



**ASSESSMENT OF THE INCIDENCE OF MECHANICAL
COMPLICATION OF CENTRAL LINE PLACEMENT AND ASSOCIATED
FACTORS AT DIFFERENT HEALTH INSTITUTIONS IN ADDIS ABABA,
ETHIOPIA, 2021.**

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Requirement For Specialty Certificate In Anesthesiology**

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STATEMENT OF DECLARATION

I hereby declare and affirm that this research is my own original work as a partial fulfillment of the requirement for the specialty certificate training in anesthesiology. I have followed all the ethical consideration in the preparation, data collection, data analysis and completion of this research. All the sources of the materials used for this research and all people and institutions who gave support for this work are fully acknowledged. I affirm that I have cited and referenced all the sources used in this document

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Abbreviations and Acronyms

BMI.....	body mass index
CCE	Cardiac center Ethiopia
CVC	central venous catheter
CVLMC	Central venous line mechanical complication
EKH	Eka kotebe hospital
IJ	Internal jugular
NGO	Nongovernmental organization
SCV	Subclavian vein
SPSH	St. paul specialized hospital
TASH	Tikur anbessa specialized hospital
TMSC	Tazma medical and surgical center

ABSTRACT

Background

Central venous catheters (CVC) are an essential component of modern medicine. They allow delivery of medications, intravenous fluids, parenteral nutrition, and hemodialysis and monitoring of hemodynamic variables. Placement of central venous catheters is often associated with mechanical, infectious, and thromboembolic complications. Mechanical complications are tissue trauma resulting in vascular, respiratory and cardiac complications as well as device related malfunctions happening In relation to central venous line insertion.

Objective

To assess the cumulative incidence of central venous line mechanical complications and their associated factors at selected health facilities in Addis Ababa, Ethiopia, 2021 GC.

Methods

A multi centered facility based cross- sectional study design was conducted at five different centers from May to September 2021. The data was collected using structured questionnaires, adopted from previous study and modified for this study. The data was entered to Epi-data V 5 for cleaning and was exported to SPSS V 25 for analysis. Descriptive analysis and association for the variables were done.

Results

The overall incidence of CVLMC among our study participants was found to be 49(22%) out of 219 participants. The study also showed increased central line mechanical complication among patients with 2 or more needle punctures at the same site ($AOR=14.1$ 95CI: 3.59-55.28) and among junior proceduralists than consultants ($AOR=0.09$ 95CI: 0.009-0.94).

Conclusion: Central venous line mechanical complications rate is higher with multiple same site needle attempts and among junior proceduralists.

INTRODUCTION

1.1. Background

Central venous access is defined as placement of a catheter such that the catheter is inserted into a venous great vessel. The venous great vessels include the superior vena cava, inferior vena cava, brachiocephalic veins, internal jugular veins, subclavian veins, iliac veins, and common femoral veins. Excluded are catheters that terminate in a systemic artery.(1)Central venous catheters are being increasingly used in both intensive care units and general wards. Their use is associated with both mechanical and infectious complications. Central venous catheters (CVC) allow delivery of medications, intravenous fluids, parenteral nutrition, and hemodialysis and monitoring of hemodynamic variables. Central venous catheters is often associated with mechanical, infectious, and thromboembolic complications.(2)(3)

Mechanical complication includes the occurrence of 1 or more of the following events: incorrect tip position (catheter's tip not in superior vena cava with less than 40 degree of angle between the vessel wall and the catheter tip) as confirmed by the x-ray control, failure to place the catheter, pneumothorax, hemothorax, arterial puncture, cardiac dysrhythmia, and subcutaneous hematoma (any evidence of skin hematoma at the [intended] insertion points) or death mostly occurring immediately up to 24 hours(4)

Mechanical complications are important, because their effects are usually immediate and contribute to increased length of stay, increased hospital costs, need for subsequent interventions, and mortality rate.(3)

The profound impact of the complications associated with CVC use is so important that efforts to minimize and prevent their occurrence should be a routine element of quality improvement programs.(2)Data from the American Society of Anesthesiologists Closed Claims Project database have suggested that since 1990 as review by Domino et al, the majority of mechanical complications associated with CVCs are vascular injuries, and “accidental puncture or laceration” and they are reportable National Quality Measures Patient Safety Indicator.

Central line mechanical complications are reported to have an incidence from 5% to 34%.(5)The wide range of reported rates of complications may be explained by differences in case mix, by differing definitions of complications, and by the fact that most studies reporting mechanical

complications after placement of central venous catheters are small (<2000 patients). Moreover, increasing use of ultrasound during placement may influence the incidence of complications(6).

Arterial puncture, hematoma, and pneumothorax are the most common mechanical complications during the insertion of central venous catheters. Overall, internal jugular catheterization and subclavian venous catheterization carry similar risks of mechanical complications. Subclavian catheterization is more likely than internal jugular catheterization to be complicated by pneumothorax and hemothorax, whereas internal jugular catheterization is more likely to be associated with arterial puncture. Hematoma and arterial puncture are common during femoral venous catheterization. Because mechanical complications are most likely during catheterization at the femoral site, the internal jugular or subclavian venous route should be chosen unless contraindicated. However, the rate of serious mechanical complications (e.g., pneumothorax requiring insertion of a chest tube or hemorrhage requiring blood transfusion or surgery) associated with subclavian insertion is similar to that associated with femoral insertion.(7)

