Management of functional complications of totally implantable

venous access devices by an advanced practice nursing team: 5

years of clinical experience

Authorship

All authors have made substantial contribution to all of the following: (1) the conception and design of

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Abstract

Purpose: Our aim is to describe the number and distribution of requests addressed to an Advanced Practice Nursing team for functional problems of totally implantable venous access devices (TIVADs) and to describe, in detail, the malfunction management by the type and number of additional investigations and treatment modalities.

Method: The Advanced Practice Nursing team recorded data about all requests for support as part of the standard care. A specific protocol, the Leuven Malfunction Management Protocol was used for troubleshooting. In this descriptive, retrospective study, data of 3950 consecutive requests for TIVAD-related functional problems in 2019 patients were analyzed. Data collection included (1) demographic information, (2) device-related details, and (3) malfunction and follow-up details.

Results: 'Easy injection, impossible aspiration' was the most frequently documented functional problem (66.9%) for all requests for help. Of all malfunctions, catheter tip was in an optimal position in 73.4%, thrombolytics were administered in 59.0%, and a linogram was performed in 4.9%. TIVAD removal/exchange was advised in 4.4% of the requests.

Conclusions: TIVAD malfunction—defined operationally in terms of injection and/or aspiration problems—reflect all functional complications encountered in practice. Adherence to the Leuven Malfunction Management Protocol can ensure that, in most cases, catheter patency can be fully restored without removing or replacing the TIVAD. The Advanced Practice Nursing team coordinates the following treatments, investigations, and procedures: radiological catheter tip verification; thrombolytic agent administration and, if necessary, subsequent injection of solutions to dissolve drug precipitates or lipid deposits; linogram; percutaneous sleeve stripping; and TIVAD removal/replacement.

Key words

Catheters, Indwelling; Catheterization, Central Venous; Functional outcomes; Neoplasms; Advance Practice Nursing; humans; Study, Retrospective

Introduction

Implantable ports or totally implantable venous access devices (TIVADs) such as port-a-cath, have become an important and safe tool in treating chronic diseases. In cancer patients TIVADs are used primarily for chemotherapy administration and blood sampling. Therefore, well-functioning devices are highly desired. However, malfunction can occur according to different degrees of injection and/or aspiration problems. Reported malfunction incidence rates in the adult onco-hematology populations vary between 0% and 47% of inserted TIVADs and between 0.24% and 26% of accessions (Goossens et al., 2011). In addition, functional problems have multiple causes, such as incorrect needle placement, catheter tip thrombosis (CTT), incorrect catheter tip location, catheter sleeve formation, catheter tear or embolisation, intraluminal clot formation, port chamber defect, drug precipitate accumulation in the port reservoir, superior vena cava (SVC) thrombosis and perforation (Hardy and Ball, 2005; Krzywda, 1999; Schulmeister, 2010; Schummer et al., 2003; Stephens et al., 1995; Surov et al., 2008). After accessing a port, oncology nurses have been estimated to spend an extra 27.1 to 29 minutes on troubleshooting problems due to malfunction (Lamont et al., 2003). Malfunction compromises treatment and causes stress to patients and health care providers.

Once a malfunction occurs, a broad range of measures is available for troubleshooting.

Troubleshooting starts with a careful clinical examination and meticulous history taking. Additional investigations, such as a chest X-ray or contrast dye injection through the device (linogram), can

Troubleshooting starts with a careful clinical examination and meticulous history taking. Additional investigations, such as a chest X-ray or contrast dye injection through the device (linogram), can determine the origin of the malfunction. Depending on the findings, treatment can be initiated with thrombolytics or solutions that dissolve drug precipitates and lipid deposits. Sometimes more invasive interventions are needed, such as percutaneous sleeve stripping (PSS) (Heye et al., 2011), catheter repositioning, or even whole device replacement. However, health care providers in charge of patients with TIVADs often lack knowledge about how to deal with the management of functional complications. An Advanced Practice Nursing team (APN team), a group of nurses specifically trained to troubleshoot complications involving venous access devices, may therefore be of added value. Indeed, their specific clinical expertise enables them to provide expert advice and advanced care to patients (Goudreau et al., 2007). The purpose of this paper is to determine the number, type, and distribution of: (1) requests for malfunction, (2) supplementary investigations, (3) thrombolytic and other treatments.

Methods

Advanced practice nursing team

The University Hospitals Leuven (UHL), Belgium, has an APN team belonging to a larger reference team for long-term venous access systems. The reference team consists of five specialized nurses of the APN team and two oncology surgeons. The APN team specializes in preventing and troubleshooting complications involving venous access devices. Managing TIVAD malfunctions is one of its major duties. The APN team works in close collaboration with treating physicians and physicians belonging to the departments of vascular medicine and hemostasis, interventional radiology, and microbiology; with pharmacists; and also with head nurses, staff nurses, and community nurses. Although the team focuses on problems occurring in long-term devices, they deal with problems associated with other types of access systems, such as non-tunneled central venous catheters (CVCs), especially those in hematological patients.

