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Complications and its risk factors of percutaneous subclavian vein catheters in pediatric patients: enhancing the outcomes of a university hospital in a low-income and middle-income country

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#### ABSTRACT

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Objective Assessing central venous catheter-related complications with regular feedback and investigating risk factors are mandatory to enhance outcomes. The aim of this study is to assess our experience in the management of pediatric subclavian vein catheters (SVCs) and to investigate the main risk factors for complications. Methods In this prospective observational study, we included children aged 3 months to 14 years who underwent infraclavicular subclavian vein catheterization consecutively using the anatomic landmark technique. Patients were divided into two groups: group 1 included complicated catheters and group 2 included noncomplicated catheters. The management protocol was standardized for all patients. After comparing the two groups, univariate and multivariate logistic regression were used to investigate the risk factors for complications. **Results** In this study, we included 134 pediatric patients. The rate of complications was 32.8%. The main complications were central line-associated bloodstream infection (63.6%), bleeding and/or hematoma (22.7%), mechanical complications (13.6%), and vein thrombosis (13.6%). After adjustment for confounding factors, predictors of catheter-related complications were difficult insertion procedure (adjusted odds ratio (aOR)=9.4; 95% confidential interval (CI): 2.32 to 38.4), thrombocytopenia (aOR=4.43; 95% CI: 1.16 to 16.86), comorbidities (aOR=2.93; 95% CI: 0.58 to 14.7), and neutropenia (aOR=5.45; 95% CI: 2.29 to 13.0).

**Conclusions** High rates of complications were associated with difficult catheter placement and patients with comorbidities and severe thrombocytopenia. To reduce catheter-related morbidity, we suggest an ultrasound-guided approach, a multidisciplinary teaching program to improve nursing skills, and the use of less invasive devices for patients with cancer.

#### INTRODUCTION

Pediatric percutaneous central venous catheters have improved the care of children requiring prolonged intravenous lines for prolonged therapy.<sup>1</sup> Subclavian vein catheters

# WHAT IS ALREADY KNOWN ON THIS TOPIC

- ⇒ Catheter-related complications depend on the experience of the healthcare team and nursing skills.
- ⇒ To improve venous catheter outcomes, regular feedback on complications and investigation of risk factors is required to guide actions.

### WHAT THIS STUDY ADDS

- ⇒ The main complications were central line-associated bloodstream infection (63.6%), bleeding and/or hematoma (22.7%), mechanical complications (13.6%), and vein thrombosis (13.6%).
- ⇒ Catheter-related complications were associated with difficult catheter placement, comorbidities, and severe thrombocytopenia.

### HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

- ⇒ To improve venous catheter outcomes, actions were guided by the complication risk factors.
- ⇒ We suggest an ultrasound-guided approach, a multidisciplinary teaching program to improve nursing skills, and the use of less invasive devices for patients with cancer.

(SVCs) can provide safe long-term venous access.<sup>2</sup> However, several complications with an incidence ranging from 1% to 10% have been reported.3 The type, incidence and risk factors for complications depend on the experience of the healthcare team, the indications for central line insertion and the nursing skills.<sup>4</sup> In high-income countries, subclavian vein catheterization is underused despite its safety because of the emergence of less invasive new devices that can save central access.<sup>5</sup> On the other hand, in low-income and middle-income countries, the rate of complications of central catheters can be higher because of multiple insufficiencies, such as the unavailability of ultrasounds and

adequate venous access devices, the lack of experience, and nursing quality.<sup>4</sup> Therefore, enhancing healthcare team outcomes by assessing complications, investigating the risk factors for complications, and using an interprofessional approach with regular feedback is mandatory to reduce catheter-related morbidity.<sup>6</sup>

The aim of this study is to assess our experience in the management of pediatric SVCs and to investigate the main risk factors for complications.

