm the patient[7]. It is important to keep in mind that an adverse drug event is any unfavorable medical occurrence that may emerge during treatment with a medication and encompasses both medication errors and Adverse Drug Reactions (ADRs).[8] According to the National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP), medication errors can be defined as any preventable event that can cause or lead to the inappropriate use of a medication while it is in the possession of a health professional, a consumer or a patient.[9] On the other hand, ADRs are any unintended, harmful or undesirable response to a medication, which occurs at doses usually used for prophylaxis, diagnosis, therapy or for modification of physiological functions.[8]

In order to monitor risk circumstances and incidents during patient care, many institutions have implemented spontaneous pharmacovigilance reporting systems in their care routines.[10] Made voluntarily and by health professionals, the reports are epidemiological and non-punitive, and help to identify patterns and trends in patient safety, make necessary investments in continuing education and offer ways to solve the risks or problems caused by them.[11]

Although many scientific papers investigate the consequences generated by adverse events in drug therapy, it is known that Oncology is a medical area in constant change, which aims at developing new drugs, reducing toxicity and harmful effects to the body and changing dosages already described so that they are better suited to each patient's case.[12] For this reason, the reporting of adverse reactions and other events that may or may not exert a serious impact on the patient's health must be carried out in order for the competent authorities to promote safety in the use of medications in the health services.[10]

In a hospital with high demand for the Oncology service, it is fundamental to characterize the events that occur and, thus, identify the medications that are most reported, the patients most susceptible to the occurrence of these events, and the type of neoplasm that affects them.[13,14] When analyzed together, these factors make it possible to track the stage at which the event occurred and, thus, the health team can intervene and stop an error at any time during the course of the medication, preventing it from happening again. In this way, this paper aims at characterizing and quantifying the safety incidents reported in the period from 2018 to 2020 at the Santa Rita hospital of the Santa Casa de Misericórdia Hospital Complex in the city of Porto Alegre, as well as to identify the profile of the patients most affected by them.

Methods

A cross-sectional study with collection of retrospective data from 2018, 2019 and 2020. It was conducted based on documentary analysis from the internal system of spontaneous reports of the Santa Casa de Misericórdia Hospital Complex in Porto Alegre, focusing on notifications from the Santa Rita Hospital, a center specialized in the care of cancer patients within the Institution. As the only Oncology hospital in the state of Rio Grande do Sul, the place has 185 beds, seven operating rooms and a specialized multidisciplinary team; in addition to having more than 468,000 outpatient visits in the three years of study, of which more than 106,000 were intended for chemotherapy.[15]

In the intranet, the institution makes available a form for recording spontaneous notifications of safety incidents to the hospital complex Risk Management area. Any collaborator of the institution can make the notifications. In order to select and group the data, the researchers conducted a search in this risk management system - "*SA Occurrence Manager*", which stores all the notifications received and previously analyzed by the hospital's risk management area. Afterwards, the data of interest were imported into a spreadsheet prepared by the authors.

In order to account for the notifications and to know about the safety occurrences, in 2018 the pharmaceutical team of the institution's Clinical Pharmacy did the same data grouping from the internal notification system. Consequently, the data used, referring to 2018, were extracted from the document they had previously prepared. Regarding the data from 2019 and 2020, the researchers obtained them through an active search in the Risk Management system. The information related to the patients was sought in the electronic medical charts.

The inclusion criteria included the notifications involving incidents that occurred in the Santa Rita Hospital (both at an outpatient and inpatient level), exclusively related to medications. As an exclusion criterion, the notifications that were duplicated in the system were removed. The data collected were grouped in a spreadsheet and separated into variables related to the safety incidents notified and to the patients' characteristics. With regard to the safety

incidents reported, the researchers collected information on the medication(s) involved, the time of the event, classification of the report, the incident and the medication error, when applicable. As for the variables related to the patients, they were age, gender and diagnosed neoplasm. To minimize potential measuring biases, data collection and the classifications were conducted by one of the researchers, trained for such task.

