ANALYSIS OF INCIDENT REPORTS OF MECHANICAL COMPLICATIONS RELATED TO VASCULAR ACCESS DEVICES IN CRITICALLY ILL PATIENTS

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Abstract

Background: Vascular catheterizations are common in critically ill patients, but are often associated with mechanical complications during placement, maintenance and removal. The objective of this study is to describe the mechanical complications related to vascular access devices, risk factors and associated harm.

Methods: A retrospective study was conducted of all voluntary incident reports of mechanical complications related to vascular access devices for the period from March, 2010 to September, 2012 in a tertiary-care intensive care unit. A tool was developed and validated to assess the characteristics and contributing factors. The category of harm was determined by using the National Coordinating Council for Medication Error Reporting and Prevention(NCC-MERP) Index.

Results: During the study period, there were 60 incident reports of mechanical complications: 13 (21.7%) was placement-related, 44 (73.3%) maintenance-related and 3 (5%) removal-related. The most frequent placement-related complications were pneumothorax 23.1% and bleeding 15.4%; with dislodgment 47.7% and accidental migration 40.9% the most frequent maintenance-related complications. Bleeding was the only removal-related complication. The category of harm ranged from Category-C (reached patient with no harm): 23.3%, Category-D (reached patient and required monitoring to confirm no harm): 33.3%, Category-E (resulted in temporary harm and required an intervention): 40%, Category-F (caused temporary harm and required initial/prolonged hospitalization): 1.7% and Category-H (required a life-sustaining intervention): 1.7%.

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Conclusion: Mechanical complications related to vascular access devices are not uncommon in critically ill patients. The incidence and category of harm of such complications are probably underestimated. These complications should be targeted for quality improvement projects.

Keywords: Incident Reports, Vascular Access, catheterizations, Mechanical Complication, Critical Care

Introduction

Central venous and arterial catheterizations are common in critically ill patients for diagnostic or therapeutic purposes¹. However, placement, maintenance and removal of these devices are often associated with mechanical, thromboembolic, and infectious complications in clinical practice². Infectious complications have been the subject of major quality improvement initiatives^{1,3} and are often monitored at unit and hospital level and benchmarked against national and international rates. Mechanical complications, however, are frequently not subjected to the same level of monitoring.

Mechanical complications related to vascular access devices contribute to patient harm through increased length of stay, family dissatisfaction, increased hospital costs, and the need for additional interventions⁴⁻⁶. These complications have been reported in 11-19% of critical care patients7-9. The most frequently reported mechanical complications include placement failure, arterial puncture, hematoma, misplaced catheter, pneumothorax and air embolism^{5,7-11}. Operator experience/knowledge, morbidity, number of insertion attempts, site of insertion, catheter type, gender, age and no ultrasound guidance were reported as risk factors for mechanical complications related to vascular access devices^{8,12-14}.

Incident reporting systems (IRSs) are considered as one of the key strategies to detect, reduce and prevent errors. Analysis of data from incident reports generates valuable information that can be used for system-based quality and safety improvements¹⁵. This is particularly relevant in high-risk areas such as an intensive care unit (ICU) where the incidence of errors has been reported as high as two per ICU patient per

day and it is estimated that one in five patients may sustain a serious adverse event with significant harm¹⁶. Reporting catheter-related incidents including vascular access devices in IRSs is highly recommended to guide interventions to prevent these incidents in critical ill patients⁴.

The objective of this study was to describe mechanical complications related to vascular access devices, analyze the risk factors and the associated category of harm based on voluntary incident reports at the ICU in a tertiary care hospital.

Methods

Setting

This was a retrospective study conducted at the ICUs of King Abdulaziz Medical City in Riyadh, Kingdom of Saudi Arabia of all voluntarily incident reports of mechanical complications related to vascular access devices for the period from March 2010 to September 2012. The hospital is a 1000-bed university-affiliated tertiary care center, accredited by the Joint Commission International. The intensive care department encompasses a 21-bed medical-ICU, 9-bed surgical-ICU, 8-bed trauma-ICU, 8-bed neurologic-ICU and 14-bed intermediate-care-unit. These units are staffed by onsite board-certified intensivists on 24 hours/7 days a week basis. The average nurse patient ratio is 1:1. The study was approved by the Research Committee at the King Abdullah International Medical Research Center, Riyadh, Saudi Arabia, and as the study did not involve any patient intervention or risk to subjects, approval from the Institutional Review Board was waived.

