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ORIGINAL ARTICLE

A dedicated protocol and environment for central venous catheter removal in pediatric patients affected by onco-hematological diseases

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ABSTRACT

Purpose: **The removal of long-term central venous catheters (CVCs) is not performed according to evidence-based guidelines, thus conveying the message that it is a procedure of secondary importance. Our study aims at comparing the experience at Bambino Gesù Pediatric Hospital before and after the implementation of a dedicated protocol and the identification of a specific area to perform such a procedure under the so-called nonoperating room anesthesia (NORA).**

Methods: **Starting on January 1, 2010, an appropriate protocol regarding long-term CVC removal was applied. Then, data from all patients who underwent CVC removal under NORA regimen were compared with patients who have undergone the same procedure before the beginning of such protocol in terms of complication rate, duration of procedure, and costs.**

Results: **Between January 2010 and December 2012, 266 patients were evaluated for long-term CVC removal under a NORA regimen. Of these, 194 underwent the procedure. In the period from January 2007 to December 2009, 60 out of 82 patients scheduled for elective removal of long-term CVC in the operating theatre were eligible for this study. Median procedure time was 7 min for removal in NORA and 10 min for the operating theatre (p=0.016); no complications occurred.**

Conclusion: **Long-term CVC removal is an often-neglected procedure, carrying a small, but definite rate of complications. Our study shows that CVC removal performed in NORA regimen is safe and feasible, also allowing multiple procedures in the same session with prompt management of possible complications and reduction of the anxiety and pain associated with the procedure.**

Key words: **Central venous catheter, Procedure room, Removal**

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INTRODUCTION

Central venous catheters (CVCs) are a mainstay in the management of critically ill children and are commonly used in the treatment of childhood cancer. In this patients' population, partially or totally implanted long-term CVCs, such as Hickman–Broviac or Groshong catheters, are the most common devices used over the course of the disease. They are used in children with cancer to provide consistent and convenient intravenous access, reducing both the discomfort associated with venipunctures and the incidence of burns from cytotoxic/histiolesive agents.

Unlike the device insertion and maintenance, governed by detailed evidence-based guidelines (1, 2), long-term CVC removal once the treatment is over is usually performed according to the physician's personal experience without established rules. Although removal is considered as a minor surgical procedure, often performed by young and not fully experienced staff, it has been shown to be associated with non-negligible incidence of complications, such as retention of CVC fragments within the subcutaneous tunnel or in the vessel, with subsequent high risk of foreign body embolism or thrombosis, or air embolism during the procedure (3-8). In addition, the removal could be troublesome if the cuff is far from the exit site, it is placed deep in the subcutaneous tissue, or the device has been inserted in place for a long period (3, 4). Second, children with malignancies often perceive

it as one of many painful procedures they endure during the course of the disease and it may also be traumatic for parents who try to comfort their children during the procedure. To decrease the likelihood of complications and psychological trauma to the children, we developed a protocol that calls for CVC removal under deep sedation performed by trained personnel in a non-operating room anesthesia (NORA) setting, wherein other elective diagnostic and therapeutic procedures, such as bone marrow aspiration or biopsy and lumbar puncture, are routinely performed. Therefore, we investigated the characteristics of the patients who have undergone to long-term CVC removal evaluating the impact of different regimens to perform such procedure under NORA setting or without dedicated facilities and protocol.

METHODS

Description of NORA protocol

According to institutional protocol regarding management of minor invasive procedures, based on Joint Commission International Standards for Healtcare and on American Society of Anesthesiology recommendations (Continuum of Depth of Sedation: Definition of General Anesthesia and Level of Sedation/analgesia - http//www.asahq.org/publicationsAndServices/sgstoc.htm), children with onco-hematological diseases undergo elective diagnostic and/or therapeutic procedures (lumbar punctures, bone marrow aspiration/biopsies, and non-septic partially implanted CVC removal) performed on an outpatient basis in a room where NORA can be performed. Dedicated personnel staff this room. Patients who undergo procedures in the NORA setting must be at least 12 months of age and be in American Society of Anesthesiology (ASA) risk class I-II. Assessment of children with Hickman/Broviac CVCs that are to be removed is conducted by a single pediatric surgical team that, for elective procedures, evaluates the position of catheter cuff and the exit-site a week before the scheduled day of intervention. Contraindications for NORA procedure include the presence of exit site inflammation, the position of the cuff far from the exit site as well as deep within the subcutaneous tissue, the presence of a totally implanted device (port-a-cath), or documented patient's allergy to peanut, soy, or egg.