In cases of device malfunction, staff nurses are trained to initiate measures to restore patency. Most of these measures involve freeing the catheter tip from the vein wall, sleeve, or blood clot by repositioning the patient or by changing intrathoracic pressure. If attempts are unsuccessful, nurses can contact the APN team for further help. The team acts according to the Leuven Malfunction Management Protocols (LMMPs), which describes in detail the standard procedures for handling malfunctions. The APN-team developed the LMMPs, which were progressively improved along new insights over the years, The LMMPs provide a support to the team in a logical approach of the problems although not all steps of the LMMPs could be underpinned with evidence.

For each request for help, the APN team asks the requester details related to the malfunction aspects (e.g., difficulty or inability to inject, to aspirate, or both). The data were registered on a specific designed form, which is included in the hospital information system (HIS): this enables the team and other care givers to review all contact details.

Device insertion and maintenance

At the UHL, oncology surgeons insert TIVADs by means of per-operative electrocardiographic guidance for catheter tip positioning. The procedure takes place in the operation theatre. The patients are usually under local anesthesia and are not required to take prophylactic antibiotics. Intravenous therapy through the device can begin on the day of insertion, if needed.

Clot formation is prevented by performing a pulsated flush method at the end of each infusion therapy session. After delivering 10 ml of normal saline (NS) through the device a positive-pressure lock is established. Positive pressure is maintained by closing the clamp on the extension set of the puncture needle (or the three-way stopcock) while injecting the last millilitres of solution at a constant flow rate. A flush of 10 ml of NS is used soon after accessing the port, and prior to and after each blood sampling. After administration of packed cells or parenteral nutrition, 20 ml of NS is flushed. A 3 ml heparinized saline (100 IU/ml) lock is used prior to Huber needle removal. When the device is in use, the Huber needle is changed weekly. Otherwise TIVADs are flushed every 6 to 8 weeks with 10 ml of NS followed by a 3 ml heparinized saline lock (100 IU/ml).

Design and data collection

This descriptive retrospective study was conducted from November 1, 2005, to October 30, 2010, at the UHL. The APN team recorded details of each single request for support for TIVAD problems as part of the standard care delivered by the team. From April 2008 onwards, the team switched from data collection on paper to a standardized electronic form that was integrated into the HIS. Data on functional problems (type of malfunction, suggested investigations and treatments, and results) were recorded by the team. Demographic information as gender, age, condition (malignant or not), and device-related details (insertion date, device type, vein used) were added retrospectively. Data were presented without any reference to individual patients.

Definitions

Definition and classification of functional problems

We defined catheter function according to the ability to inject and/or aspirate through this catheter. In all, there are nine different combinations based on how easy, difficult, or impossible injection and/or aspiration is. Hence, eight combinations describe functional problems in terms of difficult or impossible injection and/or aspiration, and one combination (easy injection and aspiration) describes a well-functioning catheter. Seven additional categories partially describe the malfunction problem, in cases in which injection and/or aspiration descriptions were incomplete. This results in 16 different operational definitions for malfunctioning devices and one definition for well-functioning devices.

Definition of correct catheter tip location

For catheters inserted through the SVC system, correct catheter tip location is in the vicinity of the lower one-third of the SVC, near the juncture with the right atrium (RA).(NAVAN Position statement, 1998) For catheters originating from the inferior vena cava system, optimal tip position is at the level of the transition between the inferior vena cava and RA.(Wolosker et al., 2004) For devices inserted through the SVC, tip locations in the deep RA or the upper two-thirds of the SVC were considered suboptimal and tips located outside the SVC or RA were considered as clear malpositions.

Definition of administration modalities of thrombolytic agents or solutions to dissolve drug precipitates or lipid debris

We defined an instillation as an injection of product, which remains in the device for less than 4 hours. By contrast, we defined a lock as an injection of product, which remains into the device for longer than 4 hours (and up to 8 weeks) and a continuous infusion as an intravenous infusion of a product at a constant flow rate for a certain period of time.

Statistical Analysis

All data were analyzed using SPSS 16 for Windows. Descriptive statistics for nominal data were expressed in absolute numbers and percentages. Medians and quartiles were computed for continuous variables with a non-normal distribution. Inferential statistical tests used for nominal variables were the $\chi 2$ test and the Fisher's exact test (if the assumptions for $\chi 2$ were not fulfilled). All statistical tests were two-sided and conducted at a 0.05 level of significance.