Incident reporting system (IRS)

An electronic IRS has been introduced in March 2010 in the ICU as part of a hospital-wide project. The Quality Management Department monitors the incident reports and provides training for front-line staff¹⁷. Reporting was voluntary, but not anonymous. The NCC-MERP Index was used to categorize the harm¹⁸. All ICU incident reports are reviewed, analyzed and managed by an IRS Committee, which is a physician-

led multidisciplinary committee working closely with the quality management department. The committee consists of physician, nurse, respiratory therapist, pharmacist and quality management specialist¹⁷.

Inclusion and exclusion criteria

We included all incident reports for adult critically ill patients of mechanical complications related to vascular access devices including peripherally inserted central catheter (PICC) lines from March 2010 to September 2012. We excluded incident reports of peripheral venous-access devices. The details of each incident report were reviewed and additional data were collected by two members (physician and clinical research coordinator) through reviewing the medical charts and ICU-database.

Data collection

A team, consisting of the chairman of the intensive care department, the director of the quality management department, ICU physicians, quality specialists and a clinical research coordinator, conducted multiple roundtable meetings to discuss and evaluate the incident reports of mechanical complications related to vascular access devices. Through reviewing a sample of these incident reports and the related literature, the team developed and validated a tool to assess the characteristics and the potential contributing factors of mechanical complications of vascular access devices. The tool was assessed by the members of an expert team and modified accordingly. It was tested on five medical charts before it was used for this study.

The vascular access mechanical complication data collection tool consisted of five main sections:

Incident report information: date, time, location of incidence, classification of complication as per occurrence phase: A) Placement-related complications which includes bleeding, pneumothorax, wrong insertion site (catheter insertion in the artery instead of vein), guide wire-related (leaving a guide wire inside patient body), wrong catheter size (using catheter size and fixing it at wrong level), wrong fixation (no proper fixation of catheter), and lung collapse, dilator-related

(the trauma catheter introducer not removed during insertion). B) Maintenance-related complications which includes leaking (the fluid start to flow outside the body), dislodgment (accidental removal of catheter by patient), non-functioning port (no flow in catheter port), accidental migration (removal of catheter during care), ischemia and cyanosis. C) Removal-related complications including bleeding.

Patient information: age, gender, weight, height, Glasgow coma scale (GCS), type of admission, medical diagnosis, mechanical ventilation use and duration.

Risk factors: Central venous pressure (CVP), sequential organ failure assessment score (SOFA) and acute physiology and chronic health evaluation-II (APACHEII) score at ICU admission, dehydration or hypovolemia, history of sternotomy, local radiation therapy, clavicular fracture, skeletal deformities, myocardial infraction, venous thrombosis at insertion site, use of anticoagulation or fibrinolytic therapy, sepsis, ventricular arrhythmia, chronic obstructive pulmonary disease (COPD), positive end-expiratory pressure (PEEP), history of difficult intravascular (IV) access, deep vein thrombosis (DVT), platelets count, international normalized ratio (INR) and partial thromboplastin time (PTT) readings.

Procedure information: date and time of ICU admission, date and time of catheter insertion, duration of catheterization, number of insertion attempts, site of insertion, size and type of catheter, previous catheterization, previous surgical operation, use of ultrasound guidance, chest X-ray placement confirmation, operator experience, supervisor presence and level, emergency nature of procedure of procedure, and therapeutic anticoagulation use.

Incident report analysis: category of harm.

Statistical analysis

We describe baseline characteristics, risk factors and consequences of mechanical complications related to vascular access, classified as per phase of occurrence into placement, maintenance and removal-related. Continuous variables were described as mean and standard deviation (SD). Categorical variables were expressed as absolute and relative

frequencies. Computations were performed by IBM SPSS Statistics V22 (IBM Corp., Armonk, NY).

