

Postmarketing surveillance in Brazil: vascular catheters – an overview of notifications of adverse events and technical complaints

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Abstract *This article identifies, quantifies and categorizes adverse event notifications and technical complaints related to the use of vascular catheters, received by the Notivisa system in the period from January 2007 to June 2016. It is a descriptive, retrospective, documental study with a quantitative approach. Data requested and supplied by Anvisa were analyzed and presented in the form of charts and tables. The study covered 4,682 notifications of technical complaints, and 671 adverse events. There was a progressive increase in notifications during the period studied. As to the type of technical complaint, the majority referred to ‘suspected quality failings’, the largest component being due to ‘catheter rupture during procedure’. The adverse event most notified was ‘catheter broke in the vein and migrated to another part of the body’. In the period studied there were four notifications of deaths, the most severe level of adverse event. The study made it possible to visualize the importance of after-sales surveillance of vascular catheters, as well as supplying a wide-ranging overview of their use. Provision of this overview could support technical surveillance activities and serve as input for public policies relating to this product.*

Key words *Vascular access device, Postmarketing surveillance, Adverse events, Patient safety*

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Introduction

Incorporation of new technologies is an irreversible aspect of health work today. Based on advances in scientific knowledge and the demands of society, it seeks improvement in diagnosis and better provision of healthcare¹.

Due to the possibility of health products causing damage to their users, monitoring of their production and use has been accepted as necessary, to achieve knowledge of their characteristics and for planning preventive action to reduce risks. In Brazil, this was made possible by the creation of the National Health Products and Services Agency (*Agência Nacional de Vigilância Sanitária – Anvisa*). The role of Anvisa is directly related to guarantee of health, but one of the biggest challenges for the health oversight system is establishment of an assessment of risks to health, especially those associated with new and emerging technologies, relating to health products².

Among the health product and service problems arising from the use of these products in healthcare establishments are adverse events (AEs) and Technical Complaints (TCs). These are the problems that lead to serious health deterioration, complications or, indeed, death of users, or of health professionals, involved in their operation, handling and application¹.

The accepted definition of an AE is unintentional injury caused by the healthcare and not by the natural progress of the underlying illness³. The concept of TC refers to any notification of suspicion of alteration or irregularity of a product or company, in relation to technical or legal aspects that may or may not cause damage to individual collective health².

“The occurrence of an AE is considered to be a problem of international importance”⁴, and is recognized as one of the largest problems in health area⁵.

Both AEs and TCs have an important impact on Brazil’s Unified Health System (*Sistema Único de Saúde – SUS*), in that they can lead to increased morbidity, mortality, patient treatment time or the cost of care, as well as reflecting in other fields of the country’s social and economic life⁶. Damage to the user arising from healthcare also has a significant effect on health care expenditures – otherwise unnecessary expenditure of funds that could be used to finance other health needs of the population⁷.

Considering that the use of products for health can cause some type of risk to the user, it is of extreme importance that the use of these prod-

ucts under real conditions should be monitored, when they are used in the after-sales situation on a large scale – indicating the great importance of post marketing surveillance. This area – usually referred to as the AE and TC surveillance system of health products in the post-marketing phase – is still recent in Brazil and even in the world. It can be seen as a growing disciplinary field, whose purpose is to recommend the adoption of measures for the safety of the population⁸.

Safety is understood to mean the absence of unacceptable risk – that is to say: the possibility of occurrence of damage should not be greater than the benefits generated by exposure of a user to a product used in healthcare⁹. Thus, the monitoring, by post marketing surveillance, of notifications of AEs and TCs aims to find a constructive response in that it should make it possible to recognize the pattern of failings, for the purpose of preparing programs of control and preventive policies. Prevention of the occurrence of these events should be perceived as a priority of all those involved in this process, from development of the product right through to its use¹⁰.

Investigation of occurrences related to health products in the post-marketing phase makes it necessary to obtain information of quality on what takes place with these products, but Anvisa was lacking this information until the creation and implementation of the Sentinel Hospitals Project (*Projeto Hospitais Sentinela*), a system that exceeded all the initial expectations with its strong action throughout the country¹.