The safety incidents notified were classified from the description of each incident, as follows: incident without harm, incident with harm, and near miss. Afterwards, they were subcategorized into Adverse Drug Reactions (ADRs), therapeutic ineffectiveness, deviations in the quality of medication or technical complaints, medication errors or others (those in which the incident was caused accidentally or not by the patient, such as chemotherapy leakage).[7] Medication errors were classified using an adaptation published by Otero *et al.* (2000*)*. As this is a non-excludable classification, that is, it accepts more than one medication error category, it is ideal for application in record databases, as well as for information analysis and aggregation. In addition to that, it is adapted to the health professionals' needs.[16]

To identify the neoplasms, when known, the primary site described in the medical evolution was observed. Afterwards, the data were allocated according to the TNM classification – Classification of Malignant Tumors, which divides cancer cases into groups, according to the anatomical location and the so-called stages.[17] Only the anatomical location was considered in this research. Regarding the classification of the medications, they were grouped by the Anatomical Therapeutic Chemical – ATC, which takes into account the drug's action sites and their therapeutic and chemical characteristics.[18]

Initially, the data were analyzed descriptively and presented as mean values, standard deviations and absolute and relative frequencies. The Chi-square test was carried out to verify whether there was an association between observed frequencies of the years of the study (categories) and the classification of safety incident notifications. In other words, whether there was a significant difference in the notifications throughout the years. The post-hoc test was performed based on the residuals of Pearson's chi-square test for counting data using the Bonferroni method. The chi-square test and its respective post-hoc test are performed in the *chisq.posthoc.test*[19] package from the R software[20] (R Core Team, 2021), using a 5% significance level.

The study was approved by the Research Ethics Committees of the Federal University of Health Sciences of Porto Alegre and the Santa Casa de Misericórdia hospital institution of Porto Alegre, under the CAAE numbers 40478120.9.0000.5345 and 40478120.9.3001.5335, respectively.

Results

According to data from the institution, in the period from 2018 to 2020, 10,616 safety incidents were reported in all hospitals of the Santa Casa de Misericórdia Hospital Complex of Porto Alegre, which comprised all classes of incidents: falls, related to vascular catheters and injury by patch, hemotherapy, or drug-related incidents. Of these, 2,940 were related to medications.

This analysis included 861 drug-related incidents that occurred at the Santa Rita Hospital, the cancer treatment, prevention and diagnosis center in the hospital complex, during the aforementioned period. In all the years analyzed, there was predominance of the female gender as the most affected by the safety incidents, corresponding to 62.7% (n=540). The percentage of notifications involving men was 33.3% (n=287), and 3.9% (n=34) corresponded to unidentified patients. The prevalent age group was that of adults, aged between 18 and 59 years old, accounting for 49.9% (n=430) of the notifications. The patients' overall mean age was 57.3 years old (± 14.1). The shift with the highest number of notifications recorded was the afternoon period, with 61.8% (n=532).

Table 1 presents the safety incidents notified and their distribution across the years investigated. The chi-square test indicated that there was no significant relationship between the "year" and "classification of the safety incident notified" variables. However, in the period observed, there was predominance (87.3%) of adverse events (incidents with harm) as main incidents involving medications within the institutions. Near miss incidents corresponded to the second most frequent classification (6.4%), followed by incidents without harm (6.3%). This pattern was noticed in 2018 and 2019. However, in 2020 there was an increase in the number of incidents without harm when compared to the near miss incidents (Table 1).

Adverse events significantly stood out in relation to the other classifications due to the high occurrence of ADRs, which represented 57.6% (n=496) of all the subclassifications. Immediately after, medication errors corresponded to the second cause of safety incidents observed, representing 38.1% of the notifications analyzed (n=328) (Table 1). The association between the classification of the medication-related incidents and the study years proved to be statistically significant. ADRs were more related to 2018 and 2019; medication errors, to 2018; and other incidents, to 2019 and 2020 (Table 1).