After obtaining parental consent, the children and one of their parents are admitted to the NORA room, where, using sterile techniques, deep sedation, intravenous (IV) level on Ramsay sedation scale, is induced with a bolus of Propofol 2 mg/kg through the CVC. A peripheral venous access is established through a 20/22 gauge needle and used to maintain the sedation. The central line is then closed and sedation is maintained with booster doses of 0.5-1 mg/kg, whenever necessary, switching to a continuous infusion of 6-9 mg/kg/h, if the surgical procedure takes longer than expected. Pain assessment is performed according to physiological monitoring of bodily processes, such as heart and respiratory rate, oxygen saturation, deep nasolabial groove, and so on. In this respect, if a deeper pain control is required, Fentanyl is added at a dose ranging from 1 µg/kg I.V. up to a maximum of 3 µg/kg (9). Once the child is under sedation, the parent is invited to leave the room. Then, under a sterile field, the surgeon infiltrates the exit site around the cuff with Lidocaine hydrochloride and bluntly dissects the cuff, while applying a gentle traction to the catheter, until the cuff is completely freed from the subcutaneous tissue. After freeing the cuff, the device is pulled out with a swift maneuver during the expiratory phase, while the nurse applies a firm compression on the jugular vein on the side where the catheter was placed. The wound is then closed with absorbable sutures or fibrin glue and covered with an occlusive dressing. After the procedure is completed, the patient is transferred to a bed of the outpatient unit, upon reaching an ALDRETE score of 9. Post-procedure analgesia consists of administration of Acetaminophen 3 gtt/kg per os (1 gtt=2.7 mg) or intrarectal (200 mg Paracetamol and 5 mg Codeine) twice or three times a day according to pain evaluation with scales appropriated for intended age group (Visual Analogic Scale—VAS scale for children over 2 years of age; Face, Legs, Activity, Cry, Consolability—FLACC scale for children under 2 years of age). For both the scales, a score more than 4 was considered to indicate the need for an intervention to control the pain.

Two hours after the end of the procedure, fluid oral intake can be resumed and, after 5 h, the patient is promptly discharged from the outpatient ward in case no complication has occurred.

Data collection and analysis

After Ethical Committee approval, to describe our experience with this protocol, we retrospectively reviewed data collected from clinical records on all patients who were evaluated for elective long-term CVC removal before and after the implementation of the NORA regimen. All these patients had a partially implanted long-term catheter placed for treatment of cancer or other hematological diseases. Data collected from patient records included demographic characteristics, diagnosis, duration of the indwelling catheter time, the duration of the removal procedure, and any complication that occurred as a result of the removal. In the period from January 2007 to December 2012, a total of 346 patients were evaluated and scheduled for elective long-term CVC removal. Population was then divided into two separate groups, according to the procedure setting: group A (January 2007-December 2009) is composed of patients who have undergone to the removal in the operating theater, before

the beginning of NORA protocol in January 2010. Group B includes all the patients treated under such regimen, with dedicated facilities, nurse, and medical staff, from January 2010 to December 2012.

Patients characteristics were compared used the Chi-square test for categorical variables and Mann-Whitney test for continuous variables. Multivariate logistic regression analysis was carried out. *P* values less than 0.05 were considered statistically significant.

RESULTS

Of the total of 346 identified patients, 80 patients were treated in the period from January 2007 to December 2009 (Group A), and 266 in the period from January 2010 to December 2012 (Group B). Fifty-seven patients were excluded from further analysis because of the presence of totally implanted (port-a-cath) device (12 in Group A; 45 in Group B), and 16 because of less than 12 months of age (eight in Group A and B, respectively). Additional 19 patients in group B were excluded for a deep and distant position of the cuff from the exit site.

Of the remaining 254 patients, 60 were included in Group A, and 194 in Group B. Characteristics of the patients included in the analysis are summarized in Table I and Table II. The two groups were similar for all characteristics except type of tumor, being hematologic malignancies significantly more frequent in Group B than in Group A. Median indwelling catheter time was 279 days (range 10-1250 days) for Group A and 249 days (range 41-893) for Group B (p=ns).

In 76 children in Group B (39%), other procedures were performed during the same session, including bone marrow aspiration (n=52), lumbar puncture (n=12), bone marrow aspiration and biopsy (n=7), and bone marrow aspiration and lumbar puncture (n=5). No procedure other than CVC removal was performed in Group A.

The median procedure time was 10 min (range 2-135) for Group A and 7.5 min (range 2-26 min) for Group B (p=0.016).

Post-procedural pain was evaluated, according to age group criteria, with VAS score for 229 patients (51 in Group A, 178 in Group B) and FLACC score for 25 (nine in Group A, 16 in Group B) patients, resulting in a score of less than 4 for all the patients.