This product gave rise to a period of stronger activity by post marketing surveillance for secondary prevention, because it made it possible, by a risk management team put in place in every institution relating to the Project, for deep work to be done with the themes of quality of healthcare, health product and service risk, and surveillance by sector. This in turn made it possible for there to be active and planned intra-hospital monitoring acquiring essential information for taking of decisions or corrective actions, but principally preventive actions, since the activity of this team – the result of putting the Sentinel Hospitals Project in place – reformulated the way of working in health environments. The Sentinel Hospitals became more in the nature of partners in oversight actions focused on investigation, providing prevention and minimization of risks during the period of hospitalization, as well as optimization of cost and enhanced healthcare quality¹¹.

With the creation and implementation of the Notivisa system and the Sentinel Hospitals Proj-

ect, Anvisa was finally able to provide itself with quality information about the occurrences of AEs and TCs related to health products. Notivisa makes it possible to obtain and circulate information on users' adverse health events, sudden or undesired effects and/or failings of functioning related to the health products sold in Brazil¹⁰; and the Sentinel Hospitals Project has as its principal focus the construction of a network of hospitals throughout the country that are able to monitor performance and notify AEs and TCs².

Notivisa was started in Brazil in December 2006 as an official system of information on post-use/post-sales surveillance (Vigipós)². It is an IT-based system, created by Brazilian's The Minister of Health "Portaria numero" 1,660 of July 22, 2009¹² and "Portaria numero" 529 of April 1, 2013¹³, and Anvisa RDC 36 of July 25, 2013¹⁴, created to receive notifications of AE and TC incidents relevant to the use of products and services that are under the surveillance of the general oversight system. Today it is the nationwide computerized system for registry of problems related to the use of technologies and care processes, through monitoring of the occurrence of TCs on drugs and health products, incidents and AEs, for the purpose of strengthening after-use oversight of products for health¹⁵.

One important product among these is the vascular catheter, widely used in health recovery. In the hospital context, introduction of a vascular catheter into a blood vessel is one of the most frequent procedures¹⁶, and also one of the first and most important steps in care and maintenance of hospitalized patients^{17,18}. However, its use can result in a wide range of complications, including, in the most serious cases, death. An evaluation and analysis on its use can be helpful in making possible measures that reduce the occurrence of complications, leading to increasingly safe, and higher-quality healthcare^{19,20}.

There are various types of catheter that can provide vascular access. This study considered the Peripheral Intravenous Vascular Catheter (PIVC) of the Jelco® or Abocath® type, or of the 'scalp' type, usually for short periods of use; the catheter for hemodialysis (dialysis catheter or DC), which may be peripheral if for short-period use or central if for use over long periods; the Peripherally Inserted Central Venous Catheter (PICC), the semi-implantable catheter (SIC), and the Totally Implantable Catheter (TIC), for long-term insertion; and the umbilical catheter (UC)².

The use of a vascular catheter can result in various complications, during and/or after insertion, and also at the time of withdrawal. Systemic

complications can result in risk to the user's life – examples are septicemia, circulatory overload, pulmonary edema, gasembolism, shock and catheter embolism. Local complications are lesions around the location of insert, which are very rarely serious, and can be evaluated early by simple observation²¹.

There is a need to seek scientific evidence that analyzes AEs relating to vascular catheters, which have implications in period of hospitalization, costs and increase of morbidity and mortality. Evaluation of complications can help in creating measures of prevention, supervision, identification and their repercussions²⁰.

Among significant complications arising from use of a vascular catheter, the one which is more worried is infection²²⁻²⁴, and the approach to measurement and analysis, for measures to contain this effect is through receipt of notifications. Thus, it is evident the importance of the Notivisa system, because through the investigation of QT and EA reports related to vascular catheter it will be possible to minimize and / or avoid risks to the health of the population, and thus improve both the quality of these products and healthcare in general in Brazil²⁵.

Objective

To identify, quantify and categorize the occurrence of notifications of AE and TC related to the use of vascular catheters received by the Notivisa system, nationwide, over the period from January 2007 to June 2016.

Method

This is a descriptive, retrospective, documental study with a quantitative approach. To evaluate notifications of AE and TC related to vascular catheters, and thus monitor quality of these products and their use in the post-marketing phase, the information recorded in the Notivisa system over the period from January 2007 to June 2016 was used.

First, the data on notifications was requested from the Management Center of the National Health Oversight Notification and Investigation Center (Nuvig) of Anvisa, by filing of the *Fale Conosco (Talk to Us)* form for access to information, at the link: <http://portal.anvisa.gov.br/fale-conosco>. The requested data were released and sent to the investigator by email in an Excel file.

