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Neonatal Bleeding: A Single-center Egyptian NICU Cross-Sectional Study

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ABSTRACT

Background: Neonatal bleeding disorders can be quite challenging in neonatal intensive care units (NICUs) and are often linked to primary or secondary haemostatic defects. In Egypt, the high prevalence of rare inherited bleeding disorders (RIBDs) is attributed to consanguinity and close community marriages. We aimed to evaluate the bleeding phenotype of a neonatal cross-section and to assess the usefulness of the International Society for Thrombosis and Haemostasis bleeding assessment tool (ISTH-BAT) in identifying neonates with potential RIBDs.
Methods: A cross-sectional research was conducted over one year, including all neonates (n = 61) with any bleeding symptom/s admitted to Cairo University Hospital NICU. Clinical evaluations, laboratory testing (CBC, PT, aPTT, INR, TT, fibrinogen, factor VII), and ISTH-BAT scoring were performed.
Results: Upper gastrointestinal tract (36.1%) and pulmonary (19.7%) hemorrhages were the most common bleeding sites. Our study was separated into 2 groups: healthy (n = 10) and unhealthy (n = 51). An abnormal ISTH-BAT score (≥ 3) was found in 42.6% and was significantly higher among septic neonates (p-value = 0.013). Among the healthy group, 7 had vitamin K deficiency bleeding (VKDB) and 3 had afibrinogenemia, the latter showing the highest ISTH-BAT scores (7–8).
Conclusion: VKDB and sepsis were the commonest causes of bleeding in healthy and unhealthy neonates, respectively. Bleeding due to afibrinogenemia represented 4.9% and 30% of the whole cross-sectional study and healthy neonates, respectively. The ISTH-BAT can be a useful screening tool for assessing significant bleeding in neonates, particularly identifying those with RIBDs.

Keywords: Afibrinogenemia, Neonatal bleeding, Neonatal sepsis, Vitamin K

Introduction

Neonatal bleeding disorders are a significant concern and can be quite problematic in the NICU, contributing to neonatal morbidity and mortality. These disorders are categorized into primary and secondary haemostatic defects (1). Primary haemostatic defects involve disorders of vascular integrity, thrombocytopenia, or platelet dysfunction. Secondary haemostatic defects include inherited and acquired factor deficiencies. Inherited deficiencies involve von Willebrand disease, hemophilia B, hemophilia A, and other rare coagulopathies. Acquired deficiencies include vitamin K deficiency (VKD) and disseminated intravascular coagulation (DIC), which lead to impaired clot formation and an increased risk of severe bleeding (2, 3, 4). Bleeding into soft tissue,

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muscles, and joints often indicates a secondary haemostatic problem, in contrast to mucocutaneous hemorrhage symptoms, which are more suggestive of a primary haemostatic problem (5).

Newborn thrombocytopenia, characterized as a platelet count below 150 × 10^3/cmm, is most commonly due to neonatal alloimmune or autoimmune thrombocytopenia and infections. All causes can lead to neonatal bleeding complications, including serious hemorrhages (e.g., intracranial hemorrhage (ICH)) (6, 7, 8).

Coagulation factor deficiencies include hemophilia A and B (FVIII and FIX deficiencies, respectively) and rare coagulopathies, and they can present with a very wide spectrum of bleeding manifestations of variable severity, ranging from umbilical stump hemorrhage, intracranial hemorrhage, to prolonged bleeding following procedures (9, 10, 11). Vitamin K deficiency bleeding (VKDB), particularly in exclusively breastfed babies, remains a preventable cause of neonatal hemorrhage, categorized into classic, early, and late-onset forms with variable bleeding symptoms (e.g., bleeding from the skin, umbilical stump, gastrointestinal tract, post-circumcision, and ICH) (12, 13). Additionally, DIC, triggered by sepsis, asphyxia, or perinatal infections, results in consumptive coagulopathy, further complicating neonatal management (14).

