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ORIGINAL RESEARCH ARTICLE

Potential role of a subcutaneously anchored securement device in preventing dislodgment of tunneled-cuffed central venous devices in pediatric patients

Andrea Dolcino[1,2], Antonio Salsano[1], Andrea Dato[2], Nicola Disma[3], Alessio Pini Prato[4], Filippo Bernasconi[5], Luigi Montagnini[2], Stefano Avanzini[2], Michela Bevilacqua[2], Giovanni Montobbio[2], Girolamo Mattioli[2], Clelia Zanaboni[2]

[1] University of Genoa, Genoa - Italy
[2] Giannina Gaslini Institute, Genoa - Italy
[3] Department of Anaesthesia, Great Ormond Street Hospital, London - UK
[4] Antonio e Biagio e Cesare Arrigo Hospital, Alessandria - Italy
[5] University of Milan, Milan - Italy

ABSTRACT

Introduction: The potential drawbacks of tunneled-cuffed catheters are complications such as local or systemic infection, dislodgment, rupture, malfunction, and deep venous thrombosis. Aim of this study is to describe the incidence of complications, focusing on dislodgment and on the role of new securement devices in reducing this annoying issue.

Methods: We enrolled all pediatric patients with tunneled-cuffed central venous catheters (CVCs) inserted at the Giannina Gaslini Institute during a 16-month period. Demographic data, technical details, intraoperative and postoperative complications were recorded and stored in a digital database according to Data Protection Act.

Results: During the study period, we collected 173 tunneled-cuffed CVCs. All but three insertions were successful. There were 50 complications involving 47 CVCs. Complications included 13 infections, 27 dislodgments, 4 thromboses, 3 obstructions, and 3 malfunctions/breaking. In 51 of 173 CVCs, we used subcutaneously anchored securement device (SAS).

Conclusions: The use of SAS proved to significantly reduce the incidence of complications in pediatric patients, particularly during the first 30 postoperative days. Basing on our results we suggest to routinely adopt this new securement device for high-risk CVC.

Keywords: CVC, Pediatric, SAS, Securement devices, Tunneled-cuffed central venous catheter

Introduction

Tunneled tunneled-cuffed central venous catheters (CVCs) are essential in the management of children with cancer, hematological and nephrological disorders, as well as for those requiring long-term parenteral nutrition (PN) (1). CVC-related complications, such as thrombosis, dislodgment, obstruction and infection have been reported in up to 40% of patients with a rate of nearly one event every 450 catheter days (2). Those complications interfere with the correct function of the catheter and may ultimately require repositioning. Several studies addressed the role of materials used for CVCs, chosen site for cannulation, type and length of tunneling, and devices used to fix the CVC to the skin (2-4). The aim of this study was to analyze the incidence of dislodgment in children who had undergone tunneled-cuffed catheter placement with a new catheter securement device comparing with an historical cohort of CVC placement when the SAS was not applied. The secondary outcome is to review the incidence of the other complications and risk factors.

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Corresponding author:
Andrea Dolcino
University of Genoa
Giannina Gaslini Institute
Largo G. Gaslini 5
16147 Genoa, Italy
adolcino@libero.it

Materials and methods

Data on patients undergoing percutaneous ultrasound guided (USG) positioning of tunneled-cuffed CVCs between 1st of May 2015 and 31st of August 2016 (16-month period) at Giannina Gaslini Institute were prospectively collected in a specifically implemented database. Institutional Review Board and Ethical approval was waived for this study, given the routinely and widely employed procedure and the observational feature of

the study, because this was not considered a research protocol but an institutional improvement of clinical practice. All parents signed an informed consent related to the use of personal data. All data were stored according to Personal Data Protection Act. The following data were collected by members of the multidisciplinary team dedicated to CVC positioning and management (Vascular Access Team - VAT):

- Demographic data (sex, age, weight)
- Primary diagnosis
- Reason for positioning (administration of intensive and/or high-dose chemotherapy, supportive measures, such as frequent transfusions of blood products and/or parenteral nutrition, and hematopoietic stem-cell transplantation)
- Operator (member of the VAT)
- Technical details
- Chosen vein for cannulation
- Size and type of CVC used (tunneled-cuffed CVC, in silicon or polyurethane, single lumen or double lumen)
- Number of attempts for cannulation
- Used securement device (Statlock, SorbaView Shield, SAS, stitches, Tape, etc.)
- Intraoperative and postoperative complications (rate and type) – primary outcome measure.