Several studies have identified factors associated with mechanical complications. These factors include low or high patient body mass index (BMI), prior catheterization, prior surgery, prior radiotherapy, number of venipunctures, advanced age, and the time needed for catheter placement. Other factors of potential interest, such as the emergent indication for the CVC include Pre procedural coagulopathy, Subclavian vein insertion the time of day the catheter was placed, the patient's state of consciousness, and the supervisor's training level, have not been fully explored. Furthermore, prior studies differ on whether complication rates are influenced by the training level of the operator and whether ultrasonography should be used to locate the vessel cannulated.(8)

A 2006 study published by Leung et al. demonstrated that ultrasound guidance for internal jugular CVC improved successful placement by 15.4% and reduced complications by 12.3%.(9)

Interventions intended to prevent mechanical trauma or injury associated with central venous access include but are not limited to (1) selection of catheter insertion site; (2) positioning the patient for needle insertion and catheter placement; (3) needle insertion, wire placement, and catheter placement; (4) guidance for needle, guidewire, and catheter placement, and (5) verification of needle, wire, and catheter placement. (1)

1.2. Statement of the problems

Studies showed that mechanical complications of central line insertion can be associated with serious complications with incidence rates in 5% to 34% of catheter attempts. Risk of having severe complications like grade 3 and 4 bleeding, arrhythmias as well as pneumothorax and nerve injuries were close to 0.2% and this complication required immediate interventions.(5)

Even though ultrasound-guided vascular cannulation has drastically decreased the incidence of insertion-related central line mechanical complications, many hospitals in developing countries still rely on the landmark-based technique for cannulation with reported success rates of 75–99%.(4)

In the health care setting the recommended prevention mechanisms include recognition of difficult cannulation based on predisposing risks ahead of time, use of ultrasound for insertion, avoiding routine catheter exchange and getting an experienced operator.(7)

Although the incidence of CVLMC is low in most of the studies done in developed nations, there is a paucity regarding the incidence in low-income countries where landmark techniques are practiced more often. We haven't found a study specifically covering this topic in Ethiopia through our search in electronic and partial gray literature search.

1.3. Significance of the study

In some of the studies done in low-income countries, results showed higher incidence of CVLMC and this should be further studied in detail so that our intervention will be targeted, full, and effective in reducing the burden for the health system as well as for the country as a whole. In addition to this, since this indicator is used as a metric for the quality of health care expertise, knowing the actual incidence and predicting factors associated with the incidence of CVLMC is very essential in making improvement towards delivering better health care which is the ultimate goal for all health systems. Because of the potential high impact of CVLMC, prevention and timely management of central line mechanical complications is vital. So this study will assess the incidence and associated factors of CVLMC at different centers in Addis Ababa and become an input for such measures.

2. Literature Review

In recent multi center retrospective cohort study done in Sweden including 10 949 central line insertions, 118 (1.1%) incidents of mechanical complications were identified, of which 85 (0.8%) were bleedings, 21 (0.2%) were pneumothoraces, 7 (0.06%) were transient nerve injuries, and 5 (0.05%) were self-limiting arrhythmias. Severe mechanical complications occurred in 23 (0.2%) cases. From multivariate analysis of this study Pre procedural coagulopathy; number of needle passes and arterial puncture were associated with grade 2-4 bleedings. Also Subclavian insertion route was associated with statistically significant pneumothorax than internal jugular vein insertion route(6).

A study which was done in India by ICU consultant or by a 2nd or 3rd year registrar (with a minimum prior experience of at least 25 CVC insertions, under the supervision of a consultant) through landmark-based CVC insertions, the overall mechanical complication rate was 17.9% with the major complication being bleeding. This bleeding complications include 28 arterial traumas and 20 subcutaneous hematomas. The other complications include 11 pneumothoracies 15 catheter tip malposition and 11 guide wire kinks. IJ route was associated with a significantly higher incidence of bleeding complications and pneumothorax occurred significantly more often in those who had “two or more” attempts at needle insertion site .The SCV and the IJV routes had similar numbers of catheter-related complications.(10)

From a retrospective study in high volume trauma center in South Africa using landmark technique mostly done by junior doctors, A total of 178 mechanical complications (18%) occurred in 1,015 patients undergoing CVC: 117 pneumothoraces, 25 malpositions, 18 catheter dislodgements, 14 arterial cannulations, one air embolism, one chylothorax, one pleural cannulation and one retained guide-wire. The internal jugular vein (IJV) approach was associated with a higher overall complication rate than the subclavian vein (SCV) approach with Pneumothorax and arterial cannulation being more common with the IJV. Catheter dislodgement was more common with the SCV. Junior doctors performed 66% of the CVCs and this was associated with a significantly higher complication rate.(4)

In another study done in Colombia, researchers were able to demonstrate that the overall mechanical complication rate is 17% (51 patients from three hundred critically ill patients

requiring their first central venous catheter insertion). In this study there was a linear slope increased odds ratio with more punctures in comparison with one until 3 punctures after which the curve becomes exponential after adjustment for covariates. In this study other factors like patients sociodemographic characteristics, indications for central line insertion, insertion site as well as insertion characteristics including operators level of experience were studied but none of them had statically significant cause and effect relationship with central line mechanical complications (5)

According to study done by (Eisen et al) in boston, USA on 385 patients over 6 months period, total rate of complications excluding failure was 14% and three factors were found to be significantly associated with mechanical complication rate. The first factor was the attempted insertion site, the subclavian approach having the highest complication rate. The second factor was number of percutaneous punctures per attempt (attempts requiring more than 2 percutaneous punctures had a 54% rate of failure or other mechanical complication). The last factor found to be associated with complication rate was the gender of the patient with male patients had a higher complication rate than women in this study.(3)