In Egypt, RIBDs, including coagulopathies, are more prevalent than in other countries due to consanguinity and closed community marriages (15). Despite advances in neonatal care, data on the prevalence, etiology, and outcomes of neonatal bleeding in Egyptian NICUs remain limited.

This research aimed to estimate the causes and bleeding phenotypes of a neonatal cross-section in a single-center Egyptian NICU, and to evaluate the utility of the ISTH-BAT as a useful screening tool for significant bleeding in neonates and for identifying patients with RIBDs, thereby helping in early identification and subsequent treatment to minimize morbidity and mortality and improve patient outcomes.

Methods

Study Population

This cross-sectional study included all preterm and full-term neonates (≥ 24 - ≤ 42 weeks of gestation) who presented with bleeding symptom(s) of any severity and were admitted to Cairo University Hospital NICU during the 1-year study period. The research was approved by the Research Ethics Committee of the Faculty of Medicine, Cairo University, code MD-149-2021. The neonates' legal guardians provided written informed consent for enrollment in the research, and all procedures were performed in compliance with the 1964 Declaration of Helsinki and any subsequent revisions or similar ethical norms.

Bleeding Assessment and Laboratory Work-up ISTH-BAT

The ISTH-BAT was used to assess bleeding symptoms in the neonates examined. The ISTH-BAT is available at https://www.mdcalc.com/calc/10580/isth-scc-bleeding-assessment-tool. It comprised fourteen categories for evaluating bleeding symptoms, and it was illustrated that a high hemorrhage score is correlated with the presence of an inherited hemorrhage disorder. Each of the fourteen parameters was scored from 0–4 (except for CNS Bleeding, in which the scores were 0, 3, or 4), and based on this, a final score was derived. A score equal to or greater than three in neonates was regarded as abnormal (16). Although the ISTH-BAT included domains assessed in the neonatal period, its efficacy as a reliable tool wasn't evaluated in the newborn. In previous studies, neonates were covered under the pediatric age range; however, these studies did not focus specifically on neonates or validate the tool for that subgroup (17, 18).

In Egypt, as in many countries, the national policy aligns with international guidelines, administering one milligram of vitamin K intramuscularly (IM) at birth to all newborns to avoid VKDB following the World Health Organization (WHO) recommendations (19).

Laboratory Work-up

All specimens were analyzed at the local hematology laboratory of Cairo University New Children's Hospital.

Complete Blood Picture and Platelet Count

The Sysmex XS-800i (Sysmex, Kobe, Japan) fully automated hematological analyzer was used to perform a complete blood picture. The blood specimens were collected in 2-mL K3-Ethylenediaminetetraacetic acid (EDTA) blood collection tubes. If the automated platelet count was < 100 × 10^3/cmm, a peripheral blood smear was prepared and examined microscopically for manual platelet estimation (20, 21).

Coagulation Tests

Blood was collected in citrated tubes (9:1

blood-to-anticoagulant), gently mixed, and centrifuged. The plasma was analyzed for activated partial thromboplastin time (aPTT), prothrombin time (PT), fibrinogen (FI) level, thrombin time (TT), and factor VII (FVII) level. The International Normalized Ratio (INR) was calculated from the reagent's ISI. Factor VII (FVII) level was measured utilizing a one-stage clotting assay: patient plasma was mixed with FVII-deficient plasma (STA-deficient VII, Stago (REF 00743)) and clotting was triggered. Fibrinogen (FI) level was measured by the Clauss method (22–25).

The reference values for the coagulation tests were obtained from the hematological reference ranges (Appendix 1) published in Lanzkowsky's Manual of Pediatric Hematology and Oncology (Sixth Edition) (26).