#### **METHODS**

We collected data from infants and children referred to the pediatric surgery department for percutaneous infraclavicular subclavian vein catheterization under general anesthesia in the period lasting from July 2021 to September 2022, with regular follow-up visits until 1 month later.

In this study, we included all children aged 3 months to 14 years admitted to the pediatric surgery department for infraclavicular subclavian central vein catheter placement. We included medical, surgical, critically ill, and hematology/oncology patients. We did not include patients with subclavian vein thrombosis, fracture of the clavicle, or local infection at the insertion site. Neonates and patients whose parents did not consent to participate in the study were not included. We excluded cases of placement failure and patients who died before the removal of the catheter if the death was not caused by catheter complications.

The variables included demographic parameters (age, age <1 year, weight, weight <10 kg, comorbidities, American Society of Anesthesiologists (ASA) class, history of central venous access, context, and indications for catheter placement). The main indications were difficult venous access or inability to obtain peripheral venous access, parenteral nutrition, major surgery requiring prolonged infusion, and chemotherapy. We assessed the difficulty of catheter insertion by assessing the duration of the insertion procedure, the number of punctures (number of attempts), and the occurrence of an accidental arterial puncture. A difficult catheter placement was considered when the physician needed more than two attempts to insert the catheter. To assess catheterrelated complications, the site was inspected, and the nurses' reports were reviewed daily. The complications assessed were infection or central line-associated bloodstream infection (CLABSI), bleeding and/or hematoma, pneumothorax, vein thrombosis or vein damage, nerve damage, air embolism, and mechanical complications such as dislodgement and malposition. The duration of a catheter was defined as the length of the period between placement and removal. Early removal was considered when the duration of the catheter was <10 days.

All patients had the same protocol for SVC placement. All catheters were placed in the pediatric surgery operating room under general anesthesia (sevoflurane inhalatory sedation with facial mask) by the same team of experienced anesthetists (consultant having >5 years of experience in the field of pediatric anesthesia) using the anatomic landmark technique for infraclavicular subclavian vein catheterization. We used the same commercially available, prepackaged and sterilized catheter (adhe-els) for all patients. Catheter insertion was performed under aseptic surgical conditions. The nurse first cleaned the site with sodium hypochlorite 5% Amuchina. Then, after surgical hand hygiene, physicians took sterile gloves and sterile casaques and disinfected the site initially with 7.5%povidone-iodine (Betadine Surgical Scrub) for 1 min before cleaning the site with normal saline and sterile gauze swabs. After that, the site was disinfected with a Betadine alcoholic 5% solution before starting the CVC insertion procedure. Aseptic conditions were met until the end of the procedure and the placement of a transparent adhesive dressing. The CVC was inspected daily, and the dressing was changed every 2 days. The maintenance of the SVCs was managed by experienced nurses according to a standardized protocol. In the event of the failure of the procedure, a Broviac catheter or peripherally inserted central catheter (PICC) line (if available) were useful alternatives. Patients with thrombocytopenia in life-threatening situations (children with cancer) received a prophylactic platelet transfusion 2 hours prior to central venous catheter placement when the platelet level was under  $50 \times 10^6 / L$  and if peripheral venous access was available. The catheter can be removed in the supine position by experienced nurses after the doctor's approval. Then, patients were divided into two groups according to the incidence of complications: group 1 included complicated SVCs and group 2 included no complicated SVCs.

The sample size was calculated to be 88 (44 patients in each group) considering 60.3% the incidence of complications in a previous study in the same department<sup>4</sup> vs 34% in the preliminary results from the data of the first 50 patients included in this study. A study sample of 44 patients in each group is required for a 95% confidential interval (CI) level and a 5% margin of error.

All statistical analyses were performed using the SPSS V.25.0 (SPSS, Chicago, Illinois, USA) statistical package. The comparison between the two groups was achieved by Student's t-test for continuous variables and the  $\chi^2$  test for categorical variables. Fisher's exact test was used when the  $\chi^2$  test was not applicable. Univariate and multivariate logistic regression models were used to investigate the risk factors for complications. Odds ratios (ORs) along with their 95% CIs are provided. Differences of p<0.05 were considered to be statistically significant.