In Prospective 5-year observational study on two intensive care units in Germany to find the Incidence of primary mechanical complications and malposition associated with landmark-guided central venous access procedures (CVAP) performed by experienced operators, the rate for mechanical complications was low (3.3%) and of the analyzed 1794 (1017 right- and 777 left-sided CVAP), of which 87.7% were accomplished without adverse events. But their conclusion is that even experienced operators cause a considerable number of early mechanical complications and malposition. After two unsuccessful cannulation attempts, failure and associated complications are very likely. (11)

From A retrospective chart review was conducted over 9 months at Georgetown University Hospital and Washington Hospital Center with the aim of comparing define site-specific mechanical complications in 3 common anatomic insertion sites: internal jugular, subclavian, and femoral veins,1179 CVC insertions in 801 adult patients were analyzed, 1.5% mechanical complication were found with no statistically significant difference between site-specific complications(12)

From a research done in turkey among pediatrics patients, Central venous catheterization in critically ill children is a relatively safe procedure, with a 1.3% rate of serious complications and no mortality. Insertion-related were including 33 arterial punctures (8.9%), 27 cases of malposition (7.3%), 19 hematomas (5.2%), 12 cases of minor bleeding (3.3%), and three cases of pneumothorax (0.8%), and they were more common in the subclavian vein than in the internal jugular and femoral vein. Multiple attempts and failed attempts significantly correlated with higher incidence of complications.(13)

In developing countries, central line placement is frequently performed by physicians in training and without the availability of ultrasound guidance. A study by Wigmore, et al. in London demonstrated a significant reduction in complication rates following implementation of the NICE guideline.(14) Also A recent Cochrane review by Brass et al. demonstrated that ultrasound guidance reduced the complication rate for the IJV approach, increased success rates and reduced the time taken to perform the procedure.(15) Interventions intended to prevent mechanical trauma or injury associated with central venous access include but are not limited to (1) selection of catheter insertion site; (2) positioning the patient for needle insertion and catheter placement; (3) needle insertion, wire placement, and catheter placement; (4) guidance for needle, guidewire, and catheter placement, and (5) verification of needle, wire, and catheter placement.(1)

3. Objectives

3.1. General objective

To assess the cumulative incidence of central venous line mechanical complications and their associated factors among selected health facilities in Addis Ababa, Ethiopia, 2021 GC.

3.2. Specific objectives

- 3.2.1. To estimate the magnitude of mechanical complications of central line placement among patients with central line at five selected health institutions in Addis Ababa, Ethiopia, 2021 GC
- 3.2.2. To assess the associated factors for the incidence of CVLMC at five selected health institutions in Addis Ababa, Ethiopia, 2021 GC

4. Method and materials

4.1. Study design

Multicenter observational cross sectional study design was conducted.

4.2. Study area and period

The study was conducted at 5 different centers located in Addis Ababa, the largest populous capital city of Ethiopia, where most of the country's medical and surgical service centers are found. Tikur Anbessa Specialized Hospital and St Paul Specialized Hospitals are the country's biggest tertiary hospitals serving more than 10 million patients across Ethiopia. ECC is the only public and NGO funded cardiac center in the Ethiopia, Eka kotebe general hospital is the pioneer and the largest COVID19 treatment center in Ethiopia and Tazma medical and surgical center is a private medical and surgical center with more than 10 years extensive experience in treating cardiac medical and surgical patients. The study was conducted from May to September 2021.

4.3. Population

4.3.1. Source population

The source population was all patients at TASH, SPSH, CCE, EKH and TMSC with central line in place.

4.3.2. Study population

The study population was selected patients with central line placed at TASH, SPSH, CCE, EKH, & TMSC.

4.4. Inclusion and exclusion criteria

4.4.1. Inclusion criteria

All patients for whom central venous line is inserted for various indications in the selected facilities were included

4.4.2. Exclusion criteria

Patients with CVCs insitu performed outside this facilities, patients with underling pneumothorax, hemothorax and hematomas at insertion sites prior to insertion was

excluded. Mechanical Complication that may happen after 24 hours were also excluded

4.5. Sample size

The sample size for this study was calculated by using single proportion population formula. We took the incidence rate of (18%) from the previous South African study(4) and taking 10% margin of error with 95% confidence interval. We added 10% no response rate and we found 249 to be our final sample size.

$$N = \frac{z_{1-\alpha/2}^2 \times p \times (1-p)}{d^2}$$

N= sample size

P= incidence rate

Z = Z value corresponding to a 95% level of significance = 1.96

D= margin of error

$$N_i(1) = \frac{(1.96)^2 \times 0.18(1-0.18)}{(0.05)^2} = 227$$

Adding 10% the total sample size became 249

4.6. Sampling procedure

We used purposive sampling for this study and included all patients for whom central line was insertion for various indications in study areas from May to September 2021,

4.7. Data collection procedure

The data was collected using self-administered questionnaires by 10 trained data collectors (1 third year anesthesia resident, three 2nd year anesthesia residents,

1 nurse anesthetist, 1 OR circulation nurse, 2 dialysis unit nurses and 2 CCU nurses) after 24 hour follow up. Explanation regarding components of the questionnaire was oriented to them. The data collection questionnaire was adopted from a research conducted in south Africa, Sweden and Colombia in 2016 and 2017 and contextualized and developed for this particular study.