It should be noted that, of the total number of medication errors reported, 247 were classified as adverse events, that is, 75.30% of them caused some harm to the patient, while 24.7% (n=81) were incidents without harm or near misses. Figure 1 presents the prevalent medication errors in the period from 2018 to 2020.

The adults, aged from 18 to 59 years old, were the most affected by the safety incidents, followed by those aged from 60 to 79 years old. Of the 430 notifications involving adults, 141 corresponded to medication errors, while 155 records were identified among the aged individuals. In both age groups there was predominance of ADRs as the main safety incident classification. This trend is not only observed in aged people over 80 years old, who, according to the analyses, were more affected by medication errors, corresponding to 61.8% (n=34) of the notifications for this age group.

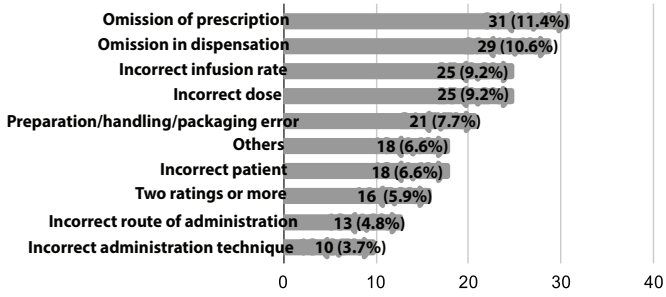
It was observed that digestive system and breast neoplasms were predominant among the patients analyzed, corresponding, respectively, to 36.7% (n=304) and 26.1% (n=216) of the patients related to the safety incidents notified. Adverse reactions and technical complaints were more frequent in patients diagnosed with breast cancer (n=175), while medication errors were more frequent in the diagnosis of digestive system neoplasms (n=148). Lymphomas and neoplasms of the hematopoietic system accounted for 12.7% of the diagnoses of patients involved in the safety incidents notified (n=105), followed by gynecological neoplasms, with 10.0% (n=83). Of the 861 safety incidents notified that were analyzed, 34 lacked the patients' identification, precluding identification of their characteristics.

Table 1. Classification of the safety incident notifications at the Santa Rita Hospital of the Santa Casa de Misericórdia Hospital Complex in Porto Alegre, by year of occurrence (N=861).

Classification		All N=861	Year n (%) 2018 N=221	2019 N=327	2020 N=313	p-value[1]
Type of incident n (%)						
Incident with harm	Frequency (%)	752 (87.3)	195 (88.2)	284 (86.8)	273 (87.2)	
Near miss	Frequency (%)	55 (6.4)	16 (7.2)	23 (7.0)	16 (5.1)	0.5010
Incident without harm	Frequency (%)	54 (6.3)	10 (4.6)	20 (6.2)	24 (7.7)	
Incidents related to medications n (%)						
ADR	Frequency (%)	496 (57.6)	103 (46.6)	208 (63.6)	185 (59.1)	
	p-value[2]		0.0018570*	0.0794560	1.0000000	
Medication error	Frequency (%)	326 (37.9)	107 (48.4)	115 (35.2)	104 (33.2)	
	p-value[2]		0.0026360*	1.0000000	0.5105910	
Quality deviations in medications or Technical complaints	Frequency (%)	14 (1.6)	4 (1.8)	4 (1.2)	6 (1.9)	<0.0001
	p-value[2]		1.0000000	1.0000000	1.0000000	
Two or more classifications	Frequency (%)	15 (1.7)	1 (0.4)	0 (0.0)	14 (4.5)	
	p-value[2]		0.1862440	0.1921080	1.0000000	
Others	Frequency (%)	10 (1.2)	6 (2.8)	0 (0.0)	4 (1.3)	
	p-value[2]		1.0000000	0.0334800*	0.0000550*	

[1]Pearson's chi-square test, a p-value considered significant below 0.05 indicates that there is an association between the year variable and the classification variables.
[2]Chi-square's post-hoc test, a p-value < 0.05 indicates which category of the variable is significant throughout the years.*Significant at the α = 0.05 significance level.

