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Incidence, Risk Factors and Management of Central Venous Catheter Thrombosis in Neonatal Intensive Care Unit

[1]Omima M.Abdel Haie, [1]Aliaa M.Diab, [2]Mohamed M.Faheem, [1]Mohammed H. Abdel Azim
[1]Pediatrics Department, Faculty of Medicine, Benha University
[2]Radiodiagnosis Department, Faculty of Medicine, Benha University
E-Mail: Drmhmdhatem89@gmail.com

Abstract

Background: Central venous catheter (CVC) thrombosis poses a significant challenge in neonatal intensive care units (NICUs). This study aimed to assess the incidence, identify risk factors, and explore management strategies for CVC thrombosis in neonates. **Methods:** The prospective study was conducted from September 2021 to February 2022 in Benha University Hospital and Benha Children Hospital. The study included 150 neonates with central venous lines. In-depth assessments, including medical history, examinations, laboratory investigations, and Doppler ultrasound, were employed. **Results:** Among the neonates, 12% experienced CVC thrombosis, with a mortality rate of 38%. Analysis revealed significant associations between thrombosis and factors such as gestational age ($P < 0.001$), weight ($P < 0.001$), and sepsis ($P < 0.001$). Laboratory findings indicated higher hematocrit levels ($P < 0.0001$) and elevated C-reactive protein (CRP) levels ($P = 0.011$) in neonates with positive thrombosis. Multivariate analysis identified duration of CVC > 8.52 as the most significant factor (OR = 109.948, $P < 0.001$), followed by infected CVC (OR = 40.203, $P < 0.001$) and hematocrit level > 54.32 (OR = 15.617, $P = 0.002$). ROC analysis demonstrated high predictive value for both hematocrit (AUC = 0.877, $P < 0.001$) and duration of CVC (AUC = 0.822, $P < 0.001$). **Conclusions:** Duration of CVC > 8.52, infected CVC, and elevated hematocrit levels were identified as significant risk factors for CVC thrombosis in neonates.

Keywords: CVC Thrombosis, Neonatal Intensive Care Unit, Risk Factors, Hematocrit, Mortality.

1. Introduction

The heamostatic system is a complex system that leads to the formation of a blood clot at the site of vessel injury while simultaneously preventing unnecessary clotting. Three phases can be distinguished: primary hemostasis or formation of a platelet plug, secondary hemostasis or formation of blood clots, and fibrinolysis, the process in which the fibrinolytic system regulates the breakdown of blood clots [1].

The hemostatic system develops over time from neonatal to adult system. Although all components of the heamostatic system are present at birth, important differences exist among preterm and term neonates, older children, and adults. These differences may have important consequences for diagnosis, monitoring, and management of neonatal thrombotic events [2].

Platelets are the most important component of primary heamostasis. The number and volume of platelets are relatively similar in neonates and adults. Although platelet ultrastructure does not differ from that in adults, neonatal platelets show decreased response to agonists. Despite this relative platelet hyporeactivity, healthy neonates have normal primary heamostasis [3].

A central venous catheter (CVC) is a catheter placed into a large vein. Catheters can be placed in veins in the neck (internal jugular vein), in the chest (subclavian vein or axillary vein), groin (femoral vein) or through veins in the arms also known as peripherally inserted central catheters (PICC). It's used to administer medication or fluids that are unable to be taken by mouth or would harm a smaller peripheral vein and obtain blood tests (especially the central venous oxygen saturation). and measure central venous pressure [4].

In critically ill (preterm) neonates, central venous catheters (CVCs) are increasingly used for administering medication or parenteral nutrition. These catheters are inserted in umbilical veins, major central veins or in smaller peripheral veins. CVCs are one of the steppingstones in improvement of care for critically ill neonates. However, one of the complications associated with CVC usage is venous thrombosis. The prevalence of neonatal CVC-related thrombosis (CVC-thrombosis) varies from 0.7% to 67% and is dependent on the type of catheter inserted, the diagnostic tests used, the study method and the index of suspicion of thrombosis [5].