Patients were followed for at least 30 days after CVC placement during daily in-patient assistance, home-delivered care, and scheduled out-patient visits. The primary outcome was the incidence of tunneled-cuffed catheter dislodgment. The secondary outcomes were catheter-related complication and the analysis of specific complications.

Insertion and securement techniques

All procedures were performed in the operating room with a percutaneous USG approach as previously reported (2). The appropriate choice for site of cannulation was performed based on ultrasound examination according to the Rapid Central Vein Assessment (RaCeVA), always taking into consideration the internal diameter of the vein (5). In our institution, we routinely resorted to the right brachiocephalic vein (BCV) in the first instance. CVC tip positioning was checked under fluoroscopy. At the end of the procedure, CVCs were secured to the skin with cyanoacrylate glue and various catheter securement devices such as StatLock (BardMedicalDivision Salt Lake City, Utah, USA), Grip-Lok (Zefon), and SecurAcath (Interrad Medical, Plymouth, Minnesota, USA). For dressing we used SorbaView or SorbaView Shield (Tristate Centurion, Williamston MI USA) or Tegaderm (3M, St. Paul, MN, USA). No systemic antibiotic prophylaxis was routinely given before the procedure or in the 24 hours thereafter (6).

CVC management

Standard routine CVC care was handled by trained pediatric nurses and included flushing, weekly cleansing with chlorhexidine 2% solution and dressing of the exit site with transparent medication (7, 8). Complications were recorded on a specific form at the time of diagnosis. After discharge, patients and parents were educated to strictly adhere to the same methodology.

Definitions

- **CVC-related infections** were defined as bacteremia or fungemia in a patient who has an intravascular device and a >1 positive blood culture result obtained from the peripheral vein, clinical manifestations of infection (e.g., fever, chills, and/or hypotension), and no apparent source for bloodstream infection (with the exception of the catheter). One of the following should be present: a positive result of semiquantitative (>15 cfu per catheter segment) or quantitative (>10^2 cfu per catheter segment) catheter culture, whereby the same organism (species) is isolated from a catheter segment and a peripheral blood culture; simultaneous quantitative cultures of blood with a ratio of >3:1 cfu/mL of blood (catheter vs. peripheral blood); differential time to positivity (growth in a culture of blood obtained through a catheter hub is detected by an automated blood culture system at least 2 hours earlier than a culture of simultaneously drawn peripheral blood of equal volume) (9).
- **Dislodgment** was defined as accidental removal, retraction or cuff migration, and/or malpositioning of the tip requiring CVC removal or repositioning (2). The diagnostic evaluation was based on the visual and manual assessment of the position of the Dacron cuff and a chest x-ray or line contrast study with enhancement medium to rule out CVC dislodgment, breakage, or leakage (10).
- **CVC-related deep venous thrombosis** was defined as occlusion (total or subtotal) of the large vein into which a catheter had been placed. When suggested by clinical symptoms, i.e., swelling, pain, or pulmonary embolism, color-Doppler ultrasound, computed tomography imaging was used for the noninvasive diagnosis of CVC-related thrombosis (11).
- **Catheter malfunctioning:** this diagnosis was based on difficulty, i.e., partial occlusion or complete occlusion resulting in inability to withdraw blood and/or infuse liquids through the CVC despite postural changes and in the absence of thrombosis or other mechanical complications.
- **Catheter days** were counted from the day of insertion to the end of the observation period or the day of CVC removal, if this occurred before, either due to complication, end of treatment, therapeutic choice or patient's exitus.

Statistical analysis

Continuous variables are presented as mean and interquartile range (IQR). Normality was assessed using the D'Agostino and Pearson Omnibus normality tests. Data were compared using 2-tailed t-test or Mann-Whitney test. Discrete variables were compared using the χ^2 test or the Fisher's exact test where appropriate. For descriptive purposes, demographic and clinical characteristics were compared between groups selected on the basis of the use of SAS device.

