

ORIGINAL ARTICLE

BLOOD-SMART NICUS: IMPLEMENTING A PRAGMATIC PHLEBOTOMY CARE BUNDLE TO REDUCE DIAGNOSTIC BLOOD LOSS AND ANEMIA – A SINGLE-CENTRE EXPERIENCE

K.S.Kumaravel, V.Anurekha, A.Sivagami, M.Poornima.

Department of Pediatrics, Govt. Mohan Kumaramangalam Medical College, Salem.

ABSTRACT

Background:

Phlebotomies in neonates can cause severe anemia and warrant blood transfusions. This study aims to evaluate the impact of a Phlebotomy Care Bundle (PCB).

Methods:

This case-control study was done from April'25 to June'25 in a tertiary care hospital. In February 2025, the study hospital introduced a PCB that included: 1) The use of 'Small-Volume Tubes' for 7 common tests. 2) Determining the minimum blood volume for these tests and 3) Training residents and nurses to minimize pre-analytical errors, such as overdraws. Controls were taken from a study on 'Phlebotomy blood loss in hospitalised neonates', done in the same unit between November'2024 and January'2025 (historical controls). The Primary endpoint was a Reduction in blood volume withdrawn. Secondary endpoints were Changes in delta hematocrit and the number of RBC transfusions. The collected data from both groups were equated based on gestational age, diagnosis, and birth weight using SPSS software and analysed.

Results (N=92):

The phlebotomy volume was significantly reduced by 29.88% in the post-PCB group ($P=0.006$). There was a significant reduction in the delta hematocrit by 42.84% in the post-PCB group ($P<0.001$). Though there was a decrease of 33.33% in RBC transfusions in post-PCB, it was not statistically significant ($P=0.514$). There was no significant difference in the number of tests, sample wastages, and number of phlebotomies between the groups.

Conclusion:

The inclusion of Small Volume Tubes in protocols and improvement in phlebotomy care can minimize phlebotomy blood loss and can have a huge impact on the prevention of anemia.

Introduction

Advancements in neonatal care and reductions in neonatal mortality have led to longer hospital stays and an increase in blood sample collections for various tests¹. Although these tests are essential for saving lives, monitoring patient health, and improving neonatal survival rates, they are also linked to iatrogenic anemia, which often necessitates blood transfusions. The extent of blood loss due to phlebotomy is directly influenced by factors such as the length of stay, the severity of illness, and the level of care provided.² The blood loss is sometimes large enough to result in severe anemia and warrant blood transfusions. In a study by Counsilman et al., the median cumulative iatrogenic blood loss was 24.2 ml/kg per patient, the

median number of punctures per neonate was 47, and the median volume of RBC transfusions administered was 30 ml/kg.³ While many non-invasive monitoring devices have been introduced, a considerable number of tests still require blood draws for effective neonatal management.⁴ The causes of this blood loss are multifactorial, including overdraw, failure to consolidate tests, and sometimes insufficient sample volumes, all of which result in wastage of collected blood. In a study by Lin et al., a 19.0% overdraw rate was observed in neonatal care units.⁵ He also found that the lightest neonates experienced the highest levels of overdraw. Additionally, considerable variation in overdraw was observed between different phlebotomists.

As a strategy to reduce iatrogenic anemia, small-volume blood collection tubes (SVT) were introduced.⁶ Standard volume tubes are calibrated to withdraw a predefined blood volume, usually between 4 and 6 ml, often in vacuum containers. However, modern analyzers require small-volume samples, usually less than 0.5 mL, leading to significant blood waste. SVTs

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Address for Correspondance: K.S.Kumaravel, M.D (Paediatrics), 191A, Shankar Nagar,

Salem, Tamil Nadu, India.

Email: kumaravelks@rediffmail.com

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are designed to collect 50% less blood than standard tubes and are compatible with most modern analyzers.⁷ Although SVTs are known to reduce iatrogenic blood loss, they are not part of standard protocols and are not widely used in all neonatal units. Surprisingly, many adult studies have demonstrated the significant advantages of these SVTs.^{8,9} A multicenter cluster randomized controlled trial conducted in 2023, known as the STRATUS (Small-Volume Tubes to Reduce Anemia and Transfusion) study, evaluated the benefits of using SVTs in adult ICU patients.⁶ The study concluded that SVT use significantly reduced the number of Red Blood Cell (RBC) transfusions without affecting biospecimen adequacy for analysis. However, to date, no consensus exists on the use of SVTs in neonatal units. In this study, we evaluated the impact of a pragmatic 'Phlebotomy Care Bundle' (PCB), including the use of SVTs in our neonatal care unit.

Aims and objectives

This study aims to evaluate the impact of the implementation of a pragmatic Phlebotomy Care Bundle (PCB) in a neonatal care unit. The primary endpoint is the reduction in blood volume withdrawn. The secondary endpoints are the changes in delta hematocrit and the number of RBC transfusions.