There are many disadvantages in the use of the central venous line. There are many complications associated with their insertion including pneumothorax/hemothorax, arterial injury and hemorrhage, infection, air embolism and thrombosis. The use of central venous lines in emergency situations for the treatment of critically unwell patients further exposes patients to these complications [6].

Symptoms of neonatal CVC-thrombosis include swelling, erythema, skin discoloration, increased warmth, pain, and/or tenderness of the affected arm or leg, venous distension, presence of subcutaneous collateral veins, superior vena cava syndrome, loss of central venous catheter patency, prolonged catheter related septicaemia, unexplained thrombocytopenia, arrhythmia and hemodynamic instability [7].

Symptomatic CVC-thrombosis has to be confirmed by Doppler ultrasonography. CVC-thrombosis is diagnosed via ultrasonography if a non-

compressible segment of a vein, absence of flow, or an echogenic intraluminal thrombus is present [5].

This study aimed to estimate the incidence of CVC thrombosis in neonates in NICU in Benha university hospital and Benha children hospital and determine their possible risk factors for developing CVC thrombosis and the most screening modality.

2. Methods

Patients:

This study is a prospective screening study. The study was done in neonatal Intensive Care Unit (NICU) in Benha university hospital and Benha Children Hospital (BENCH). Our sample included 150 neonates with central venous line during the period from September 2021 to February 2022.

The study was done after being approved by the Ethics Committee in the Faculty of Medicine, Benha University before preceding the study. An informed written consent was obtained from parents, and they received an explanation of the purpose of the study and had a secret code number.

Inclusion criteria were full term and preterm neonates with indication of central venous catheter in NICU and patients less than 28days age.

Exclusion criteria were patients who doesn't need central venous line insertion, patients with congenital malformation and patients more than one-month of age.

Sample Size and Sampling:

The sample included neonates with central venous line indications, less than 28 days old, and admitted to the NICU during the study period. The estimated sample size is 150 neonates. The patients were selected using non-probability convenience sampling.

All studied cases were subjected to the following:

Medical history

Full history taking: Personal history (Name, age, sex, order), cause of admission, incubated in another place or not and maternal history including risk factors (preeclampsia, prothrombotic disorders, oligohydramnios, infertility & auto immune disorder).

By including maternal history and these risk factors in the study, the aim is to determine if there is an association between these factors and the development of CVC thrombosis in neonates in the NICU.

History of neonatal risk factors (sepsis, congenital heart diseases CHD, arterial catheters).

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General examination, including anthropometric measurements (Weight, height, BMI and head circumference).

Central venous catheter CVL Assessment: Central venous catheter (CVC) assessment involved a thorough examination of the CVC site, including its position, presence of edema, and any signs of infection. Factors like the type of central line, the technique used for CVC insertion, and details regarding the onset and duration of the central line were documented.

Investigations

Complete blood picture (CBC) and C-reactive protein (CRP), Prothrombin time (PT), Partial thromboplastin time (PTT), International normalized ratio (INR) and cultures.

Microbiological cultures were obtained from the tip of the CVC, blood samples, and any other clinically relevant site if there was suspicion of infection. The samples were collected according to standard protocols, using sterile technique. The cultures were sent to the hospital's microbiology laboratory for processing and analysis.

The cultures were incubated for a period of 24-48 hours, and the bacterial growth were identified using standard biochemical tests. Antibiotic susceptibility testing was also performed for the identified bacteria, using the disk diffusion method or automated systems. The results of the cultures and antibiotic susceptibility testing were used to guide the selection of appropriate antibiotic therapy, if needed.

D-dimer if indicated: D-dimer was measured using a commercially available immunoassay kit. Blood samples were collected from each neonate at the time of CVC insertion and at regular intervals thereafter, according to the clinical protocol of the NICU. Additional samples were obtained if there was clinical suspicion of CVC thrombosis. D-dimer levels were expressed in units of fibrinogen equivalent units (FEU)/ml.

