STUDY OF BLOOD SUGAR ESTIMATION IN HIGH RISK NEONATES USING GLUCOMETER AND LABORATORY OXIDASE METHOD

**Dr. Pankaj Barabde[1], Dr. Aditi Ravindranath Katkar[2*],
Dr. Ninad Chaudhari[3], Dr. Rakesh Nasna[4]**

[1] Associate Professor at Dept. of Paediatrics, Dr. Panjabrao Deshmukh
Memorial Medical College, Amravati, Maharashtra, India
[2] Assistant Professor at Dept. of Obstetrics and Gynecology, Dr. Panjabrao
Deshmukh Memorial Medical College, Amravati, Maharashtra, India.
[3] Assistant Professor at Dept. of Paediatrics, Dr. Panjabrao Deshmukh
Memorial Medical College, Amravati, Maharashtra, India
[4] Junior resident Doctor at Dept. of Paediatrics, Dr. Panjabrao Deshmukh
Memorial Medical College, Amravati, Maharashtra, India
Email: [1]drpvbarabde@gmail.com, [2]aditikatkarb@gmail.com,
[3]drninadchaudhary@gmail.com, [4]rakajds63@gmail.com

Abstract

Background: Hypoglycemia, a prevalent metabolic disorder observed in newborns, can manifest with or without symptoms. The glucose oxidase method is specific and accurate for measuring glucose, it may take some time for result so that they can be utilised for rapid and effective treatment. Glucometers offer several advantages, including simplicity, requiring less blood, quick readings, and the ability to be used by unskilled personnel.

Objective: To evaluate the effectiveness, dependability and accuracy of glucometers in estimating blood glucose levels in high risk newborns.

Methods: The Department of Pediatrics and Department of Obstetrics and Gynecology carried out a hospital-based cross sectional study at tertiary care hospital, Amravati from October 2021 to April 2023 after ethical approval was taken from scientific community. The study included 100 neonates from the Department of Pediatrics, post natal ward (Obstetrics) and high risk neonates admitted to NICU.

Results: Out of 100 cases, 34% of cases were investigated for hypoglycemia by glucometer and 37% of cases were investigated with the laboratory oxidase method. There was a robust positive association observed between the mean glucometer value and the diagnosis by laboratory method value. For the diagnosis of hypoglycemia in neonates, we found an accuracy of around 87.50% for glucometer when we compared with oxidase methods. However, accuracy, detective rate, positive predictive value(PPV) and negative predictive value(NPV) were found to be 97.30%, 94.20%, 95.90 % and 91.80% respectively.

Conclusion: The utilization of glucometer for blood glucose estimation is a reliable approach for the detection of hypoglycemia in newborns.

Keywords: *Hypoglycemia, Glucometer, Glucose oxidase method, Accuracy*

7896

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 – 7903

1. Introduction

Hypoglycemia is a prevalent metabolic issue frequently observed in neonates. It can manifest with or without symptoms and has the potential to result in brain dysfunction and delays in neuromotor development.[1,2] Glucose is a crucial carbohydrate in the body, and typically, its concentration in the bloodstream remains stable within the range of 80 to 120 mg/dl. Due to the potent reducing properties of glucose, its measurement is relatively straightforward. Familiarity with blood glucose measurement methods assists clinicians in interpreting accurate values and avoiding the limitations of inaccurate testing. Although the concentration of glucose is highest in arterial circulation, laboratory assessments are commonly performed on venous samples. The laboratory-based glucose oxidase method employed for determining blood glucose concentration is known for its accuracy and specificity in measuring glucose levels. However, since this method is typically performed in a laboratory setting, the results may not be immediately available for prompt and suitable management. In contrast, glucometer are frequently utilized for blood glucose estimation in neonates receiving intensive care, as they provide rapid results. [3,4,5,6] Several studies have demonstrated a strong correlation between the results obtained from glucometers and the laboratory-measured glucose oxidase method in the normal and high blood sugar level range. However, there is inconsistency in the correlation in the hypoglycemic range, particularly when glucose levels fall below 40 mg/dl. Nonetheless, glucometers offer advantages such as simplicity, minimal blood quantity requirement, rapid readings, and the ability to be used by unskilled personnel.[6,7]

2. Aim & objectives:

- To compare blood glucose levels estimated using the glucometers and the lab glucose oxidase-peroxidase method in high-risk newborns or neonates.
- To examine the reliability and sensitivity of a glucometer as the sole method for monitoring blood glucose levels in high-risk neonates.

3. Methods:

STUDY DESIGN: This cross-sectional research took place at a tertiary care hospital within the Department of Pediatrics and Department of Obstetrics and Gynecology situated in Amravati.

STUDY PERIOD: Duration from October 2021 to April 2023.

STUDY POPULATION: The study included all inborn neonates admitted to NICU as well as high-risk neonates who were placed under observation in the ward.

SAMPLE SIZE AND SAMPLE TECHNIQUE: A total of 100 infants, comprising neonates with IUGR and preterm neonates with a gestational age greater than 28 weeks and birth weight exceeding 1000 grams, were included in the study. Both male and female infants admitted to the NICU and high-risk neonates in the post-natal ward during the study period were considered.