The study was focused on the analysis of tunneled-cuffed CVC complications. To this aim, we obtained the estimate of the cumulative incidence function for the marginal probability of complications and mortality for all causes, stratified according to the use of SAS. To compare results and complications, patients were divided into two groups namely Group A (no use of SAS) and Group B (use of SAS). The competing risks were employed since mortality precludes the occurrence of any other event. The related curves were plotted and compared with the modified χ^2 statistic. Complications in detail between groups were compared using the χ^2 or the Fisher's exact test. In our analysis, the significance level was set to $p<0.05$. All the analyses were performed using R Statistical Software (version 3.2.2; 153 R Foundation for Statistical Computing, Vienna, Austria).

Results

During the study period, 136 patients underwent 177 CVC placements, 4 were unsuccessful, 173 CVC were inserted. The mean length of CVC duration was 188 ± 143 days for a total of 32,537 catheter days.

Demographic data, diagnosis, insertion site, attempts and type, diameter and material of CVC are reported in detail in Table I. The only significant differences between the two groups were mean age that was lower for Group B and polyurethane CVCs that were more frequently adopted in the same group (Tab. I).

During the study period, we registered 50 complications involving 47 CVCs and 9 patients who died with no relationship to either insertion, use or maintenance of CVC.

Probability of complications at 30, 60 and 90 days in patients in Group A were 18%, 23% and 27%, respectively, compared to 4%, 8% and 13% observed in Group B (Fig. 1). The curves of complicated CVCs were significantly different and proved not to be influenced by competitive risk of mortality.

We recorded a 27.2% incidence of complications. Three CVCs were complicated twice. The overall complication rate was 1.54 per 1000 catheter days. The most common complication

TABLE I - Overall features

Variable	All catheter (n = 173)	Group A (n = 122)	Group B (n = 51)	p
Age, mean mo. (IQR)	72.32 (16-105)	79.24 (16-110.5)	56.24 (14-92.5)	0.04
Males no. (%)	103 (59.5%)	73 (59.8%)	30 (58.9%)	0.9
Weight mean kg (IQR)	20.8 (10-28)	22.63 (10-30)	16.53 (8.5-22.5)	1
Diagnosis				0.42
Solid tumors no. (%)	60 (34.6%)	46 (37.7%)	14 (27.4%)	
Hematological malignancies no. (%)	56 (32.4%)	37 (30.4%)	19 (37.3%)	
Non-malignant diseases no. (%)	57 (33%)	39 (31.9%)	18 (35.3%)	
Insertion site				0.32
IJV right no. (%)	14 (8.1%)	12 (9.8%)	2 (3.4%)	
IJV left no. (%)	5 (2.9%)	5 (4.1%)	0	
BCV right no. (%)	109 (63%)	73 (59.8%)	36 (70.6%)	
BCV left no. (%)	34 (19.7%)	24 (19.6%)	10 (19.6%)	
AV right no. (%)	4 (2.3%)	2 (1.6%)	2 (3.9%)	
AV left no. (%)	7 (4%)	6 (4.9%)	1 (1.9%)	
Bilumen no. (%)	37 (21.4%)	25 (20.5%)	12 (23.5%)	0.66
Diameter mean fr (IQR)	6.08 (5-7)	6.31 (5-7)	5.56 (4,6-7)	0.4
Material				<0.0001
Polyurethane no. (%)	95 (54.9%)	51 (41.8%)	44 (86.3%)	
Silicon no. (%)	78 (45.1%)	71 (58.2%)	7 (13.7%)	
Attempt				0.09
1 no. (%)	139 (80.3%)	98 (80.3%)	41 (80.4%)	
2 no. (%)	21 (12.1%)	12 (9.8%)	9 (17.6%)	
>2 no. (%)	13 (7.5%)	12 (9.8%)	1 (1.9)	

IQR = interquartile range; IJV = internal jugular vein; BCV = brachiocephalic vein; AV = arteriovenous; mo = month(s).