4.8. Data analysis procedure

Data was checked for completeness manually and entered using Epi-data software and cleaned then the data was exported to SPSS version 25 software for analysis. Descriptive statistics such as frequency, percent, mean, median and standard deviation was employed for Sociodemographic and clinical characteristics of the participants as well as operator factors. Binary and multivariable logistic regression analysis was done to evaluate the degree of association between associated factors and the outcome variables. Crude and adjusted odds ratio with 95% confidence intervals was used to inform the strength of the association. Variables with P-value <0.20 during the binary analysis was included in the multivariable logistic regression analysis to see further association. In multivariable logistic regression analysis covariates having p-value less than 0.05 was considered as statically significant.

4.9. Data quality assurance

The data collectors was trained before data collection and there were frequent meeting during data collection to clear up ambiguities during data collection. Data was cleaned on daily basis checked for its completeness.

4.10. Study variable

Dependent variable – central venous line mechanical complications

Independent variable – age, sex, BMI, pre procedural coagulopathy, catheter size and lumen number, urgency of insertion, number of attempt of needle insertion, operators level of experience, use of ultrasound and hemodynamic status

4.11. Ethical issue

Ethical clearance and support letter was obtained from Addis Ababa University College of Health Science department of anesthesiology and Support letters was also delivered to CCE, TMSC, SPSH, EKH responsible personnel to conduct the study.

Verbal informed consent was obtained from patients or their guardian on whom central line placement has been undertaken after explanation was given regarding the objective of observing the procedure and follow-ups after the procedure.

The participants were informed that there will be no direct benefit in participating in this study and he/ she has the right to withdraw from the study at any time he/she wanted.

The proceduralists and their patient's confidentiality was kept unrevealed by removing personal identifications but instead using codes and not sharing their information to anyone other than the study team.

4.12 Result dissemination plan

The study result will be submitted to Addis Ababa University School of medicine health science community and to the study centers where the study was conducted. The result will be published on peer reviewed scientific journal.

5. Operational Definitions

- **Central line mechanical complications**= the occurrence of 1 or more of the following new clinical events within 24 hours of insertion (arterial puncture, significant bleeding, pneumothorax, significant arrhythmia, miss placed central line and subcutaneous hematoma)
- **Arterial puncture** = needle insertion in the major arteries as evidence by a return of witnessed pulsatile blood flow or confirmed by any clinical maneuvers
- **Significant bleeding** = bleeding from catheter insertion site that creates hemodynamic instability requiring blood transfusion or vascular intervention to restore hemodynamics
- **Pneumothorax** = puncture of the pleura with evidence of air in the pleural space detected clinically or by imaging modalities after internal jugular or subclavian insertions.
- **Significant arrhythmia** = any new onset arrhythmia observed after central line insertion with hemodynamic instability requiring intervention.
- **Subcutaneous hematoma**= fluctuant mass first detected after needle puncture trial at central line insertion site.
- **Missed placement**= tip placement bellow the superior vena cava and right atrium junction during internal jugular and subclavian route insertions
- **Proceduralist**= any health professional performing central line cannulation regardless of his prior work experience.

6. Result

6.1 Sociodemographic characteristics

In this study 219 participants were involved, making response rate of 88%. Twenty percent of the participants were from CCE and 63% of them were in the age group of 20-64 years with median age of 38 years. The sex distribution of the participants was almost equal and 53.3% of the participant had normal body mass index as shown the table below

Table 1. The sociodemographic characteristics of study participants who had a central line insertion procedure in the study area, Addis Ababa, Ethiopia, 2021.

Variable	frequency	Percent
Institution		
TAZIMA MSC	34	15.5
BLH RENAL UNIT	35	16.0
BLH OR and ICUS	38	17.4
CCE	45	20.5
SPSH	29	13.2
EKA COVID CENTER	38	17.4
Age of the study participants		
≤11 years	32	14.6
12-19 years	23	10.5
20-64 years	138	63.0
≥65 years	26	11.9
Sex of study participants		
Male	111	50.7
Female	108	49.3
Body mass index (n=184)		
Normal	98	53.3
over weight	23	12.5
Obese	7	3.8
Underweight	31	16.8
Weight for Height b/n 5 th -90th percentile	23	12.5
weight for length < 5th percentile	2	1.1

6.2 Participants medical characteristics

Regarding the medical characteristics of study participants, 85.8% of them had normal coagulation profile and 53% of the case were admitted for the surgical procedure and 62.1% of the procedure were done for an indication of Resuscitation and drug administration and 81.7 % the participants were not in shock during central line procedure.

Table 2. The medical characteristics of study participants who had a central line insertion procedure in the study area, Addis Ababa, Ethiopia, 2021.

Variable	frequency	Percent
coagulation status of the patient		
normal(platelet>100 OR INR<1.5 OR no clinical bleeding tendency)	188	85.8
abnormal (platelet<100k or INR>1.5 or thrombolytic use OR clinical bleeding tendency)	31	14.2
Reason for Patient admission		
surgical preoperative	116	53.0
Medical	41	18.7
ICU	52	23.7
post-partum	6	2.7
Pregnant	4	1.8
Indication for central line insertion		
Resuscitation and drug administration	136	62.1
Hemodialysis	43	19.6
TPN	4	1.8
Resuscitation, drug administration and hemodialysis	36	16.4
Patient circumstance during central line insertion		
not in shock	178	81.3
In shock	41	18.7

6.3 Characteristics of central line insertion

Regarding to central line insertion characteristics, 74.4% participants site of insertion was on the right internal jugular and 49.3% central venous catheter size was >5F but <12F and 58.9% had double lumen and 1/3rd of the procedure was done by 3rd year resident and 40.2% of insertion were guided by ultrasound and 51.1% had only one needle puncture at the same insertion site.