Materials and methods

This is a case-control study conducted in a neonatal care unit at an urban public hospital. The neonates admitted to the neonatal care unit from April 2025 to June 2025 were included as cases. Neonates admitted for surgical conditions and those with major congenital anomalies were excluded. In February 2025, the study hospital introduced a 'Phlebotomy Care Bundle' (PCB) in the neonatal care unit, as described below. The PCB was introduced following a study titled 'Phlebotomy blood loss in hospitalized neonates' done in the same neonatal care unit between November 2024 and January 2025. The study demonstrated that the mean blood volume drawn was 8.07 ± 4.96 ml (Range: 1-21 ml).¹⁰ The neonates included in that study served as controls (historical controls). The study included only the 7 common and often repeated tests performed in the NICU: Complete Blood Counts (CBC), Serum Bilirubin, C - Reactive Protein (CRP), Serum Calcium, Serum Creatinine, Serum Electrolytes, and Blood Urea Nitrogen. The phlebotomy for the other tests was not included in either of the groups. The tubes were calibrated manually (± 0.1 ml). Informed consent was obtained from the parents, and approval was granted by the institutional human ethics committee.

Phlebotomy Care Bundle (PCB)

The PCB included 3 components:

1. The use of SVTs for the 7 common tests listed above. The SVTs from Ultimate Moulds & Products® were used in the PCB group. For CBC, a K2 EDTA microtube was used. For the other six tests, Mini Clot Activator tubes were used. The same analyzers were used in both groups.
2. Determining the minimum blood volume (MBV) for the above 7 common laboratory tests and communicating it to the residents and nurses.
3. Training residents and nurses who perform

phlebotomy by a biochemistry specialist on preanalytical sample processing, especially blood collection, and minimizing overdraws.

Data collection and utilization

The data collected in both groups included name, date of birth, birth weight, gestational age, history of bleeding, days of hospital stay, diagnosis, outcome, on-admission hemoglobin (%), on-admission hematocrit (%), on-discharge hemoglobin (%), on-discharge hematocrit (%), delta hematocrit (on-admission hematocrit minus the on-discharge hematocrit), number of tests, number of phlebotomy counts, total volume of blood drawn, samples wasted (sample returned as insufficient) and red blood cell (RBC) transfusions. The collected data from both groups were equated based on gestational age, diagnosis, and birth weight using SPSS software. The outliers in both groups were removed and analyzed.

Sample size

This study aimed to detect a 25% reduction in mean blood volume drawn during phlebotomy between pre- and post-PCB groups (from 5.75 ml to 4.31 ml). Based on pilot data, we assumed a pooled standard deviation of 3.25 mL, resulting in a moderate effect size (Cohen's $d = 0.44$). With a two-tailed alpha of 0.05 and 80% power, a sample size of 81 neonates per group was needed. To account for potential variability and dropout, we enrolled 92 neonates in each group (total $N = 184$), ensuring sufficient power to detect the target effect. This sample size also allows for adjustments for covariates (e.g., birth weight) in secondary analyses.

Statistical analysis

Data were entered into Microsoft Excel, and analysis was conducted using SPSS 21.0. Data were presented as mean and standard deviations for continuous data and as percentages for categorical data. An unpaired t-test was used to compare the two group means. Chi-square test was used to find out the association between categorical variables. A p-value of less than 0.05 was considered significant.

Results

There were 100 neonates in the historical controls and 106 neonates in the post-PCB group. After equating the groups and removing the outliers, there were 92 neonates in each group. The clinical profile of the neonates is tabulated in Table 1. The mean gestational age in the post-PCB group was 34.15 ± 2.56 weeks. The mean birth weight in the post-PCB group was 1919.45 ± 630.44 grams. The mean duration of stay in the post-PCB group was 6.65 ± 5.31 days. The bleeding manifestations were found in 8.7% of the neonates, and the most common cause of admission was RDS (43.48%) in the post-PCB group. Mortality was observed in 7.6% of the neonates in the post-PCB group. There was no significant difference in the above clinical profile between the groups.

Upon analyzing the impact of PCB implementation, a statistically significant reduction in delta hematocrit of approximately 3.5% was observed in the post-PCB group ($P < 0.001$) (Table 2). The phlebotomy volume was also significantly reduced, from 5.42 ± 4.41 ml (Range 1 – 20 ml) in the pre-PCB group to 3.80 ± 3.36 ml (Range 1 – 13.8 ml) in the post-PCB

Table 1: Clinical profile of the study groups

Characteristic	Pre-PCB no (%) N = 92	Post-PCB no (%) N = 92	P value*
Mean gestational age (weeks)	34.08 ± 3.52	34.15 ± 2.56	0.886
Mean birth weight (grams)	1943.25 ± 631.81	1919.45 ± 630.44	0.798
Mean hospitalization days	5.68 ± 3.87	6.65 ± 5.31	0.160
Bleeding manifestations	10 (10.9%)	8 (8.7%)	0.805
Outcome – Expired	11 (12.0%)	7 (7.6%)	0.458
Diagnosis			
Respiratory distress syndrome	42 (45.65%)	40 (43.48%)	0.838 [^]
Birth Asphyxia	20 (21.74%)	22 (23.91%)	
Sepsis	3 (3.26%)	1 (1.08%)	
Meconium aspiration syndrome	8 (8.69%)	7 (7.61%)	
Others	19 (20.65%)	22 (23.91%)	
Phlebotomy loss			
<5ml	54	68	0.089 [^]
5.1-10ml	23	14	
10.1-15ml	10	9	
>15.1ml	5	1	