Results

Sample Characteristics

Patient characteristics

In total, 3950 requests for malfunctioning TIVAD were addressed and concerned 2019 patients. Table 1 summarizes patients characteristics and the number of contacts the APN team had for each patient.

INSERT TABLE 1 HERE

Device characteristics

Table 2 summarizes device characteristics involved in the 3950 request. The majority of the TIVADs were inserted in our hospital, mainly Celsite ports, and were inserted through the left cephalic vein.

INSERT TABLE 2 HERE

Catheter-related problems

The team handled catheter-related problems occurring in 3771 patients, counting all together for 7248 requests. Of these contacts, 75.2% (n=5454) concerned TIVAD-related problems. The remaining contacts concerned tunneled catheters (15.9%), peripherally inserted central catheters (7.3%), non-tunneled CVCs (0.9%) and other catheter types in situ, together with pre-insertion and post-removal contacts (0.7%). Table 3 summarizes the distribution of problems for the 5454 TIVAD-problem–related contacts. Malfunctions were accountable for 72.2% (n=3950) of all TIVAD-related problems. TIVADs presenting with a malfunction were inserted in 82.1% (n= 3243) of cases in the UHL. Information on indwell time was available for 3359 devices and includes a total number of 2 156 693 catheter days with a median of 231 days (minimum=0 days; maximum=9202 days; mean = 642 days; standard deviation = 886 days).

INSERT TABLE 3 HERE

Type and distribution of functional problems

INSERT TABLE 4 HERE

Table 4 aggregates the distribution of different malfunction types for the 3950 requests. Fourteen combinations of easy, difficult, impossible, or unspecified injection and/or aspiration abilities were documented. The highest number of requests (66.9%, n=2642) concerned 'easy injection, but impossible blood aspiration'. The second highest (10.6%; n=416) was 'impossible injection and aspiration'. In 35 requests (0.9%), information on injection and/or aspiration abilities was not specified. Four percent (n=158) of requests turned out to be well-functioning catheters. These requests were follow-up contacts for prior malfunction(s).

Results of additional investigations (Chest X-rays and linograms)

INSERT FIGURE 1 HERE

In 70.8% (n=2797) of all requests, data on catheter tip position visualized by x-ray were available. In the remaining cases, chest X-ray images were not available when malfunction occurred or results were not adequately documented. Catheter tip position was considered to be optimal in 69.9%

(n=1954); to be suboptimal in 28.4% (n=795); and to be a malposition in 1.6% (n=46) of all cases. A statistically significant difference in correctly or incorrectly located catheter tips was found between TIVADs inserted in the UHL compared to those inserted in other hospitals (Pearson Chi-Square=67.752; df=1; p<.001). Figure 1 summarizes, for all malfunction types, the catheter tip location categories and the differences between correct and incorrect tip location of TIVADs inserted at the UHL versus those inserted at other facilities.

INSERT TABLE 5 HERE

The results of the radiological findings after linogram were summarized in Table 5. In total, in 4.9% (n=192) of requests a linogram was available. The most frequently radiological findings were sleeve formation in 40.6% (n=78); a normal contrast jet in 26.0% (n=50); a CTT in 7.8% (n=15); and a combination of a sleeve and a CTT in 7.3% (n=14) of findings. The top 3 of malfunction problems which led to a linogram was difficult injection in combination (1) with impossible aspiration (11.9%), (2) with easy aspiration (8.1%) and (3) with difficult aspiration (7.8%). Proportionally, sleeve formation was found more frequently in case of aspiration problems (while injection was easy or difficult).

Treatment Options

INSERT FIGURE 2 HERE

Figure 2 summarizes how thrombolytic agents were administered. In 41 (1.8%) cases, the following two study drugs were evaluated: alfimeprase (n=9) (Moll et al., 2006) and microplasmin (n=32) (Verhamme et al., 2009). In all other cases, a small amount of Actosolv.100 000 (urokinase, 100 000 IU) was administered. Actosolv has been licensed for catheter-related thrombosis. Its drug substance (urokinase) is manufactured by BBT (Biotech GmbH, Baesweiller, Germany). It is extracted from human urine, purified, and tested meticulously to ensure absence of viral contamination. A lock or instillation consisted of 3ml (15 000IU) and a continuous infusion of 40 000IU urokinase.

Thrombolytics were given in 2332 (59.0%) requests for help for malfunction. A lock was the preferred method for administering thrombolytic agents and was applied in 1214 (52.1%) cases (Figure 2).