Figure 1. Occurrence of the Medication Errors, by type and frequency, notified at the Santa Rita Hospital of the Santa Casa de Misericórdia Hospital Complex in Porto Alegre from 2018 to 2020 (N=328)[1].



[1]The classifications with less than 10 occurrences corresponded to 55 records (16.8%).

As for the medications involved, the characterization based on the ATC method[15] identified group "L - Antineoplastic and immunomodulating agents" in 67.9% (n=585) of the notifications, followed by group "B - Blood and Blood Forming Organs" with 7.7% (n=66), and by group "J- Antiinfectives for systemic use" with 6.6% (n=57). Subgroup "L01- Antineoplastic Agents" prevailed in all subclassifications of safety incidents, while the other medications were more related to medication errors when compared to other causes, as shown in Table 2. The medications with the highest prevalence in the safety incidents notified were paclitaxel, with 202 reports (23.5%); docetaxel, with 97 reports (11.3%); oxaliplatin, with 57 reports (6.6%); and rituximab, with 51 reports (5.9%).

Table 2. Distribution of Medications related to Security Incidents reported at the Santa Rita Hospital of the Santa Casa de Misericórdia Hospital Complex in Porto Alegre from 2018 to 2020, according to the second ATC Level.

Medications by the second level ATC	Total N= 861	Security Incidents n (%) Medication error incidents N= 328	Incidents from other causes[1] N= 533
L01 - Antineoplastic Agents	562 (65.3)	73 (13.0)	489 (87.0)
Less frequent ratings*	81 (9.4)	68 (84.0)	13 (16.0)
J01 - Systemic Antibacterials	50 (5.8)	41 (82.0)	9 (18.8)
Notifications with two or more Ratings	46 (5.3)	41 (89.1)	5 (10.9)
B05 - Hemodialysis. Dialysis and Solutions for Perfusion and Irrigation	45 (5.2)	37 (82.2)	8 (17.8)
N02 - Analgesics	22 (2.5)	18 (81.8)	4 (18.2)
V03 - Other Therapeutic Products	19 (2.2)	17 (89.5)	2 (10.5)
B01 - Anticoagulants. Antithrombotics and Thrombolytics	14 (1.6)	13 (92.9)	1 (7.1)
N03 - Antiepileptics	6 (0.7)	6 (100.0)	-
H02 - Systemic Corticosteroids	6 (0.7)	6 (100.0)	-
J02 - Systemic Antifungals	5 (0.6)	4 (80.0)	1 (20.0)
H01 - Pituitary Hormones. Hypothalamics and Analogs	5 (0.6)	4 (80.0)	1 (20.0)

[1]RAMs. Drug Quality Deviations or Technical Complaints *Subgroup present in less than five notifications.

Discussion

The characterization of the safety incidents evidenced an association between occurrences over the years and a significant record of harmful events, especially ADRs. According to the literature, over the last fifteen years there has been a gradual increase in the number of hospitals that adopted the system of voluntary notifications in their routines, as well as in the recording of safety incidents by health professionals.[21]

A previous study carried out in the same hospital complex found that, from 2015 to 2018, there was a 427.6% increase in the total number of notifications from the institution.[22] In the current research, the growth trend was only not observed in 2020, which recorded a lower number when compared to the previous year, 2019. The new Coronavirus pandemic may be directly related to this result, as many health professionals, even not if on the front line, felt overload in their duties either due to the growth in work demand, the reallocation of colleagues and, consequently, lack of professionals, or the constant fear of being infected. Consequently, the incident notification routine may have been impaired.[23]