### RESULTS

In this study, 142 patients were admitted for percutaneous SVC insertion. Nine patients were excluded: five for insertion failure and four patients died before central line removal; 134 patients were included. The success rate of pediatric SVC insertion using the landmark technique

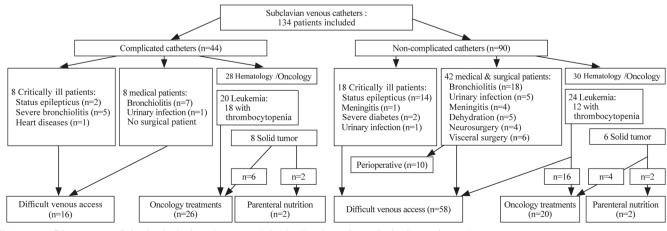
Table 1 Demographic parameters					
	Group 1: complicated SVC (n=44)	Group 2: uncomplicated SVC (n=90)	P value		
Age (years)*	3.5±3.9	3.7±4.0	0.787		
Age <1 year	18 (40.9%)	28 (31.1%)	0.176		
Weight (kg)*	15.4±4	17.0±12	0.468		
Weight <10kg	20 (45.4%)	24 (26.6%)	0.253		
With comorbidities	42 (95.4%)	74 (82.2%)	0.027		
ASA class (I/II/III/IV)	2/24/18/0	16/42/32/0	0.108		
Past of central venous catheterization	20 (45.4%)	42 (46.6%)	0.521		
Emergency	16 (36.3%)	18 (20%)	0.035		
Medical and surgical patients	8 (18.1%)	42 (45.6%)	<0.001		
Critically ill patients	8 (18.1%)	18 (20%)	0.500		
Hematology/Oncology patients	28 (63.6%)	30 (33.3%)	0.002		
Neutropenia (<1500/mm <sup>3</sup> )	18 (40.9%)	12 (13.3%)	<0.001		
Active infection and/or with fever	31 (70.4%)	71 (78.8%)	0.227		
Hemoglobin concentration (g/dL)*	88	94±17	0.092		
Hemoglobin <10g/dL	17	42	0.570		
Prothrombin ratio (%)*	89.7±10	92±9	0.089		
Prothrombin ratio <70%	0	0	_		
Platelets count (10 <sup>6</sup> /mm <sup>3</sup> )*	139±89	232±92	0.001		
SVC indications					
Difficult venous access	16 (36.3%)	58 (64.4%)	0.067		
Parenteral nutrition	2 (4.5%)	2 (2.2%)	_		
Perioeprative	0	10 (11.1%)	-		
Oncology	26 (59%)	20 (22.2%)	<0.001		

\*Data were presented with mean±SD.

ASA, American Society of Anesthesiologists; SVC, subclavian vein catheter.

was 97%. The incidence of complications was 32.8%, and 44 patients were enrolled in group 1 (complicated) and 90 patients in group 2 (uncomplicated).

Demographic parameters concerning age, weight, ASA class, and history of central line placement were comparable in both groups (table 1). The diagnoses of the included patients and the indications for SVCs are shown in figure 1. Patients with comorbidities, children with cancer, severe thrombocytopenia or leucopenia (absolute neutrophil count  $<1500/\text{mm}^3$ ), and patients



Diagnoses of the included patients and the indications for subclavian vein catheters. Figure 1

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	Table 2	Difficulty in infraclavicular subclavian venous catheterization