Instillations were done in 754 (32.3%) cases. In 111 (14.7%) of these instillations, more than one instillation (with a maximum of 7) per call for help were used in an attempt to resolve the malfunction. In 0.7% of all requests involving malfunctions, products for dissolving drug precipitates or lipid debris in port reservoirs or catheters were used. In all but one case, these products were administered as a

lock: sodium hydroxide 0.1 meq/L (n=13); ethanol 70% (n=8); sodium bicarbonate 1 mg/ml (n=4); and hydrochloric acid 0.1 M (n=2).

Further Advice for Removal/Exchange

In 175 (4.4%) requests, TIVAD removal/exchange was advised. In 141 (80.6%) of these cases, malfunction was associated with a suboptimal position or malposition of the catheter tip, or with another complication.

Discussion

An APN team specializing in long-term venous access systems can play an important role in the management of TIVAD-related problems. To date, empirical data are unavailable for the types of problems for which an APN team is consulted. Furthermore, nothing is known about what types of interventions APN teams perform and about the outcomes of these interventions. The present study is the first study to address these issues and to shed light onto the types of problems APN teams encounter and the outcomes of their interventions.

A recent systematic review on the functional problems of TIVADs found a lack of uniformity in definitions used to describe TIVAD malfunctions. (Goossens et al., 2011) Our results showed that classification of malfunctions as a combination of easy, difficult, or impossible injection and/or aspiration modalities is more appropriate. The largest malfunction categories were those where injection was easy but blood aspiration was difficult or impossible (72.2% of all malfunctions). In these cases, delivery of the intended intravenous therapy was technically feasible. Why then did ward nurses and hemato-oncologists call for help? One possible explanation could be the 'safety first' principle.

According to the standard of care, brisk blood return is required before medication—especially chemotherapy—can be injected into a TIVAD. Absence of brisk blood return can be caused by catheter fracture, sleeve formation, vein perforation, catheter migration, or incorrect Huber needle placement. In all these cases, chemotherapy administration can result in extravascular drug leakage into the surrounding tissues and cause tissue necrosis. (Schulmeister and Camp-Sorrell, 2000)

Another explanation for the high number of requests for these partially patent TIVADs is that APN teams can efficiently manage malfunction (check catheter tip location, discuss permission to administer thrombolytics, schedule appointments for linogram, PSS, or catheter exchange/removal),

allowing local staff to continue with their duties. Additionally, extra peripheral venipuncture for lab tests can be avoided and stress to the patient and nurse are reduced accordingly. Finally, the availability of a competent and efficient APN team that not only visualizes problems but also promptly tackles them provides great incentive for colleagues, thus lowering the threshold for requesting help.

The APN-team advised a chest x-ray as first investigation in malfunction management, a linogram only in limited cases to further detect the cause of malfunction. Data on catheter tip location visualized by chest X-ray showed that the proportion of correct tip positions is higher in TIVADs that are inserted in the UHL than in other hospitals. In fact, for our surgical team, a correct tip position is one of the major quality indicators due to the close relationship between catheter tip location and catheter functionality (Bansal et al., 2008; Caers et al., 2005; Petersen et al., 1999). A linogram is performed in a small percentage of all malfunctions (4.9%) and, according to the LMMP, only ordered after unsuccessful thrombolytic treatment (at least two instillations or locks, or one hour of continuous infusion). We assume that more effective thrombolytic treatment can be achieved with continuous infusion (40 000 IU) than with an instillation or lock due to the short circulating half-life (two minutes) of urokinase (Woodard, Jr. et al., 1970) and the absence of a receptor that allows urokinase to bind to fibrin (Haire, 2001). Due to time constraints in treating outpatients, we reduced empirically the six-hour urokinase infusion (40 000 IU/h) scheme described in the study of Haire and Lieberman (1992) to one hour of continuous infusion at het same dosage. We hypothesize that, if the patient is refractory to this initial thrombolytic attempt, the malfunction may be of non-thrombotic origin or may be caused by a large CTT. Indeed, we found an isolated CTT in only 7.8% of all linograms. Of all radiological findings, CTT—whether suspected, isolated, or associated with another complication—ranked only third at 21.9%, next to an isolated sleeve formation (40.6%) and normal contrast jet (26.0%). This is in contrast with the recent study of Kausche et al.(2011), who reported CTT in 62.7% and sleeve formation in 7.0% of all radiological findings in cases involving TIVAD malfunction. A potential explanation for the greater number of sleeve formation than CTTs in our study is that thrombolytics were administered prior to the ordering of linograms. Indeed, sleeve formation is known to be refractory to thrombolytics. Hence, catheter sleeve development is initiated by thrombus formation, eventually evolving into a collagen sleeve via the migration of smooth muscle cells originating from the damaged vein wall. The cells will differentiate into fibroblasts, transforming the sleeve into a collagen structure covered by endothelial cells (Xiang et al., 2001). Nevertheless, a combination of sleeve and