Results

During the study period, a total of 1,908 incident reports were reported for critically ill patients. Of these, 60 were related to vascular access devices and met the study inclusion criteria, representing 3% of all incident reports. Of them 13 (21.7%) were placement-related, 44 (73.3%) were maintenance-related, and 3 (5%) were removal-related.

The baseline characteristics of the patients are presented in Table 1. The mean age was 54.8 ± 21.7 years, 37 (61.7%) were male with a mean GCS of 9.3 ± 4.4 , mean body mass index of 26.2 ± 8.3 and APACHE II of 23.6 ± 7.0 . The majority of incident reports 53 (88.3%) were written while the patient was in the ICU. Incidents occurred equally during day and night shifts; although, placement-related and removal-related complications occurred mostly during the day shift (69.2% and 66.7%) respectively. The subclavian 34.1% and internal jugular 34.1% sites were predominant sites of maintenance-related complications, with the femoral site predominantly placement-related (Table 2).

Potential risk factors

As shown in Table 1, the majority 92.3% of the patients with placement-related complications was mechanically ventilated, with a mean age of $38.9 \pm$ 21.5 year, 23.1% had dehydration, 30.8% had sepsis and 38.5% diagnosed with a traumatic brain injury. In comparison, in the maintenance-related complications, 52.3% of the patients were mechanically ventilated, with a mean age of 58.3 ± 20.2 year, 18.2% had dehydration and 40.9% sepsis. For removalrelated complications, 66.7% of the patients were mechanically ventilated, with a mean age of 72.7 ± 4.2 year and one patient 33.3% received systemic anticoagulation therapy. Physician registrars inserted 38.5% of the catheters, residents 23.1% and fellows only 15.4% (Table 2). Difficulty of IV access, number of attempts, ultrasound and chest X-ray usage, and supervisor information were poorly documented.

Complications and outcomes

Mechanical complications are described in Table 3. Pneumothorax 3 (23.1%) was the most common placement-related complications, while catheter dislodgement 21 (47.7%) and accidental migration 18 (40.9%) were the common maintenance-related complications. Bleeding was the only reported removal-related complication. Less frequent complications were related to wrong insertion site, guide wire-related, dilator-related, wrong catheter size, wrong fixation, lung collapse, leaking, non-functioning port, ischemia and cyanosis.

As shown in Table 4, the categories of harm associated with the incident reports were: an error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention (Category E) 40%, an error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm (Category D) 33.3%, and an error occurred that reached the patient but did not cause patient harm (Category C) 23.3%, an error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization (Category F) and an error occurred that required intervention necessary to sustain life (Category H) occurred in one patient each (1.7%).

For placement-related complications, the highest proportion (61.5%) of harm related category was temporary harm requiring an intervention; with an error requiring monitoring to confirm no harm was the highest proportion (38.6%) in the maintenance-related complications.

Discussion

Our study suggests that mechanical complications related to vascular access devices are not uncommon. We found that the majority of these complications were maintenance-related, with dislodgment and accidental migration reported frequently. These complications were often associated with harm.

Data on mechanical complications related to vascular access devices in critically ill patients are limited⁷⁻⁸. Existing studies vary in study purpose,

Table 1

Characteristics of patients with incidents reports related to vascular access devices. Incident reports were divided into those related to placement, maintenance or removal of vascular access devices