Doppler ultrasound: Doppler ultrasound was used for diagnosing CVC thrombosis and assessing the extent of thrombus formation. Trained radiologists employed high-resolution ultrasound machines with Doppler probes to visualize the CVC and surrounding blood vessels, measure blood flow velocities, and identify abnormalities or obstructions in blood flow.

Diagnosis of CVC Thrombosis: CVC thrombosis was diagnosed based on specific criteria, including clinical symptoms (e.g., swelling, redness, pain, or unexplained fever), abnormalities detected through Doppler ultrasound, elevated D-dimer levels, and culture-proven catheter-related bloodstream infection in combination with clinical or laboratory evidence of thrombosis.

Therapeutic Options

The therapeutic options for CVC thrombosis included: anti-coagulant treatment, thrombolysis and thrombectomy.

Statistical analysis:

The collected data underwent revision, coding, and tabulation using the IBM SPSS Statistics software (Version 25.0, IBM Corp., Released 2017, Armonk, NY). To test the normality, the Shapiro-Wilk test was employed. Descriptive statistics included means, standard deviations (± SD) for numerical data, and frequency/percentage calculations for non-numerical data. Analytical tools included the Chi-Square test for examining relationships between qualitative variables, the Mann Whitney Test for assessing non-parametric variable differences among study groups, and Repeated

ANOVA for comparing dependent variable measurements. For categorical dependent variables, logistic regression facilitated risk prediction through odds ratios (OR), indicating the odds of an outcome with a specific exposure versus its absence, alongside a 95% confidence interval (CI) signifying OR precision. Results were deemed significant with a p-value < 0.05 at a 95% CI.

3. Results

The current study was carried on 30 child suffering from genu varum and underwent correction with 8 plate insertion. Their mean age was 6.6 years. Gender distributed as 43% females and 57% males. Their mean BMI was 21.27 kg/m^2. According to side of correction, 7% had bilateral correction, 10% had correction in the left side while 13% had correction in the right side. Correction carried on both femur and tibia in 50% of subjects, 10% had correction in femur and 40% had correction in tibia. Mean days of hospitalization was 0.8 days ranged from zero to 2 days and mean deformity correction time was 10.6 months.

According to time of removal of plates, mean time of removal was 12.57 months. Outcome in patients distributed as 7% with superficial infections, 10% had LIMITED ROM, 3% had broken screws and 80% had no complications. **Table 1**

Table (1) Outcome of the studied subjects.

		Total subjects	n=30
Time to remove plates, month	**M±SD (12.67±1.58)**	**Range (9-15)**	
Correction success rate, n (%)	Distal femur	3(100%)	
	Proximal tibia	11(91.7%)	
	Both	14(93.3%)	
	Total	28(93%)	
Complications	Superficial infections	2(7%)	
	LIMITED ROM	3(10%)	
	Broken screws	1(3%)	
	No complications	24(80%)	
Rebound phenomenon, n (%)		1(3%)	

The studied parameters were compared according to rebound phenomenon, a significant p value detected when we compared rebound and non-rebound cases according to complications. All rebound cases (n=1) were associated with complications while 13.8% of non rebound cases were associated with complications. No significant difference between the studied groups in other parameters. **Table (2)**

Table (2) Differences in studied parameters according to rebound phenomenon.