CTT can occur. Administered thrombolytics can eradicate the thrombus and free the catheter tip. In this case, even though the sleeve is still present, a linogram might show a normal contrast jet, as in 26% of all our linograms. Similarly, Surov et al. reported that no radiological findings were evident in 15.6% of linograms, and in Stephens et al. the cause of catheter dysfunction could not be explained by radiographic dye studies in 20% of linograms (Stephens et al., 1995; Surov et al., 2008). One explanation for these findings is temporary malfunction, caused by a partially obstructed catheter tip, determined only when help was requested and not when the linogram was performed. Most likely, this may be due to the patient's condition, such as pulmonary edema, emphysema, and intrathoracic tumor masses, or due to other causes such as catheter sleeve and/or CTT, catheter tip abutting a vein wall, or heart valve. Finally, the proportionally higher number of linograms in malfunction problems where injection is difficult can be explained by the more urgent need for further investigation because the administration of therapy have become difficult or impossible.

Management of malfunction was performed along three different approaches: the LMMP for (1) impossible injection (aspiration is easy, difficult or impossible); (2) difficult injection (aspiration is easy, difficult or impossible) and; (3) easy injection with difficult or impossible aspiration. However, there are two main differences between the LMMPs and other published algorithms. (Baskin et al., 2009; Mayo, 1998; Registered Nurses' Association of Ontario, 2005; Royal College of Nursing, 2010)

First, in the LMMPs, catheter tip location has to be verified prior to the use of thrombolytic agents (except in case of impossible injection). Second, thrombolytic therapy is administered prior to solutions that dissolve drug precipitates or lipid debris, because we assume that the uneven deposits easily attract fibrin deposits. Prior eradication of fibrin deposits makes drug precipitates or lipid debris more accessible. Therefore, using other products or performing linograms only takes place if thrombolytic treatment is unsuccessful.

Since this series is a single center study, its context needs to be clarified. The UHL is a tertiary reference hospital with a committed surgical oncology team responsible for all TIVAD insertions. The APN team is in charge of the follow-up of these devices. During the 5-year study period, 7118 TIVADs were inserted. Given the huge number of devices in use, nurses working in onco-hematology wards are very skilled in caring and maintaining TIVADs. Hence, the study findings should be interpreted in light of the local environment, which has available both a surgical, a radiologic and an APN team, together with skilled ward nurses and clear directives from the LMMPs for the team.

This study is a cross-sectional study and our aim was not to follow patients from the time of TIVAD insertion, nor to discuss the efficiency of the LMMP. Rather, it was to assess the number of requests for help for malfunctions. Other studies that investigate malfunction, focused on the total number of inserted TIVADs (Carlo et al., 2004; Wolosker et al., 2004) or on a cohort of patients with TIVADs requiring a certain investigation (Kausche et al., 2011; Surov et al., 2008). Therefore, a comparison of our results with available data in literature was not feasible. Furthermore, the present study is part of a 5-year review, and thus also subject to imposed changes. For instance, we noticed a reduction in missing data after our institution introduced electronic reports. Also, the LMMP evolved over time and e.g. two innovative treatment modalities emerged over the last few years: (1) we began to administer thrombolytics via continuous infusion; and (2) on the basis of the study of Bader et al., we now substitute sodium hydroxide 0.1 meq/L to ethanol 70% when we suspect that a malfunction is caused by a combination of fibrin and lipid deposits.(Bader et al., 2007)

Conclusion

We report all details of help requests for TIVAD-related malfunctions addressed to an APN team. We found that 'easy injection, difficult or impossible aspiration', was the most frequently observed problem. This is an important clinical problem in the onco-hematology population that needs attention without delay, since a brisk blood return after accessing a TIVAD is prerequisite of starting intravenous therapy. The LMMP guides these actions and emphasizes prompt verification of catheter tip position and thrombolytic use. Hence, in case of malfunction, a limited number of linograms and removals/replacements are performed. An APN team acts as an interface between patients, TIVAD users, inserters, and interventional radiologists. By means of an APN team, therefore, malfunctions can be effectively managed, giving staff nurses more time but less stress in their daily care for patients with TIVADs.

Conflict of Interest Statement

None declared.