Variable	All	Placement	Maintenance	Removal
variable	(n = 60)	(n = 13)	(n = 44)	(n=3)
Patients' demographics, n (%)				
Age (years)*	54.8 ± 21.7	38.9 ± 21.5	58.3 ± 20.2	72.7 ± 4.2
Male gender	37 (61.7)	8 (61.5)	28 (63.6)	1 (33.3)
Glasgow Coma Scale*	9.3 ± 4.4	4.7 ± 3.5	10.4 ± 3.8	11.3 ± 3.5
Body Mass Index, (kg/m2)*	26.2 ± 8.3	25.2 ± 7.3	25.9 ± 7.7	35.0 ± 17.1
APACHEII*	23.6 ± 7.0	24.1 ± 6.5	23.8 ± 7.4	20 ± 3
Sequential Organ Failure Assessment*	9.7 ± 3.7	11.4 ± 4	9.5 ± 3.5	6 ± 1
Type of admission, n (%)	'			
Medical	34 (56.7)	7 (53.8)	26 (59.1)	1 (33.3)
Surgical	26 (43.3)	6 (46.2)	18 (40.9)	2 (66.7)
Admission diagnosis, n (%)	ı	1		
Traumatic brain injury	10 (16.7)	5 (38.5)	4 (9.1)	1 (33.3)
Septic shock	9 (15)	3 (23.1)	6 (13.6)	0
Liver cirrhosis	4 (6.7)	1 (7.7)	3 (6.8)	0
Pneumonia	3 (5)	0	2 (4.5)	1 (33.3)
Post laparotomy colon cancer	3 (5)	0	3 (6.8)	0
Gastrointestinal bleeding	3 (5)	0	3 (6.8)	0
Systemic lupus erythematosus	3 (5)	1 (7.7)	2 (4.5)	0
Post liver transplant	2 (3.3)	0	2 (4.5)	0
Others	16 (38.3)	3 (23.1)	13 (43.4)	1 (33.3)
Risk factors, n (%)				
Mechanical ventilation	37 (61.7)	12 (92.3)	23 (52.3)	2 (66.7)
Mechanical ventilation duration (days)	7.5 ± 10.0	2.3 ± 2.6	9.9 ± 11.6	10.5 ± 7.8
Positive End-Expiratory Pressure, cm H ₂ O	6.5 ± 3.4	7.1 ± 5.1 6.2 ± 2.4		6.3 ± 1.5
Central venous pressure mmHg,	12.2 ± 5.8	12 ± 6.1 12.2 ± 5.9		15 ± 0
Dehydration	11 (18.3)	3 (23.1)	8 (18.2)	0
Sternotomy	1 (1.7)	0	1 (2.3)	0
Sepsis	23 (38.3)	4 (30.8)	18 (40.9)	1 (33.3)
Chronic obstructive pulmonary disease	5 (8.3)	1 (7.7)	3 (6.8)	1 (33.3)
Difficult Intravascular access	17 (28.3)	1 (7.7)	15 (34.1)	1 (33.3)
Deformities	1 (1.7)	0 1 (2.3)		0
Myocardial infraction	1 (1.7)	0 1 (2.3)		0
Deep vein thrombosis	2 (3.3)	0	2 (4.5)	0
Coagulation Blood Test*	1		1	
Platelets, (x 10 ⁹ /L)	221.5 ± 186	221.7 ± 128.9	225.5 ± 206.7	221.2 ± 92
International Normalized Ratio	1.5 ± 0.6	1.6 ± 0.6	1.4 ± 0.6	1.6 ± 0.6
Partial Thromboplastin Time	40.3 ± 17.1	50.1 ± 25.8	38.2 ± 13.1	33.6 ± 12.3
Systemic Anticoagulation n (%)	3 (5)	0	2 (4.5)	1 (33.3)

^{*}Mean \pm standard deviation; APACHEII: Acute Physiology and Chronic Health Evaluation II