Table 3. Characteristics of central line insertion of study participants who had a central line insertion procedure in the study area, Addis Ababa, Ethiopia, 2021.

Variable	frequency	Percent
site of insertion of central line catheter insertion		
right internal jaguar	163	74.4
left internal jugular	6	2.7
right femoral	41	18.7
left femoral	6	2.7
right subclavian	3	1.4
size of central venous catheter		
≤5F	38	17.4
>5F but <12F	108	49.3
12F dialysis catheter	73	33.3
number of catheter lumen		
single lumen	1	.5
double lumen	129	58.9
triple lumen	84	38.4
quadruple lumen	5	2.3
educational experience of the CVL proceduralist		
first year resident	12	5.5
second year resident	25	11.4
third year resident	73	33.3
general practitioner	10	4.6
Internal medicine fellow	41	18.7
consultant physician	57	26.0
other health professionals	1	.5
the use of ultrasound for central line placement		
Yes	88	40.2
No	131	59.8
The number of needle puncture at the same insertion site		
1	112	51.1
2	89	40.6
>2	18	8.2

6.3 The incidence of mechanical complication

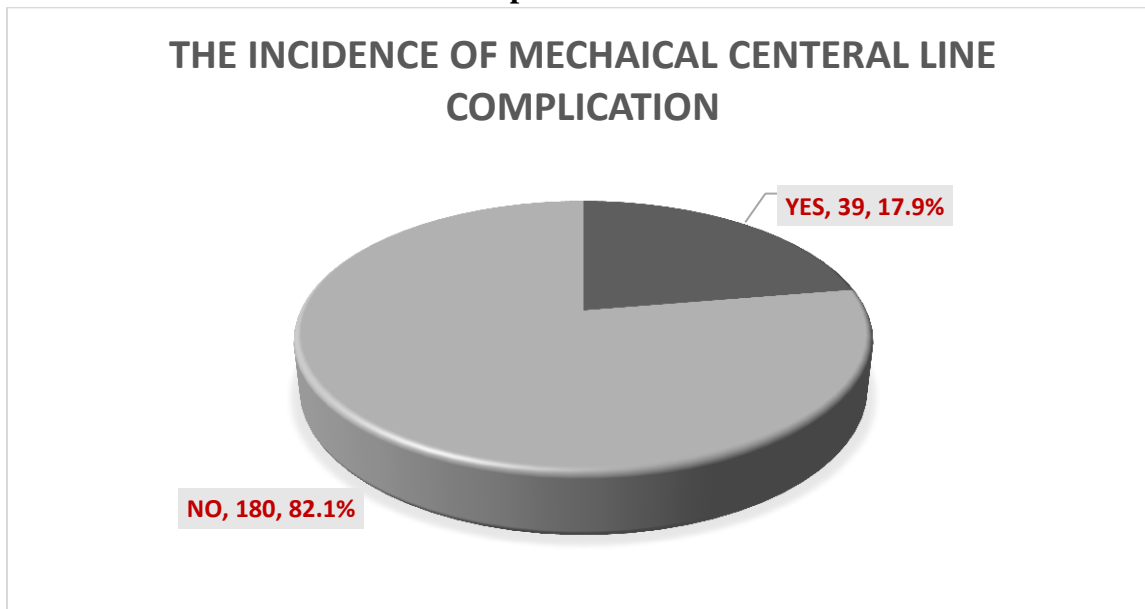


Figure 1. The incidence of mechanical complication of central line placed in study participants who had a central line insertion procedure in the study area, Addis Ababa, Ethiopia, 2021

6.4 The specific types of central line complication

Concerning to the types of central line complication, 36.7% had arterial puncture followed by hematoma. The other complications include significant arrhythmias, pneumothoracics, significant bleeding complication requiring interventions and catheter miss placements. Routine catheter placement checks is only held in one of the centers (cardiac center Ethiopia) and there were two catheter miss placement detected in this center.

Table 4 complication distribution among institutions of study participants who had a central line insertion procedure in the study area, Addis Ababa, Ethiopia, 2021.

INSTITUTION vs complication Cross tabulation				
		has complication		Total
		No	yes	
INSTITUTION	TAZIMA MSC	32	2	34
	BLH RENAL UNIT	25	10	35
	BLH OR and ICUS	27	11	38
	CCE	34	11	45
	SPSH	22	7	29
	EKA COVID CENTER	30	8	38
Total		170	49	219