P value

0.002

< 0.001 < 0.001

< 0.001

0.243

< 0.001

Table 2 Difficulty in infractavicular subclavian venous	catheterization	
	Group 1: complicated SVC (n=44)	Group 2: uncomplicated SVC (n=90)
Duration of the procedure (min)*	16.4±3.9	13.7±4.8
Number of attempts*	2±0.8	1.4±0.7
Single shot	16 (36.3%)	82 (91.1%)
Difficult catheter placement (more than two attempts)	16 (36.3%)	5 (5.5%)
Accidental arterial puncture	4 (9%)	4 (4.4%)
Thrombocytopenia <50000	18 (40.9%)	12 (13.3%)
*Data were presented with mean±SD. SVC, subclavian vein catheter.		
with SVCs in emergency departments were more free in the complicated group (table 1). Difficult SVC j ment was more frequent in the complicated group a longer procedure duration and a higher numb attempts (table 2).	place- thrombocytoper , with comorbidities, per of neutropenia we	analysis, difficult catheter p nia <50000/mL, emergency hematology/oncology patie re associated with an increas morbidity (table 3).

The main complications were CLABSI (63.6%), bleeding and/or hematoma (22.7%); mechanical complications (13.6%) and vein thrombosis (13.6%). All cases of vein thrombosis occurred in hematology/oncology patients. We did not have any other complications (pneumothorax, pneumomediastinum, air embolism or vein or local nerve damage). Four patients presented with CLABSI and mechanical complications, and two patients presented with hematoma and vein thrombosis at the same time. The delay between catheter insertion and the occurrence of a complication was 10.6±6.8 days for CLABSI vs 9.1±7.9 days for mechanical complications and vein thrombosis (p=0.501). However, bleeding complications occurred at 3.9±4.4 days after catheter insertion, while other complications occurred at 10.1±7.4 days (p=0.008).

The duration of the catheter was  $12.2\pm7$  and  $11.0\pm7$  days in group 1 and group 2, respectively(p=0.386). Sixteen SVCs were removed when not needed in group 1 vs 80 in group 2 (p=0.001). Early removal of the SVC was observed in 20 patients in group 1 vs 42 in group 2, with no significant difference (p=0.521). In this study, no complications occurred while removing the catheter.

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After adjustment for confounding factors, predictors of catheter-related complications were difficult insertion procedure (adjusted OR (aOR)=9.4; 95% CI: 2.32 to 38.4), thrombocytopenia (aOR=4.43; 95% CI: 1.16 to 16.86), comorbidities (aOR=2.93; 95% CI: 0.58 to 14.7), and neutropenia (aOR=5.45; 95% CI: 2.29 to 13.0) (table 3). Neutropenia was correlated with CLABSI (OR=6.692; 95% CI: 2.74 to 16.29).

# DISCUSSION

This study reports our experience in the management of pediatric difficult venous access using infraclavicular subclavian vein catheterization with the anatomic landmark technique. We experienced high rates of success (97%) and a high incidence of early and late complications (32.8%). The main risk factors were the difficulty of the insertion procedures requiring more than three attempts, severe thrombocytopenia (<50000/mL), and comorbidities of the patients.

This study had a clinical and practical impact. It gave us feedback on our habits and warned us about the need to take urgent measures to reduce catheter-related

Table 3 Predictors of catheter-related complications					
	OR (95% CI)	aOR (95% CI)	P value		
Age <1 year	0.65 (0.309 to 1.379)	0.78 (0.157 to 3.871)	0.762		
Weight <10 kg	0.72 (0.351 to 1.513)	1.08 (0.207 to 5.650)	0.927		
Difficult insertion procedure	9.7 (3.262 to 28.92)	9.4 (2.32 to 38.4)	<0.001		
Thrombocytopenia <50000	5.2 (2.170 to 12.701)	4.43 (1.16 to 16.86)	0.029		
Emergency	2.2 (1.024 to 5.100)	1.96 (0.643 to 6.01)	0.236		
Comorbidities: ASA class >I	4.5 (0.995 to 20.710)	2.93 (0.58 to 14.7)	0.019		
Hematology/Oncology	3.1 (1.497 to 6.720)	0.97 (0.256 to 3.697)	0.967		
Neutropenia	7.6 (2.65 to 22.1)	5.45 (2.29 to 13.0)	<0.001		

aOR, adjusted odds ratio; ASA, American Society of Anesthesiologists; CI, confidential interval; OR, odds ratio.

morbidity. Investigating predictors of complications was useful to guide us to the actions required.<sup>8</sup>

The main limitations of this study are that we included a heterogeneous pediatric population, as it included patients coming from different departments and requiring central lines for different indications with different ages. This study was not specific to a particular pediatric population.