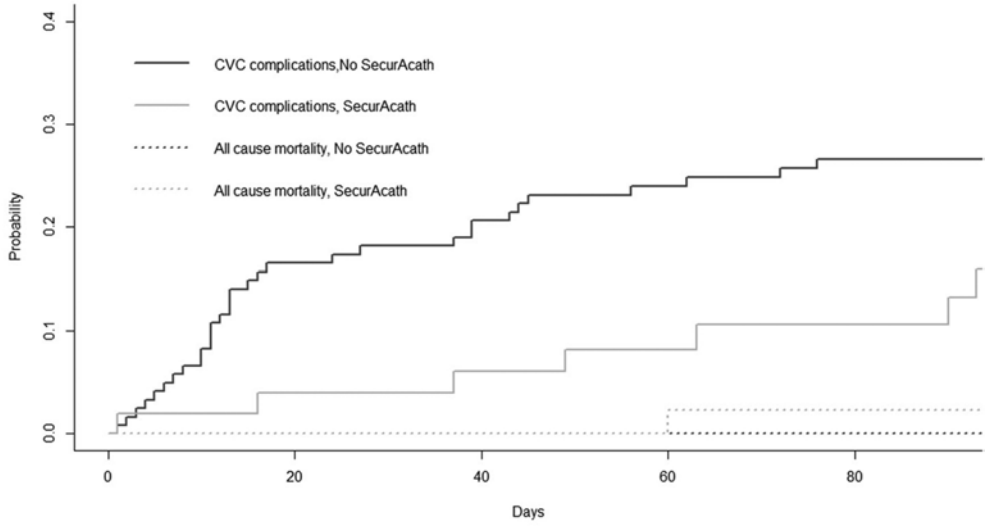

Fig. 1 - Cumulative incidence of central venous catheter (CVC)-related complications stratified based upon utilization of SAS accounting the competing risk of mortality for any cause. The trend suggests that the highest risk of dislodgment is in the very first period.

was dislodgment with an incidence of 0.83 per 1000 catheter days. Malfunctioning occurred in 3 cases of obstruction, 2 cases of kinking, 1 case of broken catheter. A minor complication was thrombosis with 2.3% and an incidence of 0.12 for 1000 days.

Comparing the group B versus the group A we found a reduction of complications in every category with 43 (24.8%) versus 7 (4.1%) p = 0.004, in particular 25 (14,4%) versus 2 (1.1%) dislodgment (p = 0.006). SAS was associated with a reduced risk of dislodgment but had no effect on other complication such as infection, thrombosis or malfunction. Complications experienced in our series have been reported and detailed in Table II.

Discussion

In this observational non-randomized study on 173 tunneled-cuffed CVCs, for a total of 32,537 catheter-days, we demonstrated that even by adopting internationally approved standards of CVC management, complications occurred in over 27% of devices inserted in children. Based on the results of our study, the CVC dislodgment proved to be the main cause for premature removal. In a prospective study on CVC complications, Fratino et al (4) observed that the rates of mechanical and infectious complications were 2.2 and 0.7/1000 CVC days, respectively. The same authors reported that 9 of 12 CVC removals were due to dislodgment (4). In 2004, Cesaro et al (12) emphasized that accidental snatching plays a key role in CVC dislodgment mostly due to the incomplete adhesion of the CVC cuff to the subcutaneous tissue in the early weeks after positioning, and to the problems involved in restricting physical activity of infants and toddlers. Most CVC dislodgments observed in this study happened during the first two months after CVC positioning, and the young age was the only significant factor in a multivariate analysis that proved to be associated with early CVC removal. These findings suggest that more effectively securing of the CVC to the subcutaneous tissue may significantly reduce the premature removal of CVCs, especially in young children (12). Therefore, securement and dressing represent key points for CVC duration. In our center, we abandoned the use of non-absorbable suture, shifting to alternative securement devices such as StatLock (BardMedicalDivision) Grip-Lok (Vygon) SorbaView (Shield) Tegaderm