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Figure captures, tables, figures

- Table 1. TIVAD-related problems (n=5454)
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- Figure 2. Thrombolytic administration: administration modalities per malfunction type

Supplementary material

Leuven Malfunction Management Protocol 1 for easy injection with aspiration problems

Leuven Malfunction Management Protocol 2 for difficult injection problems

Leuven Malfunction Management Protocol 3 for impossible injection problems

Table 1: Characteristics of patients with TIVAD malfunction and number of requests per patient (n=2019)

	All		Adult contacts (>18 years old)				
	n (%)	(≤18 years old) n (%)	n (%)				
Number of patients	2019 (100)	64 (3.2)	1955 (96.8)				
Gender	,	,	,				
Male	852 (42.2)	32 (50.0)	820 (41.9)				
Female	1167 (57.8)	32 (50.0)	1135 (58.1)				
Age (years)							
Median	59.1	5.1	58.3				
Q1-Q3	49.7-67.2	2.4-13.3	50.8-67.5				
Min - max	0.04-92.8	0.04-17.5	18-92.8				
Diagnosis							
Malignant	1903 (94.3)	51 (79.7)	1852 (94.7)				
Non-malignant	116 (5.7)	13 (20.3)	103 (5.3)				
Number of requests							
Median	1	1	1				
Q1-Q3	1-2	1-3	1-2				
Min-max	1-15	1-8	1-15				

Table 2: Characteristics of malfunctioning TIVADs (n=3950)

TIVAD type		(%)			
Celsite		1 (56.5)			
Port-a-cath	869	(22.0)			
BardPort	268	(6.8)			
Districath	242	(6.1)			
Vortex	32 (0.8)			
Dome port	7 (Ô	.2)			
P.A.S.PORT	6 (0	,			
Unspecified plastic chest port	,	(Ś.7)			
Unspecified non-plastic chest port	53 (` '			
Unspecified arm port	10 (
Unspecified dualport	8 (0				
	3 (3	,			
Unspecified vein and body side (left /right)	12 (0.3)				
Vein used	Left (n)	Right (n)			
Cephalic	1827 [^]	824			
External jugular	336	142			
Internal jugular	58	14			
Subclavian	18	12			
Saphenous	11	9			
, Femoral	0	2			
Other	2	3			
Unspecified	372	307			
Total n (%)	2624 (66.4%)	1314 (33.3%)			

Table 3: TIVAD-related problems (n=5454 requests)

Problem type	n (%)
Functional problems	3950 (72.2)
Local problem (insertion or access site, subcutaneous catheter course)	473 (8.7)
Difficult access	443 (8.1)
Pain problem	123 (2.3)
Central venous thrombosis (suspected and proven)	106 (1.9)
Extravasation/Infiltration	88 (1.6)
Other	76 (1.4)
Advise to patient or health care worker	61 (1.2)
Local infection (suspected or proven)	58 (1.1)
Reservoir rotation	59 (1.1)
Systemic infection (suspected or proven)	28 (0.5)

Table 4: Classification of catheter function according to infusion and aspiration abilities (n=3950)

Injection Aspiration	Easy	Difficult	Impossible	Unspecified
Easy	158 (4.0%)	62 (1.6%)	2 (0.05%)	-
Difficult	210 (5.3%)	129 (3.3%)	2 (0.05%)	6 (0.2%)
Impossible	2642 (66.9%)	294 (7.4%)	416 (10.6%)	5 (0.1%)
Unspecified	-	16 (0.4%)	2 (0.05%)	6 (0.2%)

Table 5: Radiological findings of linograms per malfunction type

	Sleeve	Normal contrast jet	СТТ	Sleeve and CTT	Catheter tip abutting vein wall/heart valve	Sleeve and suspicion CTT	Suspicion of CTT	Discrete or ire- gular contrast jet	Extravasation	Superior Vena Cava Syndrome	CTT & suspicion of sleeve	Sleeve &catheter tip abutting vein wall/heart valve	Malposition	Catheter frag- ment removal	Pinch off	No result due to difficult injection	CTT & tip abut- ting vein wall or heart valve
Number, percentage of linograms on the total number per malfunction type	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %	n %
All functional problems (n= 192; 4.9% of 3950 malfunctions)	78 40.6	50 26.0	15 7.8	14 7.3	9 4.7	6 3.1	4 2.1	3 1.5	2 1.0	2 1.0	2 1.0	2 1.0	1 0.5	1 0.5	1 0.5	1 0.5	1 0.5
Easy injection, easy aspiration (n=5; 3.2% of 158 malfunctions)	-	4 80	-	-	-	-	-	1 20	-	-	-	-	-	-	-	-	-
Easy injection, difficult aspiration (n=8; 3.8% of 210 malfunctions)	1 12.5	4 50.0	-	1 12.5	1 12.5	-	-	-	-	1 12.5	-	-	-	-	-	-	-
Easy injection, impossible aspiration (n=124; 4.7% of 2641 malfuncitons)	58 46.8	26 21.0	12 9.7	8 6.5	5 4.0	4 3.2	2 1.6	1 0.8	1 0.8	-	2 1.6	2 1.6	-	1 0.8	1 0.8	-	1 0.8
Difficult injection, easy aspiration (n= 5; 8.1% of 62 malfunctions)	-	4 80	-	-	-	-	-	-	-	-	-	-	-	-	-	1 20	-
Difficult injection, difficult aspiration (n=10; 7.8% of 129 malfunctions)	1 10	3 30	-	1 10	1 10	-	2 20	1 10	-	-	-	-	1 10	-	-	-	-
Difficult injection, impossible aspiration (n=35;11.9% of 295 malfunctions)	17 48.6	7 20.0	2 5.7	4 11.4	1 2.9	2 5.7	-	-	1 2.9	1 2.9	-	-	-	-	-	-	-
Impossible injection, easy aspiration (n=0; 0% of 2 malfunctions)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Impossible injection, difficult aspiration (n=0; 0% of 2 malfunctions)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Impossible injection, impossible aspiration (n=2;0.5% of 416 malfunctions)	-	1 50	1 50	-	-	-	-	-	-	-	-	-	-	-	-	-	-
Unspecified injection and/or aspiration abilities (n=2; 5.7% of 35 malfunctions)	-	1 50	-	-	1 50	-	-	-	-	-	-	-	-	-	-	-	-