Regarding the classification of the safety incidents notified, previous studies carried out in Oncology centers or hospitals also identified a high occurrence of adverse events (with harms to the patients).[3,24,25,26] Various factors contribute to this result, namely: the narrow therapeutic window of antineoplastic drugs, as well as the high toxicity, use of multiple medications, associated comorbidities and the disease process itself, which makes the patients' bodies fragile.[26]

The predominance of adverse drug reactions among the adverse events can also be related, in addition to drug toxicity and to the increase in the number of patients monitored by the institution's outpatient service. In 2020, according to internal data, 6,560 parenteral solutions of chemotherapeutic agents were prepared, 24.2% more than the previous year, 2019. According to a study by Chopra *et al.* (2016)[27], the highest occurrence of adverse reactions in Oncology centers was attributed to female patients diagnosed with breast cancer and in the age group between 41 and 50 years, results similar to the findings of the current research.

Although reported less frequently when compared to adverse reactions, medication errors exert a major impact on patient safety and on the costs for the health services, especially when they are not prevented in time.[28] A number of studies that evaluated the errors reported in patients undergoing chemotherapy indicate the prescription and administration stages as the most critical for the occurrence of errors. In our study, according to the classification of medication errors, administration was the moment of care that most concentrated safety reports.[29,30] Errors involving prescriptions may have been underestimated by the lack of electronic recording of the interventions made by the pharmacy, as all prescriptions are reviewed and clarified with the physician when there are discrepancies. The discrepancy observed between the number of ADR records and medication errors may be directly related to the fact that the notification of medication errors involves or is carried out by the professional in charge, which can cause embarrassment and/or fear of punishment.

As already mentioned, aged individuals over 80 years old were more affected by medication errors, when compared to ADR occurrences. This fact can be related to older patients being less exposed to chemotherapy treatments when compared to adults, precisely to preserve their quality of life and not to expose them to toxicity.[31] However, other medications are part of the therapeutic regimens used especially for aged people with comorbidities, and these, in turn, can be linked to medication errors.[32]

As this is an Oncology hospital, which concentrates a large outpatient and inpatient flow of patients, the Antineoplastic group was the most attributed to the safety incidents, a result that is in line to that of studies that used the *Trigger Tool* methodology in the active search for adverse reactions.[26] The Blood and Hematopoietic Organs group is attributed as the second most frequent group due to the fact that electrolyte solutions are present in this classification and are commonly used in the routine, even as a vehicle for the dilution of chemotherapeutic agents. Antiinfectives for Systemic Use, the third most notified group, are described in the literature as one of the major causes of adverse drug reactions, especially the subgroup of antibacterials.[33] In cancer patients, this class of medications is used due to their action against microorganisms, in addition to promoting apoptosis in cancer cells, preventing metastases and potential inhibition of neoplasm growth.[34]

Paclitaxel, rituximab, oxaliplatin and docetaxel were mostly determined to be the main causes of safety incidents, especially adverse reactions. As described in the literature, combined therapies with the use of paclitaxel, or its use as a single agent, often lead to hypersensitivity reactions, hematological toxicity, peripheral sensory neuropathy, myalgia or arthralgia.[36] While for docetaxel, symptoms involving the gastrointestinal tract are described, in addition to heart problems and hand-foot syndrome.[35] The high frequency of the aforementioned drugs is attributed to the number of patients undergoing treatment for breast cancer, as both are therapies of choice for management of the disease.[37,38]

Reactions involving oxaliplatin are observed in digestive system diagnoses, especially advanced-stage colorectal cancer. It is commonly used in association with *5-fluorouracil* and folinic acid in the FOLFOX protocol.[37] When evaluating the profile of patients affected by the safety incidents, there was predominance of neoplasms in this system, which coincides with the large number of notifications of this drug. On the other hand, rituximab was associated with lymphomas and neoplasms of the hematopoietic system, a diagnosis corresponding to 12.7% of the patients evaluated by the notifications.