	Non Rebound n=29	**Rebound n=1**	**Test**	**p**
Age	6.6±3.46	3	Z=0.283	0.985
BMI	21.35±1.61	19	Z=1.144	0.253
Side				
Bilateral	22(78.5%)	1(100%)		
Left	3(10.7%)	0(0%)	X2=0.315	0.854
Right	3(10.7%)	0(0%)		
Correction implementation site				
Both	15(53.5%)	0(0%)		
Femur	2(7.1%)	0(0%)	X2=1.552	0.460
Tibia	11(39.2%)	1(100%)		
Time of removal	6.6±3.46	1.61	Z=0.535	0.865
Hospital stay	6.6±3.46	1	Z=0.629	0.254
Correction success rate				
Inproperly corrected	2(7.1%)	0(0%)	X2=0.074	0.786
Corrected successfully	26(92.8%)	1(100%)		
Complication				
No complications	25(87.2%)	0(0%)	X2=4.138	0.042*
With complications	4(13.8%)	1(100%)		
Correction time	6.6±3.46	13	Z=0.556	0.259

Z= Mann Whitney, X^2=Chi-Square, * Significant p value <0.05,

The studied parameters were compared according to complications. Significant differences between complicated and non-complicated subjects were detected in side of deformity, 8 plates implementation site and rebound phenomenon. Bilateral deformity was more in non-complicated group (88%) than complicated group (33.3%), while right and left deformity were more in complicated group than non-complicated. Rebound phenomenon founded in 17% of complicated cases compared to non-complicated cases who had no rebound phenomenon. **Table (3)**

Table (3) Differences in studied parameters according to complications.

	No complications n=24	Complication n=6	Test	p
Age	6.12±2.33	9±6.78	Z=0.729	0.466
BMI	21.36±1.65	20.8±1.48	Z=0.624	0.533
Side				
Bilateral	21(88%)	2(33.3%)		
Left	1(4%)	2(33.3%)	X2=8.170	0.017
Right	2(8%)	2(33.3%)		
Correction implementation site				
Both	14(60%)	1(17%)		
Femur	0(0%)	3(50%)	X2=18.00	0.001
Tibia	10(40%)	2(33%)		
Time of removal	6.6±3.46	11.2±1.64	Z=1.936	0.054
Hospital stay	6.6±3.46	1.2±0.44	Z=1.402	0.161
Correction success rate				
Inproperly corrected	1(4%)	0(0%)	X2=0.429	0.513
Corrected successfully	23(96%)	6(100%)		
Rebound phenomenon				
Non rebound	24(100%)	5(83%)	X2=4.138	0.042
Rebound	0(0%)	1(17%)		
Correction time	6.6±3.46	12.4±1.81	Z=1.376	0.169

Z= Mann Whitney, X^2=Chi-Square, * Significant p value <0.05

ICD showed significant p value (<0.001*) when compared at 0,3,6,9,12 and 15 months after correction. Mean measurement at the beginning of the study was 10.3 cm and 0.78cm at the end of study. **Fig. (1)**