TABLE II - Details regarding complications

Complication	CVC (n = 47)	Incidence	Group A (n = 122)	Inc.	Group B (n = 51)	Inc.	p
Infection	13 (7.5%)	0.40 per 1000 CVC days	10 (8.2%)	0.38	3 (5.8%)	0.46	0.60
Dislodgment	27 (16.8%)	0.83 per 1000 CVC days	25 (14.4%)	0.95	2 (1.1%)	0.30	0.006
Thrombosis	4 (2.3%)	0.12 per 1000 CVC days	3 (1.7%)	0.11	1 (0.6%)	0.15	1
Malfunctioning	6 (3.5%)	0.18 per 1000 CVC days	5 (2.9%)	0.19	1 (0.6%)	0.15	0.67
Total complications	50 (28.9%)	1.50 per 1000 CVC days	43 (24.8%)	1.60	7 (4.1%)	1.08	0.004

CVC = central venous catheter; Inc. = incidence.

(3M) and SecurAcath® (Interrad Medical). Occlusion prompts removal only if the attempt to adjust CVC fails.

On the ground of these considerations, we addressed complication within the first 30 days after CVC positioning. When comparing the incidence of complications based on the type of used securement device, we could demonstrate that patients with SAS experienced a 4% incidence of dislodgment compared to those who used different securement devices who experienced 18% of dislodgments. SAS works like an anchor to which the CVC is clipped and secured in the long term. It can be held in place for months and, ideally, should last as long as the expected CVC duration. In our center, we started using SAS from December 2015 on high-risk patients as those reported by Cesar (infants and toddlers). Consistently, the mean age of group B patients (those receiving SAS securement) was lower than 5 years, thus underlying that the use of this device was aimed at reducing complications mostly in young children. Given the available sizes of this securement device (more compatible with polyurethane than with silicone CVCs), we are now using this device routinely, every time a polyurethane CVC is used. This datum is confirmed by the preponderance of polyurethane catheters amongst those receiving SAS securement (86%). Teflon, silicone, and polyurethane have been associated with fewer catheter-related infections than polyvinyl chloride or polyethylene. However, the available CVCs are made either of polyurethane or silicone, and there is no specific recommendation regarding materials for clinical practice (13).

Another intriguing finding is related to the dislodgment rates after the first 3-week post-positioning. Comparing catheter with or without SAS securement, the rates proved to be similar (see Fig. 1 for tendency after 20 days' post-positioning) thus suggesting that the highest risk of dislodgment is in the very first period. We could speculate that SAS securement in tunneled-cuffed CVCs could be removed 20 days after positioning being the likely cause of dislodgment, the same of CVCs without this securement device.

Other important inferences can be drawn from our study as secondary outcome: the relation between securement device and other complications. CVC shuttling and malpositioning can lead to thrombosis, which frequently is triggered by damage to vascular endothelium from the insertion of CVCs or administration of chemotherapy, and further stimulated by inflammatory responses associated with infections and chronic illness. Previous studies showed that site of catheter insertion can influence the incidence of certain CVC-related adverse events such as infections and thrombotic complications (14, 15). Tolar and Gould first suggested that various complications were related, and that most of CVC complications can lead to the development of venous thrombosis. Thirty percent of patients in their study who had CVC-related issues subsequently developed thrombosis (16, 17). To minimize this issue, as well as other complications reported in literature, we mostly adopt supraclavicular access to the BCV for catheter placement, as already reported in literature (2).

Some limitations to our conclusions arise. The nonrandomized nature of this work and the number of population represent the most severe limitations. The lower incidence of complications observed with the use of polyurethane could be a non-independent measure given the nearly exclusive utilization of SAS in this subgroup of CVCs. Majors studies must be done to prove the real influence of the different materials on complications.

Conclusion

In our study on children with CVCs, dislodgment was the complication confirmed to be the most frequently reported problem. The results of our series of patients suggest that the use of SAS significantly reduces the incidence of dislodgment in high-risk patients, particularly in the very first postoperative period. Based on these results, we strongly suggest that this new securement device be adopted for the whole life of every tunneled CVC and during the first 3 to 4 weeks after positioning for all cuffed CVCs, particularly in infants and toddlers.

Disclosures

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