Statistical analysis

All statistical computations were conducted utilizing IBM SPSS (Statistical Package for the Social Sciences; IBM Corp., Armonk, NY, USA), version 28 for Microsoft Windows. Quantitative parameters were illustrated in terms of mean, standard deviation (SD), interquartile range (IQR), median, minimum, and maximum. Qualitative parameters were described in the form of numbers and percentages. Information was explored for normality utilizing the Kolmogorov-Smirnov test of normality. Parametric tests were utilized for most of the comparisons. Comparisons among quantitative parameters were conducted using One-way analysis of variance (ANOVA) to assess differences between the groups. The relationship among qualitative parameters was carried out by the Chi-square test. Binary correlations were conducted by the Pearson correlation test. Outcomes were expressed in the form of correlation coefficients (r) and p-values. A p-value less than or equal to 0.05 was regarded as statistically significant (27–29).

Ethical approval

The Research Ethics Committee of the Faculty of Medicine at Cairo University gave its approval to the research, code MD-149-2021

Results

A total of 61 neonates were enrolled in this research. Thirty-nine (63.9%) of the examined neonates were males, and 22 (36.1%) were females. The majority of the studied neonates were preterm (< 37 weeks of gestation) (70.5%). Twenty-two (36.1%) neonates were diagnosed with sepsis (criteria for diagnosis) on enrollment. The most common sites of bleeding were upper gastrointestinal tract bleeding, pulmonary hemorrhage and intraventricular hemorrhage (36.1%, 19.7%, and 11.5%, respectively). Twelve neonates (19.7%) had multiple bleeding sites at presentation. Laboratory parameters of the studied neonates are illustrated in Table 1. Fibrinogen levels of the whole study group ranged from 49 to 570 milligrams/deciliter with a mean of 241.19 ± 117.62 milligrams/deciliter, and factor VII levels ranged from 15 to 130% with a mean of 61.73 ± 25.42%. A p-value less than or equal to 0.05 was regarded as statistically significant.

The ISTH-BAT was used to assess bleeding symptoms among the studied neonates. The score of our patients ranged from 1 to 8, with a mean of 2.4 ± 1.8 as illustrated in Table 2. Twenty-six (42.6%) of our patients examined had an abnormal score (≥ 3), which can suggest an underlying inherited bleeding disorder. ISTH-BAT score reliability in predicting different factors assay results showed sensitivity for Factor VII deficiency and Fibrinogen level deficiency was (60% and 100% respectively) in addition to specificity for Factor VII deficiency and Fibrinogen level deficiency was (100% and 70% respectively).

Comparing the bleeding score of neonates diagnosed with sepsis and healthy ones (regardless of the gestational age) using the ISTH-BAT, as illustrated in Table 3, there was a statistically significant increase in the median score among septic neonates (p-value = 0.013). When categorizing patients according to the ISTH-BAT scores, 15 neonates with sepsis (68.2%) showed abnormal ISTH-BAT scores, in contrast to 11 (28.2%) in the healthy group, and there was a statistically significant rise in the number of neonates diagnosed with sepsis who had abnormal scores (p-value = 0.002), thus suggesting that it can be a valid tool in assessing bleeding in those sick neonates.

Group 1 patients (n = 10) included healthy full-term neonates without sepsis or any other risk factor for bleeding; 7 of 10 had VKDB, confirmed by stoppage of the bleeding and normalization of the coagulation parameters after the administration of intravenous vitamin K. The other 3 healthy full-term neonates had a low fibrinogen level (< 50 mg/dL) and were diagnosed as inherited fibrinogen deficiency (afibrinogenemia). All cases with VKDB had a normal ISTH-BAT score, apart from one patient who had a score of 5. The 3

Table 1. Clinical, baseline characteristics, and laboratory data of the examined newborns (n = 61)