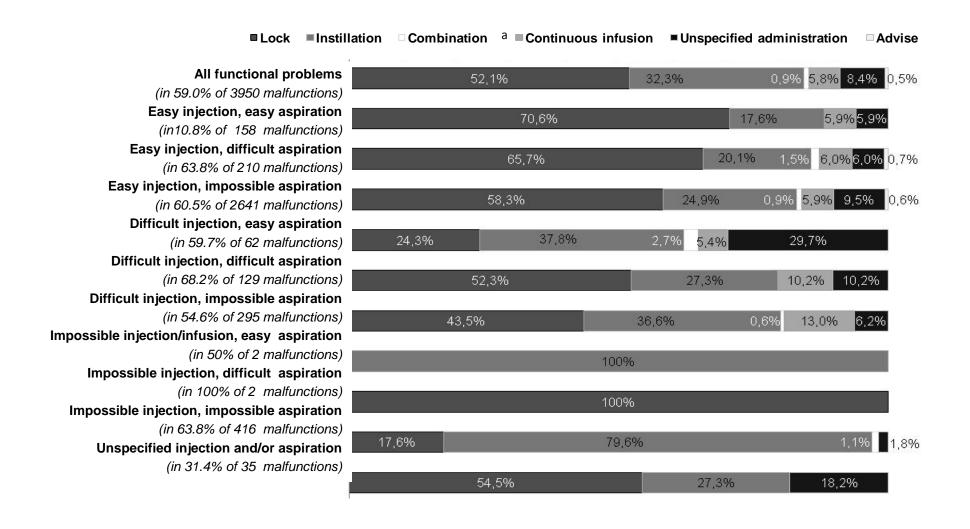
Abbreviations: CTT, Catheter tip thrombus

Figure 1: Results of classified catheter tip location on X-ray per malfunction type