In our study, the majority of catheter-related infections seem to have occurred later in the time period after insertion. This suggests that this complication may be related to inadequate protocols for maintaining the catheter once inserted and inadequate hygiene. Therefore, we suggest urgent hygiene measures with simulation-based education programs on nursing and catheter maintenance to reduce the high rates of CLABSI. A previous study in the same department including Broviac catheters in critically ill neonates and infants showed a similar rate of catheter infections.<sup>4</sup> We also suggest a larger strategy of prevention of nosocomial infection in all pediatrics units of our hospital.<sup>9</sup> The high rate of catheter-related bleeding and hematoma can be explained by including patients with cancer with aplastic anemia suffering from severe thrombocytopenia,<sup>10 11</sup> although platelet transfusion was performed prior to catheter placement.<sup>12 13</sup> For children with cancer, we suggest the use of PICCs, which is a less invasive technique compared with SVCs or totally implantable venous-access ports (TIVAPs), which is the gold standard for chemotherapy in children with malignancies.<sup>14 15</sup> However, the unavailability and the higher cost of these venous access devices (PICCs, TIVAPs, Midline) oblige physicians to manage with the available tools and to infringe on the standards sometimes.<sup>16 17</sup> Even if subclavian vein catheterization is known to be at a higher risk of bleeding, other sites can have the same complications because of the insufficiencies of our healthcare system.<sup>18</sup>

In our study, the main risk factor was multiple catheter placement attempts. To reduce this risk, we suggest the use of ultrasound-guided techniques.<sup>19-21</sup> Previous research found that the ultrasound-guided technique had a lower failure and complication rate than the anatomic landmark technique.<sup>19 22 23</sup> This use of ultrasounds may facilitate access to the supraclavicular and internal jugular veins,<sup>2425</sup> which seems more suitable than the subclavian vein for children requiring the central line for only a few days, such as surgical and medical patients. It can also help in central line placement even in newborns with low birth weight.<sup>26</sup> Changing the habits of all healthcare teams (physicians, nurses, anesthetists, etc) requires several teaching actions to convince them to be more implicated in our healthcare quality improvement approach.<sup>27 28</sup>

At the moment of catheter removal, several rare and dangerous complications have been reported.<sup>29 30</sup> However, the workload and the lack of physicians made us delegate this mission to nurses.<sup>31</sup> Although there are several barriers to improving our pediatric difficult venous access outcomes,<sup>32</sup> we have achieved some advantages by changing habits,<sup>8</sup> such as using SVCs in place of Broviac catheters, which were overused previously despite their higher rates of complications (60.2%),<sup>4</sup> but there is still a large gap to an advanced country.

In conclusion, high rates of complicated SVCs were associated with difficult catheter placement and children with comorbidities, particularly children with severe thrombocytopenia. This study gave us feedback on our habits and warned us about our deficiencies. Deduced risk factors allowed us to guide actions required to reduce catheterrelated morbidity. We suggest an ultrasound-guided approach and multidisciplinary teaching program to improve nursing skills and the use of less invasive devices for patients with cancer.

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Patient consent for publication Consent obtained from parent(s)/guardian(s).

**Ethics approval** This study was approved by the ethics committee of the University of Sfax under the reference: 00153/2021 on January 2021. Participants gave informed consent to participate in the study before taking part.

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Data availability statement Data are available on reasonable request.

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