Following receipt of the notifications of vascular catheters in Notivisa, the total number of occurrences notified per year was quantified. The notifications were analyzed and all AEs and TCs that met the criteria for inclusion were described and categorized. The criteria for inclusion in the study were: Notifications that took place in Brazil of adverse events and technical complaints related to the health product Vascular Catheter, recorded in the Notivisa system in the stipulated period.

After collection, the data extracted from the records of occurrences of AEs and TCs were meticulously analyzed. The critical analysis of the description (reason) giving rise to the notifications was evaluated and any discrepancies from the definitions in the Anvisa postmarketing manual, and those imposed by the notifier were analyzed and observed. The notifications that were classified wrongly as to their type were reclassified, and subsequently all the results were tabled in computer form, analyzed quantitatively and presented in the form of charts and tables.

The study followed the norms established by the Resolution 466/2012, of the National Health Council, which regulates research on humans. The project for this study was submitted to the Research Ethics Committee of the Federal University of ABC, and received approval.

Results and discussion

The information system is the principal instruments for the practices of oversight, and until the creation of Notivisa there was not a specific information system in the general oversight system (Visa). The Notivisa system became a strategic management element to provide for this lack, enabling greater visibility of information by all the entities and health professionals involved in the all the activity processes of Visa. It is through this information obtained by the system that it will be possible to adopt adequate control measures, safety warnings, and use of the information to update the existing legislation and/or propose new legislation or health recommendation for adoption of measures to guarantee protection and promotion of the population's health²⁶.

In the period from January 2007 to June 2016 Notivisa received 6,144 notifications covering AEs and TCs in relation to vascular catheters, but after detailed analysis, 785 notifications which did not meet the study inclusion criteria were excluded since they referred to other types

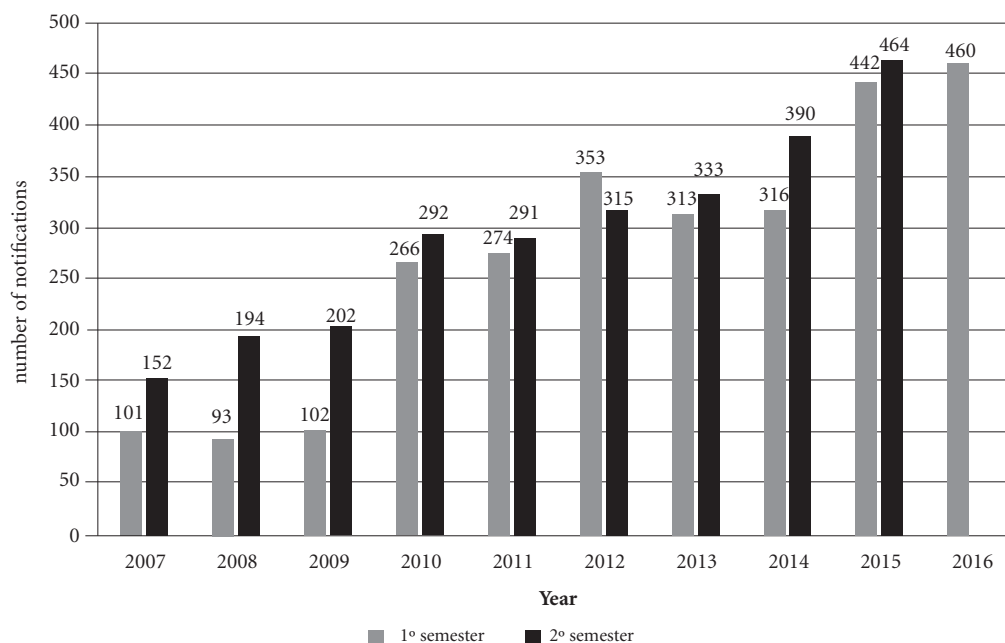
of catheters. More six were excluded because they referred to events outside Brazil. A total of 5,353 notifications met the criteria for inclusion and were included in the study. Graphic 1 shows the total of notifications over the period January 2007–June 2016:

After the notifications had been analyzed and reclassified where necessary, they were grouped as to the type of notification. 671 referred to AEs, and 4,682 referred to TCs.