Table 2
Vascular access catheterization procedure information

Variable	All (n = 60)	Placement (n = 13)	Maintaining (n = 44)	Removal (n = 3)
Duration of catheterization*	5.1 ± 10.6	1.8 ± 2	6.2 ± 12.2	3 ± 1.7
Site of catheter, n (%)				
Internal jugular	17 (28.3)	2 (15.4)	15 (34.1)	0
Right internal jugular	13 (21.7)	1 (7.7)	12 (27.3)	0
Left internal jugular	4 (6.7)	1 (7.7)	3 (6.8)	0
Subclavian	19 (31.7)	4 (30.8)	15 (34.1)	0
Right subclavian	12 (20)	2 (15.4)	10 (22.7)	0
Left subclavian	7 (11.7)	2 (15.4)	5 (11.4)	0
Femoral	12 (20)	7 (53.8)	4 (9.1)	1 (33.3)
Right femoral	8 (13.3)	5 (38.5)	3 (6.8)	0
Left femoral	4 (6.7)	2 (15.4)	1 (2.3)	1 (33.3)
PICC-line	8 (13.3)	0	7 (15.9)	1 (33.3)
Right PICC-line	5 (8.3)	0	4 (9.1)	1 (33.3)
Left PICC-line	3 (5)	0	3 (6.8)	0
Radial	4 (6.7)	0	3 (6.8)	1 (33.3)
Right radial	3 (5)	0	3 (6.8)	0
Left radial	1 (1.7)	0	0	1 (33.3)
Type of catheter, n (%)	- ()			- ()
Single lumen	5 (8.3)	1 (7.7)	3 (6.8)	1 (33.3)
Double lumen	5 (8.3)	1 (7.7)	3 (6.8)	1 (33.3)
Triple lumen	29 (48.3)	7 (53.8)	22 (50)	0
Quinton	7 (11.7)	2 (15.4)	4 (9.1)	1 (33.3)
Femoral arterial line	2 (3.3)	1 (7.7)	1 (2.3)	0
PICC-line	6 (10)	0	6 (13.6)	0
Permacath	4 (6.7)	0	4 (9.1)	0
Trauma line	2 (3.3)	1 (7.7)	1 (2.3)	0
Previous catheterization, n (%)	13 (21.7)	1 (7.7)	10 (22.7)	1 (33.3)
Ultrasound use, n (%)	- (,	()		()
Yes		0		
No		8 (61.5)		
Not documented		5 (38.5)		
Chest X-Ray, n (%)		()		
Yes	14 (23.3)	4 (30.8)	10 (22.7)	0
No	13 (21.7)	2 (15.4)	11 (25)	0
Not applicable	20 (33.3)	5 (38.5)	12 (27.3)	3 (100)
Not documented	13 (21.7)	2 (15.4)	11 (25)	0
Operator category, n (%)	,	,	,	
Resident		3 (23.1)		
Fellow		2 (15.4)		
Physician registrars		5 (38.5)		
Consultant		0		
Nephrology team		1 (7.7)		
Not documented		2 (15.4)		
Supervisor, n (%)		· · /		
Physician registrars		1 (7.7)		
Consultant		3 (23.1)		
No		4 (30.8)		
Not applicable		1 (7.7)		
Not documented		4 (30.8)		

^{**}Mean ± standard deviation

Table 3
Incident reports related to vascular access devices

Variable	All	Placement (n	Maintaining	Removal (n	
	(n = 60)	= 13)	(n = 44)	= 3)	
Incidents occurrence location and time, n (%)					
Intensive care units	53 (88.3)	7 (53.8)	44 (100)	2 (66.6)	
Emergency department	6 (10)	5 (38.5)	0	1 (33.3)	
Wards	1 (1.7)	1 (7.7)	0	0	
Occurrence during daytime	29 (48.3)	9 (69.2)	18 (40.9)	2 (66.7)	
Mechanical complications of vascular access devices					
Placement, n (%)		n = 13			
Bleeding		2 (15.4)			
Pneumothorax		3 (23.1)			
wrong insertion site		2 (15.4)			
Guide wire-related		1 (7.7)			
Wrong catheter size		2 (15.4)			
Wrong Fixation		1 (7.7)			
Lung collapse		1 (7.7)			
Dilator-related		1 (7.7)			
Maintenance, n (%)			n = 44		
Bleeding			0		
Infection			0		
Leaking			2 (4.5)		
Dislodging			21 (47.7)		
Non-functioning port			1 (2.3)		
Accidental migration			18 (40.9)		
Ischemia			1 (2.3)		
Cyanosis			1 (2.3)		
Removal, n (%)				n = 3	
Bleeding				3 (100)	

design, population and definition of terms. The current study, included medical and surgical critical care patients. Previous studies were conducted on specific populations, for example non-surgical⁸, surgical¹³, trauma⁵, emergency¹⁹, and emergency 19. Unlike other studies, our study evaluated the mechanical complications of all vascular access device types and all sites of insertion. The current study used voluntary incident reports related to vascular access devices followed by a review of the related patient charts.