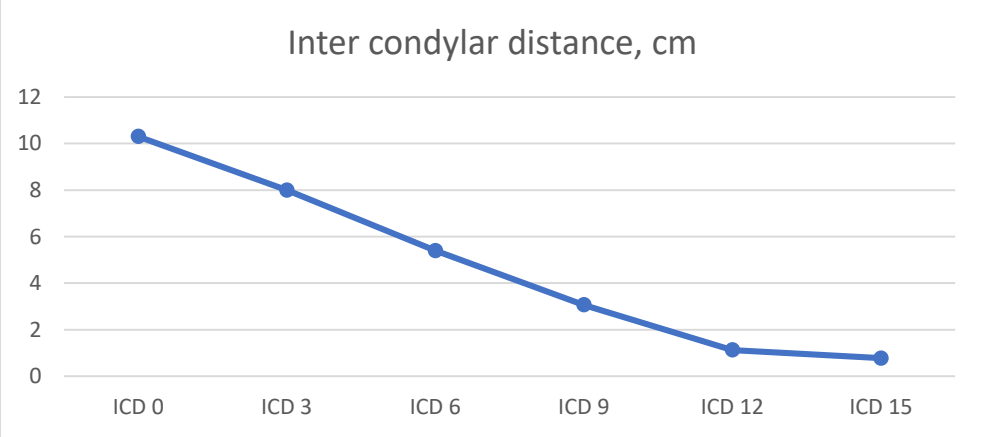

Fig. (1) ICD measurement throughout study time

4. Discussion

Hemi-epiphysiodesis is a surgical technique used to treat pediatric genu varum. It involves the partial arrest of growth on one side of the growth plate, allowing the other side to continue to grow and correct the deformity. Hemi-epiphysiodesis can be performed using various implants, such as staples, screws, and plates. One of the newer implants used for this procedure is the 8-shaped plate. The 8-shaped plate is a recently developed implant that has been shown to be effective in treating pediatric genu varum. The implant is designed to apply pressure to the growth plate, resulting in partial growth arrest and correction of the deformity.

The current study was carried out on 30 children suffering from genu varum and underwent correction with 8 plate insertion. Their mean age was 6.6 years. Gender distributed as 43% females and 57% males. Their mean BMI was 21.27 kg/m^2. According to side of correction, 7% had bilateral correction, 10% had correction in the left side while 13% had correction in the right side. Correction carried on both femur and tibia in 50% of subjects, 10% had correction in femur and 40% had correction in tibia.

A retrospective study by **Dai et al.** that included 66 patients with genu varum who underwent 8 plate insertion reported a mean age of 4.69 years, with a similar gender distribution to your study [8]. Another systematic review by **Rodrigues et al.** that included

6830 articles retrieved reported a mean age of 7.2 years, again consistent with your findings [9].

Another study by **Park et al.** included 20 patients thirty-nine physes (24 distal femoral, 15 proximal tibial) with genu varum treated with hemi-epiphysiodesis using an 8-shaped plate. The mean age of patients was 9.5 years, and there were 24 females and 22 males. The results showed that the 8-shaped plate was effective in correcting genu varum deformity, with a mean correction angle of 7.2 degrees. In terms of complications, there were two cases of implant breakage and one case of delayed union. The authors concluded that hemi-epiphysiodesis with an 8-shaped plate is a safe and effective treatment for genu varum, but implant breakage is a rare but potential complication [10].

Regarding the hospital study in the current study, the mean days of hospitalization was 0.8 days ranged from zero to 2 days and mean deformity correction time was 10.6 months.

In a similar study conducted by **Gyr et al.**, the mean hospital stay for patients who underwent hemi-epiphyseal stapling for the correction of genu varum was reported to be 3.8 days, which is longer than the current study. The study also reported a mean correction time of 12.4 months, which is slightly longer than the current study's results [11].

According to time of removal of plates, mean time of removal was 12.57 months. Outcome in patients distributed as 7% with superficial infections, 10% had LIMITED ROM, 3% had broken screws and 80% had no complications.

In a study by **Wiemann et al.**, they reported a mean correction time of 7.8 months and a mean hospital stay of 1.2 days in patients treated with 8-plate insertion [12]. These results are slightly different from those reported in the current study, which reported a longer mean correction time of 10.6 months and a shorter mean hospital stay of 0.8 days.

In terms of complications, **Dai et al.** reported a complication rate of 12% in patients treated with 8-plate insertion, with the most common complications being implant migration and implant failure [8]. In comparison, the current study reported a lower overall complication rate of 20%, with the most common complications being superficial infections and limited range of motion.

In the present study, the studied parameters were compared according to rebound phenomenon, a significant p value detected when we compared rebound and non-rebound cases according to complications. All rebound cases (n=1) were associated with complications while 13.8% of non-rebound cases were associated with complications. No significant difference between the studied groups in other parameters.

The rebound phenomenon is a known complication in hemi-epiphysiodesis with 8 plates for correcting genu varum. In a study by **Stevens et al.**, they reported rebound in 10% of their cases, which was associated with recurrence of the deformity and need for revision surgery [13].

In the current study, only one case of rebound was observed, which is a relatively low incidence compared to the literature. However, this single case was associated with complications, which is consistent with the findings of Stevens et al. regarding the association between rebound and recurrence/complications.