It was possible to separate the quantities of notifications by Brazilian state and region. São Paulo was the state with the highest number of notifications of AEs and TCs over the period – a total of 1,938 (36%). This was followed by the states of Santa Catarina, with 505 (9.4%), Ceará with 457 (8.5%), Minas Gerais with 352 (6.5%), Rio de Janeiro with 291 (5.4%), Rio Grande do Sul with 283 (5.2%), and the Distrito Federal with 222 (4.1%). The states with the lowest number of notifications were Rondônia, with a total of 4 (0.07%), and Roraima, with only 3 (0.05%).

In an analysis of the general overview of the notifications of technical complaints in adverse events relating to vascular catheters in Brazil, the Southeastern region had the highest frequency of notifications over the period (49%), followed by the South and Northeast (with 21%), the Center-West (with 5%), and the North (with 4%). The Sentinel Network was the largest source of notifications for AE and TC in the country. São Paulo had the highest number of records of products giving rise to AE to TC. The Southeast is the Brazilian region with the largest population, estimated in July 2016 to be 86,356,952, or 41.9% of the total population of the country according to the Brazilian Geography and Statistics Institute (IBGE)²⁷. This may clearly relate to its having the highest number of notifications. Another important factor is that 48.9% of the hospitals in the Sentinel Network are in this region – 28.2% of them are in São Paulo State²⁸.

In the data it supplied to the investigator, Anvisa had codified the products that gave rise to TCs and AEs. In most cases the data received enables identification of the types of catheter referred to in the notifications, since many reported the type or commercial name. Thus the products were grouped into eight categories as to type: Peripheral Vascular Catheter (PVC), Hemodialysis Catheter (HC), Semi-Implantable Catheter (SIC), Totally Implantable Catheter (TIC), Umbilical Catheter (UC), Central Vascular Catheter (CVC), Peripherally Inserted Central Venous Catheter (PICC); and a *not identified* (NID) cate-



Graphic 1. Frequency in absolute numbers of notifications of adverse events and technical complaints of vascular catheters in Brazil for each half year, 2007-2016.

gory for notifications in which it was not possible to identify the type. The figures for notifications of each type are shown in Graphic 2.

PVC was the product with the highest number of notifications, at 48% of the total, followed by PICC (21%), CVC (17%) and DC (8%). The number of notifications related to PVC may be related to the fact that insertion of a PVC is one of the procedures most frequently carried out in the hospital environment.

Use of a vascular catheter is an invasive procedure, and thus is accorded a specific classification of risk. The notifications of AEs and TCs for vascular catheters refer to the products with risk classification medium, high and maximum. Of the notifications which informed the risk class of the product, AEs had the highest number of notifications related to maximum risk (53%), while TCs had the highest number of notifications related to a product classified as medium risk (41%).

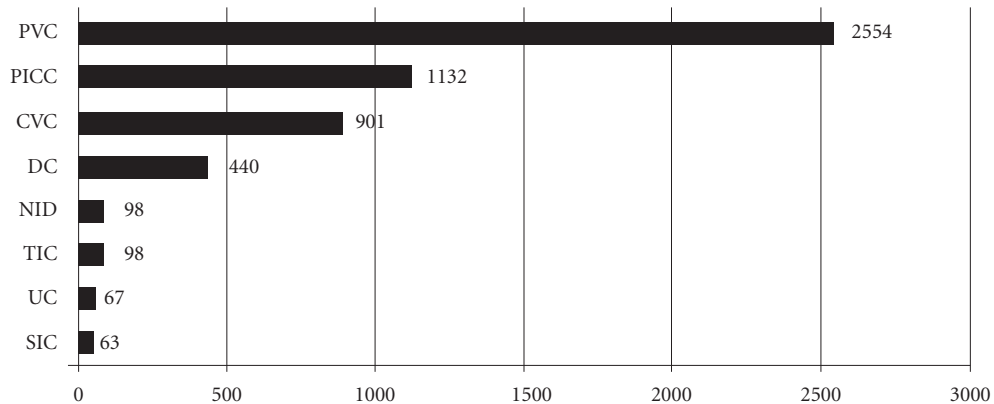
The 4,682 notifications of technical complaint were categorized by their type, and the largest group (97% of the total) referred to products with suspected quality deviations. Other types of notifications were also cited, such as: products suspected of not being registered, prod-

ucts suspected of being falsified, and products under suspicion of other irregular practices, unspecified.