*Unpaired t-test, [^]Chi-square test

Table 2: Phlebotomy Bundle Care Characteristics

Characteristic	Pre-PCB no (%) N = 92	Post-PCB no (%) N = 92	P value*
Mean On-admission Hb%	17.311 ± 2.14	16.75 ± 2.22	0.085
Mean On-admission Hematocrit%	51.93 ± 6.42	50.26 ± 6.66	0.084
Mean On-discharge Hb%	14.59 ± 2.53	15.19 ± 2.57	0.113
Mean On-discharge Hematocrit%	43.76 ± 7.59	45.58 ± 7.72	0.108
Mean Delta Hematocrit%	8.17 ± 5.69	4.67 ± 5.16	<0.001
Mean Phlebotomy Volume (ml)	5.42 ± 4.41 (Range 1 – 20ml)	3.80 ± 3.36 (Range 1 – 13.8ml)	0.006
Mean Phlebotomy count (no)	3.31 ± 2.37	3.32 ± 2.31	0.975
Mean tests (no)	8.01 ± 4.77	7.97 ± 5.60	0.966
RBC transfusion (no)	6	4	0.514 [^]
Sample wastage (no)	2	3	0.650 [^]

*Unpaired t-test, [^]Chi-square test



group ($P=0.006$). Though there was a decrease in RBC transfusions in post-PCB, it was not statistically significant. There were no statistically significant changes observed between the 2 groups in terms of on admission Hb% and Hematocrit, and on discharge Hb% and hematocrit between the groups. There was also no significant difference in the number of tests and the number of phlebotomy counts between the groups. There were 2 sample wastages in the pre-PCB group and 3 in the post-PCB group.

Discussion

In a study by Councilman, the median phlebotomy blood loss was 24.2 ml/kg.³ In the present study, the mean phlebotomy blood loss was 5.42 ml (range 1-20 ml) in the pre-PCB group. This may be because the present study has only included the common and often repeated tests and not all the phlebotomy losses. In this study, we have demonstrated a 29.88% reduction in phlebotomy blood volume, a 42.84% reduction in delta hematocrit, and a 33.33% reduction in RBC transfusions after the implementation of the PCB. The phlebotomy volume varies from study to study, depending on the proportion of extreme preterm neonates, the length of the stay, and the level of care. In a study by Tyagi et al in India, the median loss was 7 ml.¹ They demonstrated that the phlebotomy loss was inversely proportional to the gestational age; the lower the gestational age, the higher the loss. A study by Dumitrescu et al, reported a higher loss of about 83ml per neonate.⁴

Studies have demonstrated the overdraw of blood, leading to an increase in phlebotomy loss. Agarwal et al reported up to 300% overdraw for tests like CBC in their study.² The reasons for overdrawing are many: fear of repeating the tests due to inadequate sample volume, lack of awareness regarding minimum volume, and the use of unmarked tubes. A study by Valentine et al reported that the highest overdraw was associated with biochemistry tests.¹¹ In this study, we have incorporated the estimation of minimum blood volume for all the common tests and sensitized the residents and nurses regarding the minimum blood volume required to avoid overdraw.

The SVTs used in this study are easily available at a small extra cost from many manufacturers. These SVTs are compatible with most modern auto analyzers. There are many studies that have demonstrated the impact of the use of these SVTs. Also, many adult studies have explored the beneficial effects of replacing standard volume tubes with SVTs in their units.¹²⁻¹⁵ Su et al reported that the SVTs resulted in lower RBC transfusions, fewer incidences of severe anemia, and better bone marrow function at 30 days of life.¹⁶

A study by Riessen evaluated a Blood Saving Bundle with blood loss per day as the endpoint.¹⁷ There was a significant reduction in blood loss per day in mechanically ventilated adults. Though the impact of use of SVTs was demonstrated in many studies involving adult patients, the SVTs can be used universally in adults, children, and neonates. The impact will be huge in extremely preterm and very low birth weight neonates. In these neonates, the prevention of anemia of prematurity will have a long-lasting impact on growth and development.^{18,19} Even

the slightest prevention of a fall in hemoglobin will be of great benefit to the development of the neonate. The use of historical controls and the absence of blinding are the major limitations of this study. Further, the small sample size in a single centre limits the stratification of outcome measures across birth weight and gestational age categories.

Conclusion

This study has demonstrated a 29.88% reduction in phlebotomy blood volume, a 42.84% reduction in delta hematocrit, and a 33.33% reduction in RBC transfusions after the implementation of the PCB. The prevention of phlebotomy loss with small-volume tubes and improvements in phlebotomy care will have a huge impact on the prevention of anemia in very low birth weight neonates.

Compliance with Ethical Standards

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Conflict of Interest: None

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