All the patients of Group A spent one night in hospital, while patients of Group B were discharged 5 h after the end of the procedure without any complication. No complications related to anesthesia were reported to occur, while in two patients of the NORA group, the procedure was interrupted after 20 min and re-scheduled in the operating theater the following day as a result of an erroneous preoperative evaluation of the position of the Dacron cuff (data not shown in the Table).

TABLE I - TYPE OF DISEASE OF PATIENTS ENROLLED IN STUDY

Group A-Operating Theater			
Patients n=60, M=35/F=25			
Hematologic diseases	**N**	**Solid tumors**	**N**
Acute lymphoid leukemia	15	Neuroblastoma	6
Non-Hodgkin lymphoma	4	Rabdomyosarcoma	6
Thalassemia	3	Ewing sarcoma	6
Acute myeloid leukemia	2	Central nervous system tumor	6
Bone marrow aplasia	1	Wilms tumor	4
Hodgkin lymphoma	1	Germ cells tumor	3
Histiocytosis	1	Osteosarcoma	1
Wiskott-Aldrich syndrome	1		
Total	28		32
Group B-NORA			
Patients n=194, M=103/F=91			
Hematologic diseases	**N**	**Solid tumors**	**N**
Acute lymphoid leukemia	73	Neuroblastoma	10
Thalassemia	20	Rabdomyosarcoma	10
Acute myeloid leukemia	14	Wilms tumor	10
Non-Hodgkin lymphoma	6	Central nervous system tumor	8
Bone marrow aplasia	6	Germ cells tumor	7
Hodgkin lymphoma	4	Hepatoblastoma	3
Fanconi anemia	4	Renal cell carcinoma	2
Myelodisplasia	2	Osteosarcoma	1
Immunodeficiency	2	Retinoblastoma	1
Macrophage activation syndrome	1	Ewing sarcoma	1
Drepanocytosis	1		
Aplastic anemia	1		
Histiocytosis	1		
Lymphohistiocytosis	1		
Osteopetrosis	1		
X-linked agammaglobulinemia	1		
SCID	1		
Blackfan-Diamond syndrome	1		
Shwackman-Diamond syndrome	1		
Total	141		53

TABLE II - PATIENTS' CHARACTERISTICS, DURATION OF PROCEDURE AND POST-PROCEDURAL PAIN, BY STUDY GROUP

	Group A (Operating Room; N=60)	Group B (NORA; N=192)	p
Age in months			
Median (range)	73 (13-334)	77 (13-269)	ns
Gender			ns
Male	35	102	
Number (%)			
Female	25	92	
Number (%)			
Type of tumor			
Hematologic	32	144	
number (%)			
Oncologic	28	50	0.002
number (%)			
Indwelling time in days			
Median (range)	134.5 (10-1250)	144.5 (0-893)	ns
Procedure duration in minutes	10 (2-135)	7.5 (2-26)	0.016
Post-procedural pain assessment <4			ns
VAS	51	178	
Number (%)			
FLACC	9	16	
Number (%)			

TABLE III - DIFFERENCE OF DURATION OF CVC REMOVAL PROCEDURE, BY STUDY GROUP AND PATIENT CHARACTERISTICS

	Difference of procedure duration (minutes)		p	
	Mean	SD	Univariate analysis	Multivariate analysis
Group			0.001	0.002
NORA (B)	Ref	Ref		
Operating theater (A)	5.1	1.5		
Gender			Ns	ns
Female	Ref	Ref		
Male	0.8	1.3		
Type of tumor			ns	ns
Oncologic	Ref	Ref		
Hematologic	0.9	1.4		
Indwelling time in days*	0.001	0.004	ns	ns
Age in months*	-0.003	0.011	ns	ns

*For each incremental day (indwelling time) or month (age).

At multivariate analysis, only the Study Group showed a significant association with duration of procedure, although all the patient characteristics, including the type of tumor, did not (Tab. III).

In detail, the mean duration of CVC removal was 5 min longer in Group A than in Group B, independently from all other variables.

DISCUSSION

Over the last few decades, the use of CVC for treatment of onco-hematological patients has become a widely adopted strategy; as a matter of fact, in the US, about 5,000,000 (5 million) CVCs are placed annually (10). Despite this wide adoption of CVC devices, their placement and use has been associated with a variety of complications that can affect outcome, especially in the pediatric patients (11, 12). For this reason, many papers, guidelines, and protocols dealing with complications, management, methods of risk reduction, and the different events related to the routine use of a central line have been published (13-15).