Studied variables		n (%)	P value
Gender	Males	39 (63.9%)	0.0295
	Females	22 (36.1%)	
Consanguinity	Absent	45 (73.8%)	0.0002
	Present	16 (26.2%)	
Gestational age	Preterm (< 37 weeks)	43 (70.5%)	0.0013
	Full term (≥ 37 weeks)	18 (29.5%)	
Birth weight (kg)	NBW (> 2.5 - ≤ 4 kg)	24 (39.3%)	0.00036
	LBW (> 1.5 - 2.5 kg)	9 (14.8%)	
	VLBW (> 1 - 1.5 kg)	23 (37.7%)	
	ELBW (≤ 1 kg)	5 (8.2%)	
Neonatal sepsis	Absent	39 (63.9%)	0.0294
	Present	22 (36.1%)	
Site of bleeding	Upper GIT	22 (36.1%)	<0.0001
	Pulmonary hemorrhage	12 (19.7%)	
	Intraventricular hemorrhage	7 (11.5%)	
	Ecchymosis	3 (4.9%)	
	Lower GIT	2 (3.3%)	
	Subdural hemorrhage	1 (1.6%)	
	Post circumcision bleeding	1 (1.6%)	
	Umbilical Stump Bleeding	1 (1.6%)	
Number of bleeding sites	Single	49 (80.3%)	
	Multiple	12 (19.7%)	
Transfusion requirements	Packed RBCs	14 (23%)	<0.0001
	FFP	11 (18%)	
Laboratory parameters			
Hb (gm/dl)	Mean ± SD	8.5 ± 1.4	
	Min. – Max.	6 – 14	
PLT (×10^3/mm^3)	Mean ± SD	323.2 ± 148.5	
	Min. – Max.	84 – 801	
TLC (×10^3/mm^3)	Mean ± SD	9.4 ± 4.3	
	Min. – Max.	3.2 – 27	
PT (seconds)	Mean ± SD	10.4±19	
	Min. – Max.	13 – 60	
aPTT (seconds)	Mean ± SD	11.5±41.3	
	Min. – Max.	11 – 70	
PC (%)	Mean ± SD	14.7±57.8	
	Min. – Max.	32 – 92	
INR	Mean ± SD	1.8±1.9	
	Min. – Max.	1 – 10	
TT (seconds)	Mean ± SD	11.8±15.8	
	Min. – Max.	5 – 60	
Fibrinogen level (mg/dl)	Mean ± SD	241.2±117.6	
	Min. – Max.	49 – 570	
Factor VII level (%)	Mean ± SD	25.4±61.7	
	Min. – Max.	15 – 130	

n: number, P- value: probability value, VLBW: Very low birth weight, LBW: Low birth weight, PC: Prothrombin concentration, NBW: Normal birth weight, ELBW: Extremely low birth weight, RBCs: Red blood cells, GIT: Gastrointestinal tract, FFP: Fresh frozen plasma, Hb: Hemoglobin, PLT: Platelet count, TLC: Total leukocytic count, PT: Prothrombin time, INR: International normalized ratio, aPTT: Activated partial thromboplastin time, TT: Thrombin time, SD: Standard deviation, Min.: Minimum, Max.: Maximum.

Table 2. ISTH BAT score of the studied neonates (n = 61)

ISTH BAT score	Mean ± SD Min. – Max.	2.4 ± 1.8 1 – 8
ISTH BAT score interpretation n (%)	Normal (< 3) Abnormal (≥ 3)	35 (57.4%) 26 (42.6%)

ISTH BAT: International Society for Thrombosis and Haemostasis Bleeding Assessment Tool.

Table 3. Comparison between neonates with and without sepsis regarding the ISTH-BAT score

		Sepsis		Test of significance		
		No (n= 39)	Yes (n= 22)	Value	p-value	Sig.
ISTH-BAT score	Median (IQR)	1 (1 - 3)	4 (1 - 5)	-2.485	0.013*	S
Interpretation	Normal	28 (71.79%)	7 (31.82%)	9.192	0.002**	S
	Abnormal	11 (28.21%)	15 (68.18%)			

*Mann-Whitney test of significance, **Chi-Square test of significance

afibrinogenemia patients had an abnormal ISTH-BAT with a minimum score of 7 and a maximum score of 8, showing the highest ISTH-BAT scores recorded in our study.