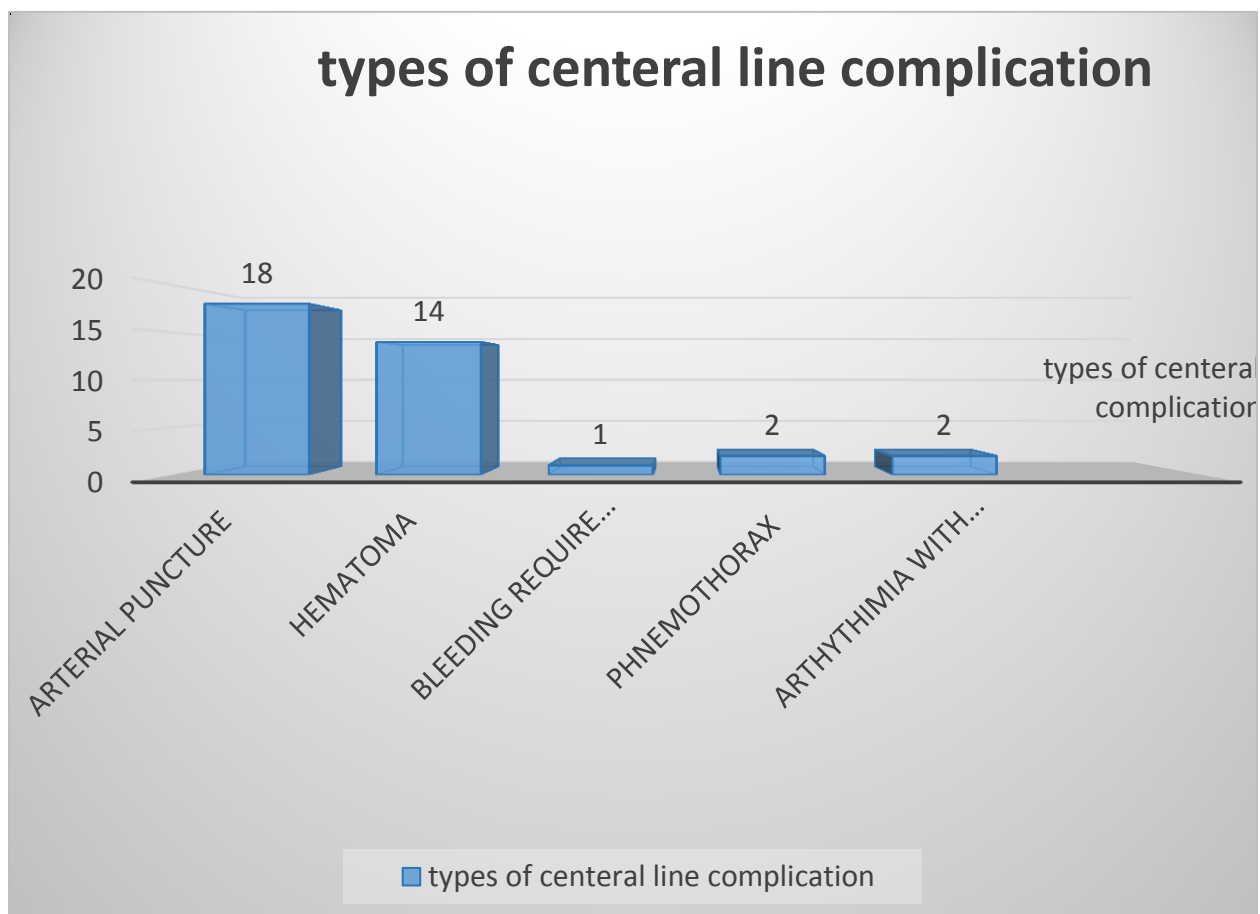


Figure 2. The specific types of central line complication among study participants who had a central line insertion procedure in the study area, Addis Ababa, Ethiopia, 2021.

6.5 The determinant of central line complication

The association of participant's independent variable were examined, strengths of relationships were quantified using Odds Ratio (OR) and 95% confidence interval. Accordingly, sex of the patient, educational experience of the CVL proceduralist, the number of needle puncture at the same insertion site had association with central line insertion complication using bivariate logistics regression model.

The report of multivariate logistic regression indicates that proceduralists whose education level of consultant physician had reduced central line complication by 91% than first year resident (AOR=0.09, 95%CI=0.009, 0.94)

On the other hand, participant who used 2 and more than two needle punctures at the same insertion site had increase central line complication by 3.7 and 14.2 times respectively than one needle puncture at the same insertion site as shown the regression table below.

Table 5. The bivariate and multivariate binary logistic regression of independent and dependent variable in Tikur Anbessa Specialized hospital and Eka koteby hospital on central line catheter insertion, Addis Ababa, Ethiopia.

Variable	Central line complication		p-value	COR (95% CI)	P-value	AOR (95% CI)
	yes	No				
Age of the study participants						
≤11 years	6	26	1		1	
12-19 years	7	16	.318	1.9(.54, 6.67)	0.177	3.8(0.55, 25.69)
20-64 years	33	105	.533	1.4(.52, 3.59)	0.565	1.8(0.25, 12.86)
≥65 years	3	23	.455	.57(.18, 2.52)	0.989	0.98(0.098, 9.91)
Sex of study participants						
Male	18	93	1		1	
Female	31	77	0.028	2.1(1.08, 4.0)	.162	1.8(0.79, 3.97)
coagulation status of the patient						
Normal	39	149	1		1	
Abnormal	10	21	0.158	1.8(0.79, 4.17)	.763	1.2(0.38, 3.69)
Indication for central line insertion						
Resuscitation and drug administration	34	102	1		1	
Hemodialysis	12	31	.704	1.2(.537, 2.51)	0.749	1.4(0.22, 8.46)
TPN	0	4	**		**	
Resuscitation, drug	3	33	.041	.27(0.079,0.95)	.787	1.3(0.22, 7.30)