The aspect of CVCs that has received the least attention is their removal, which is often conducted in the ward in the absence of anesthesia or with local anesthesia performed by surgeons/physicians not specifically trained in this area. The frequency of major and minor complications with CVC removal has not been diffusely investigated; the largest reported series of cases has been documented by Maizlin and coworkers in which four life-threatening complications occurred among 1019 CVCs removed. Most available studies of CVC removal are limited to case reports of life-threatening complications that occasionally occurred during or after the procedure (3-8).

Indeed, guidelines and protocols regarding this procedure are lacking and, in most cases, management of CVC removal is considered a minor issue, thus performed according to physician's preference and experience (16-19).

In 2005, Lee conducted an extensive literature review concerning removal of cuffed CVC and reported that most complications occurring during the procedure are related to catheter rupture, due to tethering of the device both to the exit-site skin and to the vein wall (4). If the catheter breaks, the distal fragment can embolize the vascular system, causing severe and potentially fatal complications that require emergency endovascular retrieval by the interventional radiologist. He concluded, however, that a larger number of studies are needed to standardize the management of this procedure in

order to reduce the risk of rare but life-threatening complications.

Our choice to develop a protocol in which CVC removal is performed on an outpatient basis under NORA was driven not only by the awareness of the potential risk associated with the procedure but also by the perception of the suffering of our patients and their parents. In this respect, the choice to perform all minor diagnostic procedures in a dedicated area may represent a valid option both to decrease the rate of potentially fatal events and to obtain a higher acceptance of patients and families to serial invasive procedures. One of the principal concerns of pediatric oncologists is the management of pain and anxiety related to the burden of diagnostic and therapeutic procedures. Indeed, several authors have reported that reduction of the "fear of procedure" has a direct influence on the pain actually perceived by the patient. A recent paper published by Po' and coworkers demonstrated that a dedicated environment to perform all minor procedures in oncologic patients may reduce the stress and the anxiety of both patients and families, influencing the perception of related pain (20).

Our experience showed that CVC removal performed in the NORA setting may represent a suitable model for the management, also of those considered "minor" procedures. All the interventions have been in fact performed, after a preliminary assessment, in a dedicated environment by surgeons/physicians with adequate technical expertise, resulting in a good pain management, reduction of complication rate, and high satisfaction and compliance of families and patients. The outpatient setting also permits the administration of appropriate anesthesia in a controlled environment with all resuscitation drugs and equipment available and provides the opportunity for appropriate control of postoperative pain.

No complication was reported, in our population, although, on the basis of previous data, our sample size may have been too small to adequately assess the frequency of what is likely to be a rare event. In this respect, regarding our series of CVC removal, preoperative evaluations as well as the choice of a dedicated surgical team have been realized in spite to minimize the complication rate related with the procedures.

We believe that, regardless of whether a catheter is to be removed on an outpatient basis or in the ward, a surgical check prior to removal should be done to reduce the risk of removal difficulties. In an outpatient setting, this will prevent a prolonged sedation time and a laborious procedure, especially for catheters that have been in place for several months. Such an evaluation permits the identification of cases in which freeing the cuff may be difficult and may require a different surgical and anesthesiological management that ought better be performed in the operating theater.

Concerning the anesthesiological strategy, the management of predictably severe procedural pain is under the direct control of the anesthesiologist, who can manage the deep sedation in a monitored setting with all resuscitative drugs and equipment available and can also achieve a proper control of postoperative pain, allowing a safe outpatient discharge.

An issue concerning the NORA regimen is cost. The cost of CVC removal in NORA setting was an estimated 204 Euro, including the costs of the day-hospital stay, anesthesia, and medical staff time, versus 512 Euro for the same procedure performed in an inpatient regimen with one night of hospital stay. These must be balanced against the probable decrease in complications and the psychological stress created by performing the procedure on the ward. In this respect, the possibility to perform multiple procedures in such regimen, without an increased complication risk, may represent a necessary prerequisite for the application of a health cost-cutting policy. In this respect, the significant difference regarding median procedural time between the NORA and the operating theatre population gains more importance, for the influence of reduced procedural time on the overall cost. In many patients of NORA group, in fact, multiple procedures have been performed in the same session, thus improving the efficacy of this service in terms of patients' turnover and costs if compared with the patients previously treated in the operating theater.

CONCLUSION

Although CVC removal is considered a minor procedure often performed in outpatient settings, it entails a remarkable risk of potentially severe complications and may be stressful for pediatric oncologic patients, who often undergo repetitive invasive procedures during the course of the disease. An adequate environment to perform such procedures, as well as a dedicated multidisciplinary trained staff, may reduce the complication rate and relieve the patients' and families' anxiety and procedural stress.

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