This approach was similar to the study by Needham et al. using a voluntary patient safety report system to analyze the incident reports in a critical care setting; however, their analysis included in addition to incident reports related to vascular access devices, those related to lines, tubes and drains⁴.

The rate of mechanical complications related to vascular access devices varies in the literature. Retrospective studies indicate rates varying from 0.9% to 3.4%^{5-6,19-20}; while higher rates were observed

Table 4
Categories of harm associated with incident reports related to mechanical complications of vascular access devices

Variable		Placement	Maintenance	Removal
variable	(n =60)	(n =13)	(n = 44)	(n=3)
category of harm* r	n (%)			
C: An error occurred that reached the patient but did not cause patient harm	14 (23.3)	1 (7.7)	12 (27.3)	1 (33.3)
D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm	20 (33.3)	3 (23.1)	17 (38.6)	0
E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention	24 (40)	8 (61.5)	14 (31.8)	2 (66.7)
F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization	1 (1.7)	1 (7.7)	0	0
H: An error occurred that required intervention necessary to sustain life	1 (1.7)	0	1 (2.3)	0

^{*} National Coordinating Council for Medication Error Reporting and Prevention.

in prospective studies ranging from 11% to 19%^{7-8,13,21}. Because our study is based on a voluntary reporting system, incidence cannot be estimated based on voluntary incident reports that are likely to underestimate the true incidence. However, vascular access mechanical complication reports constituted 3% of all incident reports.

This study focused on the reported mechanical complications related to vascular access devices with regards to the phases of its occurrence. The majority of incident reports were maintenance-related, in which the dislodgment and accidental migration of the catheters were the most predominant complications. Pneumothorax and bleeding were the most frequent complications during placement of vascular access devices and removal-related complications were infrequent with bleeding the only complication reported.

As reported in other studies, failure to place, arterial puncture, hematoma, misplacement and pneumothorax were reported as the most common

placement-related mechanical complications of vascular access devices^{5,7-8,13,19,21}. Similar to our study, Needham et al. indicated that maintenance-related incident reports of catheters including vascular access devices have been reported to occur in more than half of the incidents, in which accidental catheter removal by patients and removal by healthcare providers were reported to occur in 5% and 6% respectively⁴.

Notably, we found that among placement-related incidents, more than 60% of complications occurred with residents and physician registrars; at least 30.8% of reported incidents were not supervised and at least 30.8% was detected after using a chest X-ray. No placement-related mechanical complications occurred when ultrasound use was reported. This is in line of the accumulating evidence about the benefit of using the ultrasound in reducing placement complications^{12,22-23}.

In the current study, the subclavian and internal jugular sites were the most frequent sites of maintenance-related complications; the femoral site was the most frequent site of placement-related complications.

Overall, the subclavian site had the highest rate of complications followed by internal jugular site. Data regarding the site-related complications of vascular access devices is inconsistent. Eisen et al. reported that the subclavian site had higher complications rates than the internal jugular and femoral sites⁸. In contrast, Steele et al. reported more mechanical complications with the internal jugular site than the subclavian and femoral sites¹⁹. However, Merrer et al. found no significant difference in complication rates between the subclavian and femoral sites⁷.

Our results revealed that more than 40% of incident reports were associated with harm. In one maintenance-related incident, the harm was permanent requiring an intervention to sustain life. Similarly, Needham et al. found that harm was a common outcome (more than half) of the reported incidents⁴.

Incident reporting systems are considered as an important tool to detect errors, mistakes and violations²⁴. Incident reports were perceived as having a positive effect to learn and increase awareness in health care

practice^{17,25-26} and to generate valuable information that can inform quality and safety initiatives²⁵. Our study demonstrates that analyzing the incident reports of mechanical complications related to vascular access provides valuable information regarding the nature of incidence and the associated harm. Disseminating and sharing this information may facilitate opportunities for learning from defects, exchanging experiences and translating it to safe practice.

Conclusion

Based on this study of voluntary incident reports, mechanical complications related to vascular access devices are not uncommon in the critically ill patients; the incidence and harm of such complications are probably underestimated. These complications should be targeted for quality improvement projects that establish preventative measures for reducing such complications and improving the care of critically ill patients.

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