administration and hemodialysis						
Patient circumstance during central line insertion						
not in shock	40	138	1		1	
In shock	9	32	0.943	0.97(0.43, 2.20)	0.980	.98(0.23, 4.28)
site of insertion of central line catheter insertion						
right internal jugular	32	131	1		1	
left internal jugular	2	4	.420	2.1(0.36, 11.67)	0.435	2.6(0.23, 29.84)
right femoral	11	30	.315	1.5(0.68, 3.31)	0.686	0.73(0.16, 3.29)
left femoral	3	3	.093	4.1(0.79, 21.24)	0.298	2.8(0.39, 20.16)
right subclavian	1	2	.564	2.1(0.18, 23.28)	0.441	4.2(0.11, 166.6)
size of central venous catheter						
>5F but <12F	22	86	1		1	
≤5F	9	29	.338	.18(0.15, 2.25)	0.23	.28(0.04, 1.82)
12F dialysis catheter	18	55	.910	1.1(0.42, 2.64)	0.092	0.112(0.09, 1.42)
number of catheter lumen						
single lumen	0	1	**		**	
double lumen	31	98	.426	.47(0.08, 2.97)	0.997	0.99(0.097, 10.24)
triple lumen	16	68	.275	.35(.05, 2.3)	0.831	0.78(0.08, 7.94)
quadruple lumen	2	3	1		1	
educational experience of the CVL proceduralist						
first year resident	5	7	1		1	
second year resident	8	17	.565	.66(0.16, 2.73)	0.531	0.55(0.08, 3.58)
third year resident	15	58	.120	.36(0.10, 1.30)	0.131	0.22(0.029, 1.58)
general practitioner	2	8	.286	.35(0.05, 2.41)	0.605	0.55(0.057, 5.31)
Internal medicine fellow	14	27	.634	.73(0.19, 2.71)	0.918	0.89(0.109, 7.35)
consultant physician	5	52	.007	.14(0.03, 0.59)	0.044	0.09(0.009, 0.94)
other health professionals	0	1	**		**	
the use of ultrasound for central line placement						
Yes	21	67	1		1	
No	28	103	.665	.87(0.46, 1.65)	0.564	0.72(0.24, 2.17)
The number of needle puncture at the same insertion site						
1	11	101	1		1	
2	27	62	.000	3.9(1.85, 8.63)	0.004	3.7(1.53, 8.86)
>2	11	7	.000	14.4(4.64, 44.83)	0.000	14.1(3.59, 55.28)

7. DISCUSSION

Central venous lines have various utilities in modern medicine. Even though these devices are vital to patients for various indications, they are also associated with potential mechanical and infectious complications. (4) In order to reduce the mechanical complications various factors have to be given special attention by the proceduralists.

In this study, the overall incidence of CVLMC is 39 (17.9%), which is the same as to the study done in India (17.9%) (10) and it is also comparable with the South African (18%) (4). Our research has higher discrepancy in terms of CVLMC with both Swedish multi-center study and the Los Angeles retrospective review which shows incidence rate of 1.1% and 1.5% respectively. (6)(8) The varying number of reported mechanical complications may be due to differences in case mix, differing use of ultrasound guidance, or lack of a standardized definition of mechanical complications (the ignorance of arterial puncture and hematomas in the latter largest study and replace them with arterial cannulations and significant bleeding)

In this study the commonest route of insertion was right IJ (74.4%) followed by right femoral (18.7%) which is remotely followed by the other routes. Subclavian route is not commonly accessed in our setting. In South African study over two-thirds of all central venous catheters in the study were inserted via the SCV approach. (4) This difference could be due most of the studied patients in our study are surgical patients where anesthesia providers can easily access the neck whereas the latter group are trauma patients where neck collar is applied most of the time. This could also be due to lack of experience of SCV route insertion in our setting. Because of high discrepancy in insertion route frequency between the internal jugular route vs other, which route is associated with higher complications couldn't be concluded to statically significant correlation.

The top two complications in this study are arterial puncture happening 18x (46%) followed by subcutaneous hematoma 10x (25.6%). This is in line with the Colombian study. In the South African study there was 66% pneumothorax (4), in the Indian study the major complication was bleeding. The difference in the type of complications between these studies and ours could be due to the higher SCV route use in the South African study and the exclusive insertion of the CVL catheter to ICU patient which may have taken drugs to anticoagulate their blood in the Indian study.

The two statistically significant factors associated to the central line mechanical complications in this study were; more than 2 insertion site punctures and the proceduralist's educational level.

In this study the higher number of needle puncture at the same site was found to have statically significant correlation with central line mechanical complication with (**p=0.004 AOR= 3.7 95 CI: (1.53, 8.86)**) for 2 insertions and (**P=0.000 AOR=14.1 95CI: 3.59- 55.28**) for >2 insertion attempts. This finding of higher needle puncture related to CVLMC is in line with the Colombian study done by (Calvae et al)(5) as well as a landmark paper from new England journal of medicine.(7)

In this study central lines inserted by consultant physician are 90% safer than year 1 residents. (**P=0.044 AOR=0.09 95CI: 0.009-0.94**). This finding also holds true in the south African study as well as the Israeli studies with increased safety trained linearly increasing with operators experience level.(4) (3). But this didn't hold true in the Colombian study which concluded for no association between the incidence of mechanical complication and operators level of experience.(5) The possible difference this study from the letter study could be the fact that Residents and general practitioners placed the catheters always under direct supervision of 1 specialist staff member who could guide them through out the procedure.