Discussion

This research was a single-center study to evaluate bleeding among a cross-section of Egyptian neonates admitted to Cairo University Hospital NICU. Neonates have an elevated possibility of bleeding owing to factors peculiar to the neonatal population. Consequently, a comprehensive grasp of developing haemostasis, underlying pathophysiology, and risk factors is necessary for the broad differential diagnosis of neonatal bleeding (30, 31). In a healthy neonate, bleeding often indicates an inherited coagulation disorder whereas an acquired coagulopathy is more likely to be the cause of hemorrhage in a sick preterm (32, 33). In our study, fibrinogen (FI) deficiency was diagnosed in 3 (4.9%) healthy full-term neonates. Factor VII deficiency in our studied patients was diagnosed in the presence of a risk factor: prematurity, sepsis, or VKDB. Thus, FI deficiency was the most commonly diagnosed RIBD among our study of bleeding neonates. This is not in agreement with the World Federation of Hemophilia (WFH) annual global survey, in which FVII was the majority of prevalent RIBD worldwide, followed by FXI deficiency; however, according to the same poll, FVII and FI were the 2 most common RIBDs in the Egyptian population (34). Similar to our findings, Awidi previously reported that fibrinogen abnormalities were the most frequently encountered RIBDs in a 9-year study in Jordan (35). In another Egyptian study including 70 patients with RIBDs, FI deficiency was the most common (28.6%), followed by FVII (20%) (36).

The proper evaluation of bleeding symptoms helps in the identification of bleeding disorders, particularly RIBDs. However, describing and interpreting bleeding symptoms is subjective and challenging. Consequently, numerous attempts were undertaken to unify hemorrhage histories (37). In an attempt to standardize the assessment of bleeding, a variety of bleeding assessment tools (BATs) were developed; however, these instruments were not intended for routine usage with bleeding neonates. One of the BATs used in neonates is the NeoBAT, an amended WHO BAT used to standardize the clinical assessment of bleeding in both term and pre-term neonates in an intensive care unit (38). The ISTH-BAT was designed to help in the identification of a potential bleeding disorder in children and adults (39, 40, 41). This is the first research to our knowledge using ISTH-BAT for clinical assessment of bleeding in the neonate, particularly in the NICU. It was confirmed extensively in cases with suspected von Willebrand disease (VWD) and used as a screening tool for platelet function disorders and an underlying bleeding disorder in heavy menstrual bleeding (42, 43, 44, 45). We used the ISTH-BAT to evaluate bleeding in our studied neonates and to identify those with a possible underlying bleeding disorder. In our study, 26 (42.6%) of our enrolled patients had an abnormal score (≥ 3), which could suggest an underlying inherited hemorrhage disorder. However, the predictive value of the ISTH-BAT score to identify the 3 patients with afibrinogenemia could not be properly assessed in this research due to the very small number of cases. However, there was a statistically significantly higher median ISTH-BAT score among septic neonates (p-value = 0.013). Kher et al. linked sepsis to coagulopathy due to disseminated intravascular coagulation (DIC), endothelial damage, and platelet dysfunction (46). Also, Hasbaoui et al. previously reported that neonatal sepsis is a major risk factor for bleeding due to coagulation abnormalities (47). Our data recommend that ISTH-BAT score might be a useful instrument for the assessment of hemorrhage in neonates diagnosed with sepsis.

Limitations

It would be ideal to replicate this study work with a larger number of neonates as a single-center study or multicenter.

Conclusion

Fibrinogen deficiency was the most frequently diagnosed RIBD. The ISTH-BAT may be a useful screening instrument for identifying bleeding disorders in neonates, especially in septic cases. Larger studies are required to validate its diagnostic utility in this population.

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None.

Conflicts of interest

The authors declare no conflicts of interest.

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