Each TC referred to a specific reason for notification. The reasons for TCs are shown in Table 1, and were grouped in 34 categories after analysis of each one of the 4,682 TCs.

Among the notifications for TC, in some cases the notifier reporting did not give a detailed description nor the reason for the occurrence, which was an obstacle for categorization. The events were generically categorized as “Puncture difficulty, no reason given”—a total of 131 of the TC notifications.

The early study by Morais¹⁰ on CVC notifications was in accordance with the findings in this study, since they also reported a higher number of notifications involving difficulty in catheter progression, followed by deformation and excessive flexibility. Another non-compliance, with a large number of notifications in this study, was fracture or rupture of the catheter followed by “other problems”. Occurrences of functional and mechanical failures were also indicated. Excessive flexibility, rigidity and deformation of the guidewire were the most important functional failures, from the point of view of product qual-



Graphic 2. Relative frequency of notifications by type of vascular catheter, Brazil, January 2007-June 2016.

PVC – Peripheral Vascular Catheter; PICC – Peripherally Inserted Central Venous Catheter; CVC – Central Vascular Catheter; DC – Dialysis Catheter; NID – Not identified; TIC – Totally Implantable Catheter; UC – Umbilical Catheter; SIC – Semi-implantable Catheter.

ity and possible damage to the patient. The most severe mechanical failures found were difficulty in progression of the guidewire, and breakage of the catheter¹⁰.

Among the 34 categories for reasons leading to TC, the majority of notifications were of failure of the catheter product per se, the main reasons being as follows – in order: bending of catheter, difficulty of catheter progress, orifices or cracks in the catheter, and catheter uncut or with blunt end. Other reasons reported referred to failures in the process of packaging, and product registry failings; some reasons were not given. This result makes clear that in spite of the strategies used by Visa to ensure quality, safety and efficacy of products, it is not possible to foresee all the failings that could occur when using the products in practice on a large scale.

Due to lack of knowledge, health professionals frequently do not give due attention to these facts, probably due to scarcity of information and orientation on what to do in cases of deviation of quality of products used²⁹. As Anvisa says²⁸, “it is imperative that health professionals should have capability to apply the most effective actions to avoid undesired results”. At the same time it is necessary to understand that AEs and TCs are more commonly caused by failure in the system or product than by human failure³⁰.

Among the reasons for TCs, some caused damage to users – considered to be adverse events. Table 2 shows the notifications of adverse events received by the Notivisa system over the period from January 2007 to June 2016.

The AE most notified was ‘catheter broke in vein and moved to other part of body’ (29%) followed by ‘phlebitis’ (26%) and ‘vein break causing bruise’ (15%). It is essential to highlight that in the period under study there were four notifications of deaths – the most severe form of AE – related to procedures of insertion of vascular catheter: three while using PICC and one while use CVC. It is also essential to point out that the scale of occurrence of death as a complication of use of vascular catheter is unacceptable, and uniform orientations must be established to avoid this complication³¹.

Of the types with most AEs, PICC was the largest with 40% of total notifications, and PVC with 35%. PICC, among the various categories of AE, made the highest contribution in the category ‘phlebitis’. PVC, the type with the second most prevalent reason for AE notification, referred most frequently – and with the same number of notifications – to the categories ‘catheter broke in vein and moved to other part of body’, with 7%, and ‘vein break causing bruise’, also with 7%.

The AE with highest number of notifications was ‘catheter broke in vein and migrated to other

Table 1. Reasons for technical complaints, by type of vascular catheters, notified in Brazil, January 2007-June 2016.