The use of ultrasound is highly recommended in central venous line insertions.(7) major guidelines like the NICE guideline(14) recommend its use to significantly reduce CVLMCs, in our study use of ultrasound didn't significantly alter the CVLMCs. The possible reason for this finding could be most of the insertions in our study were done by year 3 residents or higher level experienced operators who assumed to acquired better technical skill than their junior counterparts

The detection of pneumothorax is higher in other studies than ours,(4)(6)(7) especially the south African one, the probable reason could be the low detection and documentation rate of the event because of limited routine use of imaging's in this study centers except one center (CCE), it could also be due to low insertion rate of subclavian route

8 Conclusion and Recommendation

8.1 Conclusion

Central line mechanical complication is high in this study which make this concerning because central line mechanical complications are potentially fatal and the most serious complications are not easily manageable in our setting. Operators educational level and 2 or more number of needle puncture at the same site was found to have association with central line mechanical complication.

8.2 Recommendation

After analyzing the findings of this research. We recommend the following

For operators-We recommend in limiting insertion site puncture to not more than 2 trial.

For researchers- to conduct further double blinded randomized control studies.

For institutions- supervision and skill up simulation trainings to be provided by the institutions for junior proceduralists.

9 Strength and Limitation

9.1Strength

It was a multicenter observational prospective study that tried to assess the incidence and associated factors of central line mechanical complications. It enrolled all age group for whom central line was inserted for various indications. This is the first of its kind in our set up as far as we have searched.

9.2 Limitation

Data collectors were not blinded so observer bias cannot be rule out confidently. We did not include late mechanical complication like nerve injuries that can happen after 24 hours. The association between the mechanical complication and the route of insertion was not done. We employed purposive sampling which makes generalizability difficult.

Annex 2: Subject information sheet

Addis Ababa University

School of medicine

Subject information sheet

Hello, my name is Dr. Tibebu Alemu, a student in Addis Ababa University School of medicine anesthesiology department. I am conducting a research on “Assessment of the incidence and associated factors of mechanical complications of central line placement at different centers in Addis Ababa, Ethiopia, 2021.

You are selected to participate in this study because you are currently the immediate observer of central line in place in this facility after giving verbal consent to the patient or there guardian. Your patient’s participation in this study will only be based on his/her willingness to participate. You have the right to choose not to take part in this study. If he/she is willing, he/she have the right to stop at any time or withdraw without giving any reason which you will not be subjected to any ill-treatment. There will be no direct benefit for you or the patients by participating in this study but in future information gathered by this study will helps policy makers, programmers and researchers to give appropriate attention on issues of interest and design specific treatment options.

The information that you provide will be kept confidential by using only code numbers and locking the data. Only coded data will be used for this study. Your willingness and active participation is very important for the success of this study.

If you need any further information or explanation regarding to the study, you can have this address to contact.

Name: Dr. Tibebu alemu

Tel- +251-939848837

Email- tibealex5@gmail.com

Annex 3: Informed Consent and/or Ascent form

Based on the understanding of the above information, are you willing to participate in this study?

A) Yes

B) No

If yes, Signature ----- Date-----

Data collector

Name ----- Signature -----

Questionnaire ID Number -----

Date of data collected -----

Result of data collected

A) Completed

B) Not completed

C) Partially completed

D) Refused

Checked by supervisor: Name ----- Signature -----

For further explanation, use the principal investigator's address:

Name: Dr. Tibebe alemu

Tel- +251-939848837

Email- tibealex5@gmail.com

Annex4: English version of the questionnaire

Questionnaire for assessment of the incidence of mechanical complications of central line and common associated risk factors, at TASH, SPSH, CCE, EKH, TMSC, Addis Ababa, Ethiopia, 2021.

Research questioner on the incidence and associated factors of CVLMC

1. Questioner number.....
2. Ward
3. Patients sociodemographic characteristics
 - A. AGE
 - B. SEX
 - C. Weight
 - D. Height
4. Patients health characteristics
 - A. Coagulation profile
 - B. Clinical bleeding tendency
 - C. Comorbid illness
5. Indication for central line insertion
 - A. Resuscitation
 - B. Drug administration
 - C. Hemodynamic monitoring
 - D. Hemodialysis
 - E. Total parenteral nutrition
6. hemodynamic status in time of insertion
 - A. In shock
 - B. Not in shock
7. Site of central line insertion
 - A. right internal jugular B. left internal jugular
 - C. right femoral D. left femoral
 - E. right subclavian F. left subclavian

8. Type of the central line
 - A. Single lumen
 - B. Double lumen
 - C. Triple lumen
 - D. Quadruple lumen
9. Size of central line catheter
 - a. $\leq 5F$
 - b. >5 but $\leq 12F$
 - c. $> 12 F$
10. Operators level of education
 - A. R1
 - B. R2
 - C. R3
 - D. R4
 - E. Fellow
 - F. consultant
11. ultrasound guided
 - A. yes
 - B. no
12. Number of needle puncture at same site
 - A. 1
 - B. 2
 - C. >2
13. Central line mechanical complications
 - A. Arterial puncture
 - B. Subcutaneous hematoma
 - C. Bleeding requiring transfusion or vascular intervention
 - D. Pneumothorax
 - E. Arrhythmia requiring intervention
 - F. failed to place central line after 2 insertion trials
 - G. catheter tip beyond SVC right atrium junction on imaging.
 - H. Others unspecified (death, retained guide wire, unintentional catheter removal.....)(please mention the complication)

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