It is worth noting that the study in question has some limitations. A single-center study was carried out with previously analyzed retrospective data, referring to the 2018 notifications; therefore, it is possible that some information is inaccurate. In addition, categorization of the notifications according to the type of safety incident was performed by the authors based on the reading of the text written by the notifying professionals, which may contribute to some misinterpretation.

It is also believed that the total number of safety incidents may be greater than that shown in this paper, as underreporting is still a reality in the health services. Although data on the severity of the events were not considered in this paper, this factor can also be related to underreporting, as less severe cases were possibly not recorded.

For future papers, the researchers plan to carry out continuing education activities for the multiprofessional teams involved in the care of cancer patients, in order to disclose the results obtained by the research and understand the limitations and challenges of the routine, in addition to encouraging notifications in the institution.

Conclusion

A significant occurrence of safety incidents was verified, especially ADRs related to the use of antineoplastic agents. The women were the most affected and predominance of occurrence was in patients with diagnoses of digestive system neoplasms.

The findings of this study can contribute to improving care quality in the health services, especially those focused on Oncology, as it allows an overview of the safety problems, as well as the needs faced by each sector.

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Collaborators

Project design: GBS, ALC, COS. Data collection: GBS, COS. Data analysis and interpretation: GBS, ALC. Article writing and responsibility for all information: GBS, ALC, COS. Critical review of content: ALC and COS

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Conflict of interest statement

The authors declare that there are no conflicts of interest regarding this article.