Regarding other complications, the incidence of superficial infections in the current study (7%) is lower than that reported by **Stevens et al. (2007)** (16%). On the other hand, the incidence of limited range of motion (10%) in the current study is higher than that reported by Stevens et al. (4%). These differences in incidence rates could be attributed to differences in patient populations, surgical techniques, and follow-up periods [13].

In a study conducted by Park et al. (2016), they found that the location of the deformity significantly affects the incidence of complications. They reported that patients with tibial varus deformity had a higher incidence of complications compared to those with femoral varus deformity. This is consistent with the findings of the current study, as patients with complicated cases had a higher frequency of tibial varus deformity (66.7%) compared to non-complicated cases (12%) [14].

In terms of the site of 8 plate implementation, a study by Park et al. (2017) reported a higher incidence of complications when the plate was implanted in the tibia compared to the femur [10].

The presence of rebound phenomenon was also found to be significantly associated with complications in the current study. This is consistent with the findings of a study by Zajonz et al., which reported a higher incidence of complications in patients who exhibited rebound phenomenon compared to those who did not [15].

A study by Vaishya et al. reported a significant reduction in mechanical axis deviation and intercondylar distance after correction, which was maintained during the follow-up period of up to 2 years [16]. Another study by Schagemann et al. also reported significant improvement in the mechanical axis deviation and intercondylar distance after 8 plate insertion for correction of genu varum in 44 patients [17].

Lateral distant femur angle repeated measurements showed a significant p value when assessed at 0,3,6,9,12 and 15 months in both right and left sides. Medial proximal tibial angle repeated measurements showed a significant p value when assessed at 0,3,6,9,12 and 15 months in both right and left sides.

One study by Ghaznavi et al. reported similar findings to the current study, showing a significant improvement in the lateral distant femur angle and medial proximal tibial angle following 8-plate correction in 109 skeletally immature patients (212 physes) with genu varum. The authors reported

significant improvements in both angles at 3, 6, and 12 months after surgery, with no significant differences between the right and left sides [18].

In the present study, logistic regression analysis was conducted for the prediction of rebound phenomenon using age, BMI, Correction side, plates time of removal, hospital stay and correction time. All parameters used in regression analysis were not shown as a significant risk factor for rebound phenomenon.

A study by Park et al. found that younger age and larger preoperative mechanical axis deviation were significant risk factors for rebound phenomenon after corrective surgery for genu varum [14]. Another study by Ulusaloglu et al. found that longer correction time and larger preoperative medial proximal tibial angle were associated with an increased risk of rebound phenomenon [19].

However, a study by Ko et al. did not find any significant risk factors for rebound phenomenon, which is similar to the results of the current study [20].

Also, in the current work, logistic regression analysis was conducted to predict complications using age, BMI, correction side, plate removal time, hospital stay, and correction time as predictor variables. In univariate analysis, the left deformity side and time of plate removal were found to be associated with the risk of complications.

One study conducted by Lee et al. (2020) showed that age (odds ratio [OR]=1.07, p=0.005), BMI (OR=1.12, p=0.04), and extent of correction (OR=1.53, p=0.002) were independent risk factors for complications [21]. Another study by Park et al. (2016) evaluated the risk factors for complications after corrective osteotomy for genu varum. They used logistic regression analysis with age, sex, BMI, deformity angle, and extent of correction as predictor variables. The results showed that BMI (OR=1.27, p=0.025) and extent of correction (OR=1.06, p=0.011) were independent risk factors for complications [14].

5. Conclusion

The 8-plate insertion proves effective for pediatric genu varum treatment, showing improved parameters like Intercondylar distance, lateral distant femur angle, and medial proximal tibial angle. Rebound phenomenon aligns with higher complication risks, while bilateral deformity is less prone to complications compared to right/left deformities. Left-side deformity and plate removal timing relate to increased complication risks.

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