Reason for TC	Type of catheter								Total
	DC	SIC	TIC	UC	CVC	PVC	NID	PICC	
Catheter									
Solid base inhibits view of venous return	0	0	0	0	0	17	0	1	18
Caliber non-compliant	4	0	3	0	11	29	1	12	60
Catheter adhered to protective cover	0	0	0	0	3	49	2		54
Catheter damaged	5	0	0	1	22	29	4	15	65
Catheter in bent packaging	2	0	2	0	20	84	3	9	120
Catheter not radio-opaque as specified	0	0	0	6	0	0	2	16	24
Catheter with obstruction	17	3	4	4	42	75	0	45	190
Catheter uncut/ blunt end	5	0	0	0	9	376	1	20	411
No cm graduation or scale in the kit	2	0	1	7	4	0	0	7	21
Catheter punctured by guidewire	0	0	0	0	0	25	0	2	27
Clamp does not close	5	0	0	0	2	1	0	0	8
Defect in connector and connection	3		2	1	19	48	2	3	78
Deformation in catheter	10	3	3	1	14	24	2	21	78
Design inhibits handling	0	0	0	1	1	35	3	3	43
Fixing tab came off	35	2	0	1	37	14	0	24	113
Difficulty in progressive insertion	57	6	8	8	144	349	17	43	632
Catheter bent	138	8	2	2	212	283	11	37	693
Failure in catheter's safety system	0	0	0	1	0	86	0	5	92
Guide thread adhered to catheter	35	0	0	0	65	51	4	11	167
Catheter with orifices or crack	19	16	5	13	42	164	6	273	538
Venous return slow	2	0	0	0	1	14	0	0	17
Catheter broke during procedure	43	7	20	8	107	246	23	261	715
Packaging									
Coloration not compliant	1	0	0	0	0	5	0	4	10
Foreign body	2	1	3	0	11	87	2	3	109
Droplets inside packaging	0	0	0	0	0	2	0	1	3
Packaging seal non-compliant	0	0	0	0	8	0	0	0	8
Packaging damaged	3	0	1	2	3	23	0	2	34
Packaging lacking parts	4	8	1	0	32	42	1	13	101
Packaging empty	0	0	0	0	1	44	0	6	51
Sterilization non-compliant	0	0	0	1	0	0	0		1
Registration									
Not compliant with identification or registry	7	0	1	2	6	13	6	15	50
Product model not compliant with package labelling	0	0	0	1	1	15	0	2	19
Suspicion of falsified product	0	0	0	0	0	1	0	0	1
Unspecified									
Puncture difficulty, no reason given	11	0	1	1	25	83	1	9	131
Total									4682

DC – Dialysis Catheter; SIC – Semi-implantable Catheter; TIC – Totally Implantable Catheter; UC – Umbilical Catheter; CVC – Central Vascular Catheter; PVC – Peripheral Vascular Catheter; NID – Not identified; PICC – Peripherally Inserted Central Venous Catheter.

part of body'. According to this study, the migration of the point of the catheter is relatively common, but it is indisputable that this is a type of AE that can lead to serious complications³¹.

Low-caliber PVCs, especially those of silicon, can easily break if inappropriately handled and can migrate to the interior of the blood vessel. For PICCs, this migration is a common complication,

Table 2. Types of adverse events with vascular catheters, by type, notified in Brazil, January 2007-June 2016.

Type of AE	Type of catheter								Total
	DC	SIC	TIC	UC	CVC	PVC	NID	PICC	
Abscess on right axilla	0	0	0	0	0	0	0	1	1
Perforation accident	1	1	0	0	0	4	0	0	6
Bacteremia	1	0	0	0	0	0	0	0	1
Catheter broke in vein and moved to another part of the body	10	2	38	0	35	53	3	54	195
Pleural effusion	1	0	0	0	1	0	0	0	2
Skin lesion	0	0	0	4	5	36	0	2	47
Puncture repeated / pain at location	8	0	1	0	5	26	0	4	44
Edema and pain at puncture location	0	3	0	0	1	1	0	4	9
Gas embolism	3	0	0	0	0	0	0	0	3
Sustained extra-sistole and arrhythmia during procedure	0	0	0	0	1	0	0	0	1
Leakage or infiltration	1	0	2	1	6	16	1	23	50
Phlebitis	2	0	0	0	1	50	1	124	178
Vein break causing bruise	2	2	0	0	11	53	2	36	106
Hyperemia	0	0	0	0	0	1	0	15	16
Respiratory insufficiency during procedure	1	0	0	0	1	0	0	3	5
Death related to procedure	0	0	0	0	1	0	0	3	4
Perforation of right atrium	1	0	0	0	0	0	0	0	1
Pneumothorax	0	0	0	0	1	0	0	0	1
Tachyarrhythmia	0	0	0	0	1	0	0	0	1
Total	31	8	41	5	70	240	7	269	671

DC – Dialysis Catheter; SIC – Semi-implantable Catheter; TIC – Totally Implantable Catheter; UC – Umbilical Catheter; CVC – Central Vascular Catheter; PVC – Peripheral Vascular Catheter; NID – Not identified; PICC – Peripherally Inserted Central Venous Catheter.

and can happen during insertion of the device or during maintenance. During internal migration the PICC may bend within the blood vessel, or advance towards the right atrium or to one of the tributary veins, or not progress far enough to reach the superior vena cava. The percentage of breakage of PICCs varies between 4% and 5%³².