References

1. Instituição Nacional de Câncer José Alencar Gomes da Silva. Estimativa 2020: incidência de câncer no Brasil. Rio de Janeiro: INCA, 2019. 122 p.
2. World Health Organization. International Agency for Research on Cancer. Global Cancer Obervatory. Cancer Tomorrow. [Internet] [citado 2021 Dec 22]. Disponível em: https://gco.iarc.fr/tomorrow/en/dataviz/isotype?mode=population
3. Gandhi TK, Bartel SB, Shulman LN, *et al*. Medication safety in the ambulatory chemotherapy setting. Cancer. 2005; 1;104(11):2477-83. DOI: 10.1002/cncr.21442.
4. Ethun CG, Bilen MA, Jani AB, *et al*. Frailty and cancer: Implications for oncology surgery, medical oncology, and radiation oncology. CA Cancer J Clin. 2017; 67(5):362-377. DOI: 10.3322/caac.21406.
5. Riechelmann R, Girardi D. Drug interactions in cancer patients: A hidden risk? *J Res Pharm Pract*. 2016;5(2):77-78. doi:10.4103/2279-042X.179560.
6. World Health Organization. Medication without harm: WHO global patient safety challenge. Geneva: WHO; 2017.
7. World Health Organization. Conceptual Framework for the International Classification for Patient Safety: Final Technical Report. Geneva: WHO; 2009.
8. Heineck I, Camargo AL, Gnatta D. Farmacovigilância na Prática Clínica. In: Associação Brasileira de Ciências Farmacêuticass, Pereira LRL, Farias MR, Castro MS. (Org.) PROFARMA - Programa de Atualização em Ciências Farmacêuticas: da Assistência Farmacêutica à Farmácia Clinica. ciclo 3. Porto Alegre: Artmed Panamericana, 2020. p. 69- 115 (Sistema de Educação Continuada à Distância, v.1).
9. National Coordinating Council for Medication Error Reporting and Prevention (NCC MERP). About medication error. What is a medication error [Internet]. 2001 [citado 2021 Jun 10]. Disponível em: https://www.nccmerp.org/about-medication-errors.
10. Milch CE, Salem DN, Pauker SG, *et al*. Voluntary electronic reporting of medical errors and adverse events. An analysis of 92,547 reports from 26 acute care hospitals. J Gen Intern Med. 2006; 21(2):165-70. DOI: 10.1111/j.1525-1497.2006.00322.x.
11. Brasil. Ministério da Saúde, Fundação Oswaldo Cruz, Agência Nacional de Vigilância Sanitária. Documento de referência para o Programa Nacional de Segurança do Paciente [Internet]. Brasília: Ministério da Saúde; 2014 p. 17.
12. Cleeland CS, Allen JD, Roberts SA, *et al*. Reducing the toxicity of cancer therapy: recognizing needs, taking action. Nat Rev Clin Oncol. 2012; 9(8):471-8. DOI: 10.1038/nrclinonc.2012.99.
13. Thurtle DP, Daffron SB, Halvorson EE. Patient Characteristics Associated With Voluntary Safety Event Reporting in the Acute Care Setting. Hosp Pediatr. 2019; 9(2):134-138. DOI: 10.1542/hpeds.2018-0142.
14. Furini ACA. Notificações de eventos adversos: caracterização dos eventos ocorridos em um hospital universitário [master's thesis]. Ribeirão Preto: Faculdade de Medicina de Ribeirão Preto; 2018. 149 p.
15. Irmandade Santa Casa de Misericórdia de Porto Alegre. Relatório anual 2019. [internet]. Porto Alegre: Irmandade Santa Casa de Misericórdia de Porto Alegre, 2019. 120 p. [citado 2021 Dez 22]. Disponível em: https://santacasa.org.br/uploads/files/1595596634.pdf
16. Otero LMJ, Castaño RB, Pérez EM, *et al*; Ruiz-Jarabo 2000 Work Group. Actualización de la clasificación de errores de medicación del grupo Ruiz-Jarabo 2000 [Updated classification for medication errors by the Ruiz-Jarabo 2000 Group]. Farm Hosp. 2008; 32(1):38-52. DOI: 10.1016/s1130-6343(08)72808-3.
17. Brasil. Ministério da Saúde. Secretaria de Atenção à Saúde. Instituto Nacional de Câncer. TNM: classificação de tumores malignos. 6. ed.- Rio de Janeiro: INCA; 2004. 254p
18. WHO Collaborating Centre for Drug Statistics Methodology, ATC classification index with DDDs, 2021. Oslo, Norway 2020.
19. Ebbert D. chisq.posthoc.test: A post hoc analysis for Pearson's chi-squared test for count data. R package version 0.1.2. [Internet]. 2019. [citado em 2021 Dez 22]. Disponível em: https://CRAN.R-project.org/package=chisq.posthoc.test

20. R Core Team. R: A language and environment for statistical computing. R Foundation for Statistical Computing [Internet]. Vienna, Austria, 2021. [citado em 2021 Dez 22]. Disponível em: https://www.R-project.org/.

21. Christianson JB, Volmar KM, Alexander J, *et al*. A report card on provider report cards: current status of the health care transparency movement. J Gen Intern Med. 2010; 25(11):1235-41. DOI: 10.1007/s11606-010-1438-2.

22. Santos CO. Educação permanente da assistência: uma sensibilização para notificação de eventos adversos a medicamentos [master's thesis]. Porto Alegre: Universidade Federal de Ciências da Saúde de Porto Alegre; 2019. 112 p. [citado em 2021 Dez 22]. Disponível em: https://repositorio.ufcspa.edu.br/jspui/bitstream/123456789/1715/1/%5BDISSERTA%C3%87%C3%83O%5D%20Santos%2C%20Calize%20Oliveira%20dos.pdf

23. Teixeira CFS, Soares CM, Souza EA, *et al*. A Saúde dos Profissionais de Saúde no Enfrentamento da Pandemia de COVID-19. Ciênc. saúde coletiva. 2020 ; 25(9): 3465-3474. DOI: 10.1590/1413-81232020259.19562020.