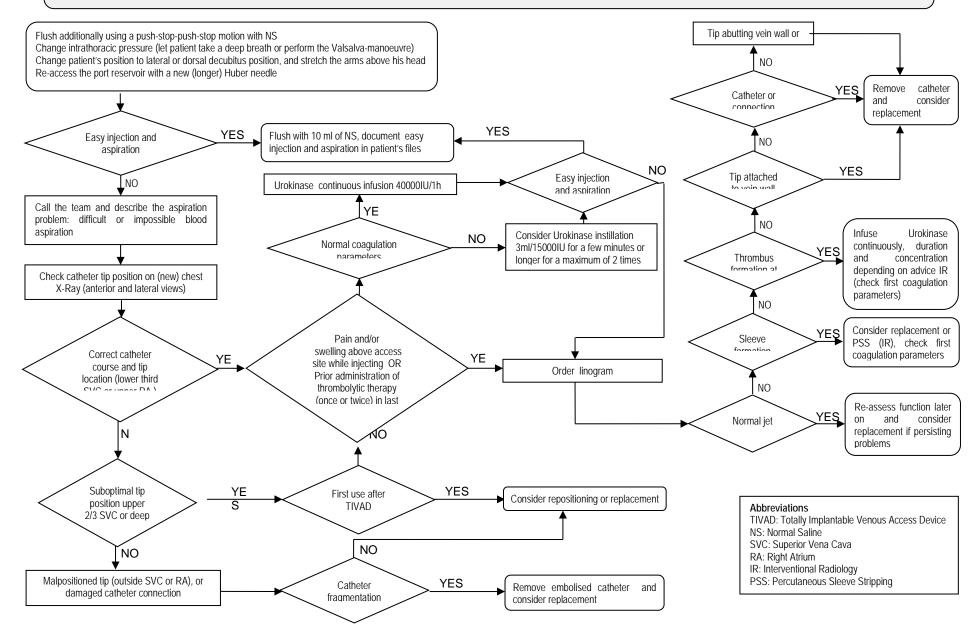
			■ Optimal ■	Suboptimal	■ Malpositio	1	
All functional problems	UHL ^a (n= 2247)		73,4%			25,3%	1,3
	not UHL (n=550)		55,5%		4	1,3%	3,
Easy injection, easy aspiration	UHL		74,5%			25,5%	
Test: x2 =1.494; df 1; p=.222	not UHL (n=14)		35,7%		64,3%	,	
Easy injection, difficult aspiration	UHL (n=		64,9%		;	33,8%	1,
Test: χ 2 =7.176; df 1; p=.007	not UHL (n=19)		78,9%			21,1%	ó
Easy injection, impossible aspiration	UHL (n=1616)		74,6%			24,1%	1,
Test: χ 2 =52.178; df 1; p<.001	not UHL		56,5%		40,1%	, D	3,
Difficult injection, easy aspiration	UHL (n= 34)		78,1%			21,9%	
Test: v2 =6 933: df 1: n= 008	not UHL	20%		80	%		
Difficult injection, difficult aspiration	UHL		75,6%			24,4%	
Test: χ 2 =7.365; df 1; p=.007	not UHL (n=20)	4	45%		50%		5
Difficult injection, impossible aspiration	UHL (n= 187)		67,4%			29,9%	2,
Test: x2 =3.981: df 1: p=.049	not UHL (n=48)		52,1%		43,89	%	4
Impossible injection, easy aspiration	UHL (n=1)			100			
	not UHL			100			
Impossible injection, difficult aspiration	UHL (n=0)						
	not UHL			100			2,
Impossible injection, impossible aspirati	on UHL (n=124)		75,0%			22,6%	
Test: χ 2 =1.973; df 1; p=.160	not UHL		62,1%			34,5%	3
Unspecified injection and/or aspiration	UHL (n=12)		50%		50%		
Fisher's Frest Tost 200	not UHL	20%		80	%		

^a UHL: TIVADs inserted at UHL; ^b not UHL: TIVADs not inserted at UHL; ^c statistical test between correct and incorrect located catheter tips between TIVADs inserted in UHL or in other hospitals

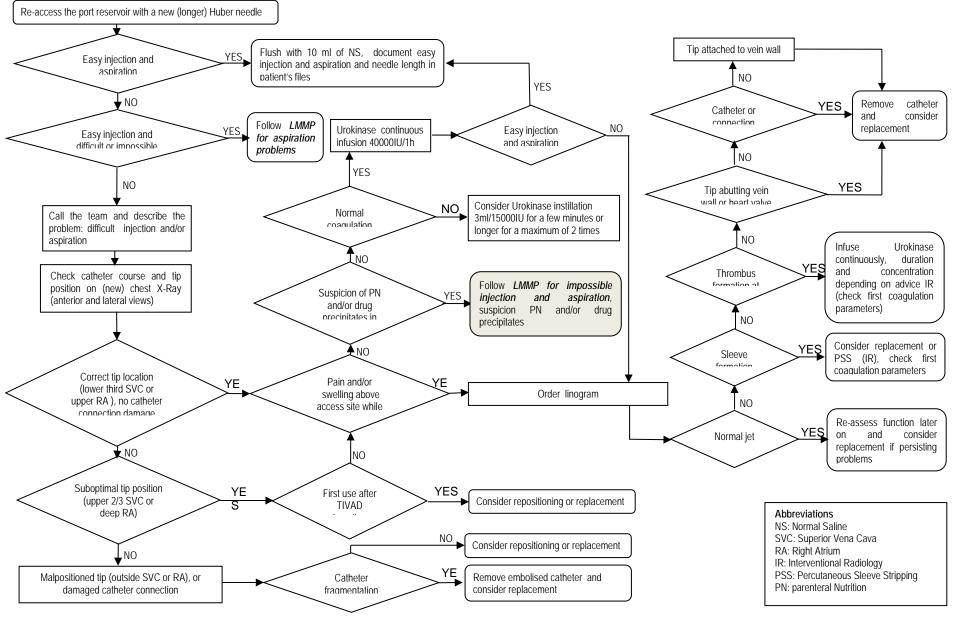
Figure 2: Thrombolytic administration: administration modalities per malfunction type



Leuven Malfunction Management Protocol (LMMP) for Totally Implantable Venous Access Devices: Aspiration problems while injection is easy



Leuven Malfunction Management Protocol (LMMP) for Totally Implantable Venous Access Devices: **Difficult injection and/or aspiration**



Leuven Malfunction Management Protocol (LMMP) for Totally Implantable Venous Access Devices: Impossible injection and aspiration