A study dealing with the reasons for removal of catheter in 239 cases of use of a PICC also referred to migration. 43 cases were recorded of devices lost by migration, 17 by rupture and 13 by obstruction³³.

In some cases the catheter that breaks, or part of it, does not cause serious damage to the user and is expelled naturally by the body, but it must be considered that failings do cause this migration and can lead to unnecessary damage from invasive procedures, increasing the risk of user infection and discomfort, prolonging the period of hospitalization, thus increasing costs arising from hospital beds, examinations and procedures to accompany or remove the migrated component. These procedures include: x-rays,

CAT scans, contrast exams, angiography, further catheter examinations, phlebotomy, and others.

The second most frequent category of AE in the Notivisa records is “phlebitis”. This is one of the most frequent complications in use of catheters^{19,34,35}. It is a significant clinical problem, creating not only discomfort but a longer period of hospitalization for the patient, increase of hospital costs and alteration of health professionals’ activities, able to affect the quality of care^{34,36}.

The rules of the Infusion Nurses Society³⁷ states the acceptable rate of phlebitis as 5% or less. On the other hand, the results of this study and others suggest a significant disparity: in this study there was phlebitis in 26% of the total of AEs notified, or approximately five times the level accepted by the INS. This also occurred in another study³⁸ where the incidence of phlebitis in adults hospitalized in a medical clinic was 25.8%.

A recent study of the incidence and attenuating factors for phlebitis in peripheral intravascular access reported a rate of 31.4% of incidence of phlebitis³⁴. Another study showed an even

higher proportion of phlebitis, at 41.2% for all peripheral intravascular insertions of catheters³⁶. In another study, of 815 CVCs in 573 patients, phlebitis was the most common AE, with 38%³⁹.

Two types of catheter presented the highest levels of AE: the PICC with 40% of total notifications, and the PVC with 35%. The PICC, among the various categories of AE, made the highest contribution to the phlebitis category. The PVC, responsible for the second highest proportion of AEs, reported an equal number in the category 'catheter broke in the vein and migrated to other part of the body', and 'vein broke, causing bruise', both with 7% of the total.

Conclusions

Monitoring of any problem related to health products constitutes the present challenge of post marketing surveillance. This study showed the importance of the post-marketing oversight of venal catheters, as well as providing a wide-ranging overview of notifications relating to them in Brazil. This can provide support for actions of post marketing surveillance in the country, and also provide inputs for public policies related to this specific product.

The findings of this study enable it to be concluded that the Notivisa system, the official system for notification of AE and TC, is a very important tool for making the activities of post marketing surveillance effective. It also makes it

possible to conclude that Notivisa contributes to facilitating and speeding the process of communication between all those involved with technology in terms of venal catheter health, and also serves as an advice system for promotion of safety, risk management in health, and provision of conditions for a continuing nationwide database.

It is possible, however, that this study has not covered the totality of the AEs and TCs in the whole of the country in the period studied, since most of the institutions that use the Notivisa system are still participants of the Sentinel Network in which they already have a Risk Management team in place. However, maintenance of the policy of stimulation of notification with quality throughout the country is considered to be indispensable.

The good functioning and effectiveness of post marketing surveillance is a responsibility held in common by users, notifying professionals and the regulatory environment. Vascular catheters with quality can make a direct and positive intervention in the healthcare provided to the user. Thus, in view of the AEs and TCs and the importance of notifications, it is believed that the development of similar studies will contribute to the development of good safety practices among those involved in such a way as to minimize their incidence. Taking into consideration the few scientific contributions in the area under study, it is concluded that this work contributes to the overall theme of 'risk management in the area of post marketing surveillance and public health'.

Collaborations

CG Oliveira worked on the conception, scope, analysis, data interpretation, article write-up and critical revision. ACD Rodas worked on the conception, scope, analysis and critical revision.

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