24. Kim J, Hurria A. Determining chemotherapy tolerance in older patients with cancer. *J Natl Compr Canc Netw*. 2013;11(12):1494-1502. DOI: 10.6004/jnccn.2013.0176.

25. Baldo P, Fornasier G, Ciolfi L, *et al*. Pharmacovigilance in oncology. Int J Clin Pharm. 2018; 40(4):832-841. DOI: 10.1007/s11096-018-0706-9.

26. Schutte T, van Eekeren R, Richir M, *et al*. The adverse drug reaction reporting assignment for specialist oncology nurses: a preliminary evaluation of quality, relevance and educational value in a prospective cohort study. Naunyn Schmiedebergs Arch Pharmacol. 2018; 391(1):17-26. DOI: 10.1007/s00210-017-1430-z.

27. Chopra D, Rehan HS, Sharma V, *et al*. Chemotherapy-induced adverse drug reactions in oncology patients: A prospective observational survey. Indian J Med Paediatr Oncol. 2016; 37(1):42-6. DOI: 10.4103/0971-5851.177015.

28. Ranchon F, Salles G, Späth HM, *et al* Chemotherapeutic errors in hospitalized cancer patients: attributable damage and extra costs. BMC Cancer. 2011; 8;11:478. DOI: 10.1186/1471-2407-11-478.

29. Walsh KE, Dodd KS, Seetharaman K, *et al*. Medication errors among adults and children with cancer in the outpatient setting. J Clin Oncol. 2009; 27(6):891-6. DOI: 10.1200/JCO.2008.18.6072.

30. Ulas A, Silay K, Akinci S, *et al*. Medication errors in chemotherapy preparation and administration: a survey conducted among oncology nurses in Turkey. Asian Pac J Cancer Prev. 2015; 16(5):1699-705. DOI: 10.7314/apjcp.2015.16.5.1699.

31. Silva NM, Santos Ma, *et al*.Idosos em Tratamento Quimioterápico: Relação entre Nível de Estresse, Sintomas Depressivos e Esperança. Psic.: Teor. E Pesq. 2019; v. 35. DOI: 10.1590/0102.3772e35441.

32. Roque KE, Melo ECP. Avaliação dos eventos adversos a medicamentos no contexto hospitalar. Escola Anna Nery. 2012; 16 (1): 121:127. DOI: 10.1590/S1414-81452012000100016.

33. Dubrall D, Schmid M, Alešik E, *et al*. Frequent Adverse Drug Reactions, and Medication Groups under Suspicion. Dtsch Arztebl Int. 2018; 115(23):393-400. DOI: 10.3238/arztebl.2018.0393.

34. Gao Y, Shang Q, Li W, *et al*. Antibiotics for cancer treatment: A double-edged sword. J Cancer. 2020; 11(17):5135-5149. DOI: 10.7150/jca.47470.

35. Chou PL, Huang YP, Cheng MH, *et al*. Improvement of Paclitaxel-Associated Adverse Reactions (ADRs) via the Use of Nano-Based Drug Delivery Systems: A Systematic Review and Network Meta-Analysis. Int J Nanomedicine. 2020; 15:1731-1743. DOI: 10.2147/IJN.S231407.

36. Pereira, LC, Nogueira, TA, Barbosa, LA, *et al*. Adverse reactions to docetaxel: an active survey. Brazilian Journal of Pharmaceutical Sciences. 2015; 51:551-559. DOI: 10.1590/S1984-82502015000300007.

37. Hospital Isaelita Albert Einstein. Guia de Protocolos e Medicamentos para Tratamento em Oncologia e Hematologia. São Paulo; 2013. 519 p.

38. Barcelos FC, de Matos GC, da Silva MJS, *et al*. Suspected Adverse Drug Reactions Related to Breast Cancer Chemotherapy: Disproportionality Analysis of the Brazilian Spontaneous Reporting System. Front Pharmacol. 2019; 10:498. DOI: 10.3389/fphar.2019.00498.