Exclusion criteria encompassed infants older than 28 days, full-term newborns without any risk factors, infants with a gestational age below 28 weeks and birth weight equal to or less than 1000 grams, newborns with sepsis or septic shock, newborns whose mothers used drugs

7897

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 – 7903

while they were pregnant, and babies with congenital disorders. Additionally, infants with severe anemia indicated by a hematocrit (Hct) level below 20% or polycythemia defined by a hematocrit level above 65% were also excluded from the study.

ETHICAL CONSIDERATION: The study received approval from the hospital's Ethical Committee, and written consent was taken from the parents of newborns who participated in the study.

DATA COLLECTION TECHNIQUE AND TOOLS: I) Glucometer: The Bayer Breeze 2 blood glucose glucometer was used to analyze the blood glucose level.

Bioamperometry : The glucose oxidase is an enzyme that was taken in the strip.With the help of this enzyme the glucose component from the blood sample was converted into gluconolactone. This process generates a safe electrical signal, which the glucometer interprets to determine the corresponding blood glucose level.

PROCEDURE: After the admission or soon after the neonatal birth, blood samples were taken within 5 minutes. Before the procedure started hands as well as pre-warm the sole were washed to ensure accurate perfusion. Blood samples were collected using a sterile lancet via pricking to the finger. Using a drop of blood, touch the curved edge of the test strip. On the strip, blood was automaticallytaken. The blood drop should not be placed on top of the strip. Within 5 seconds, a test result was obtained.

II) Laboratory method: The enzymatic calorimetric test known as GOD-POD i.e. glucose oxidase-peroxidase method, is based on the following principle: Glucose + O_2-------- Gluconic acid + H_2O_2 H_2O_2 + 4-Aminoantipyrine + Phenol ------------ Chinomine +$4H_2O_2$. In this procedure, the first step employs the enzyme glucose oxidase, while the second step utilizes the peroxidase enzyme.

PROCEDURE: The specimen was gathered promptly after delivery or within a time frame of 5 minutes following admission. A volume of 1000 microliters of monoreagent was used for the sample. A 10 microliter portion of the sample was thoroughly mixed, followed by an incubation period of 5 minutes at 37°C. The absorbance (A) against the reagent blank was then measured.

DATA ANALYSIS: The SPSS version 25 programmed was used for all of the statistical analysis. Descriptive analysis, frequencies and correlation were the statistical methods used. For continuous variables for statistics like the number of observations, mean, and standard deviation were employed. Values for categorical categories were summarized using frequencies and percentages. significance tests The percentage of instances with hypoglycemia between the two markers was calculated using the chi-square test. Sensitivity, specificity, and predictive positive and negative tests were computed utilizing a glucometer. Every value was presented using a two-tailed test with a 5% threshold of significant interpretation.

4. Results

Table-1: Obstetrics Information of the study participants

Gravida	No. of Cases	Percentages
Primigravida	78	72%
Multigravida	22	22%

7898

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 – 7903

Type of delivery		
NVD (normal vaginal delivery)	57	57.00%
LSCS	43	43.00%
Causes of admission		
IDM	15	15%
PT	59	59%
IUGR	19	19%

The above table no1 shows that 72% of the participants were primigravida and 22% of the cases ere multigravida. 57% of cases had normal vaginal delivery and 43% of cases had lower (uterine) segment caesarean section (LSCS). The neonates were admitted to the tertiary health care centre for various reasons, such as diabetic mother's infants (IDM), prematurity (PT), and intrauterine growth retardation (IUGR) in 15%, 59%, and 19%, respectively.

Table-2 Profile of study group

Variable	Mean	Std Dev
Gestational age (Weeks)	35.78	2.93
Maternal age (Years)	25.80	2.03
Birth weight (kg)	2.03	0.92
Blood glucose by glucometer (mg/dl)	51.16	17.46
Blood glucose by laboratory oxidase method (mg/dl)	50.84	17.52

Table no 2 shows that the mean and standard deviation of gestational age amongst neonates. were found to be 35.78 ± 2.93 weeks. The neonates' maternal age was discovered to be 25.80 years +/2.03, and their birth weight was approximately 2.03 ± 0.92 kilograms. Laboratory investigations, such as blood glucose level measurement using a glucometer and laboratory methods, reported mean and standard deviation values of 51.16 ± 17.46 (mg/dl) and 50.84 ± 17.52 (mg/dl), respectively

Table-3. Association between glucometer and lab glucose method

Parameter Blood glucose	Method	Mean ± SD
Random blood sugar	Glucometer	51.16 ± 17.46
	Lab Glucose Method	50.84 ± 17.52
	R	0.985 `
<40mg/dl	Glucometer	32.64 ± 6.08
	Lab Glucose Method	32.88 ± 6.84
	R	0.985
>40mg/dl	Glucometer	60.69± 13.20
	Lab Glucose Method	60.52± 12.67
	R	0.9715

7899

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 – 7903

The mean and standard deviation glucose value diagnosed by using a glucometer was found to be 51.16 ± 17.46 and the by the laboratory glucose method was found to be 50.84 ± 17.52.Thus it did not reveal any major difference between the two methods. The Pearson correlation coefficient "R" was 0.985 represented a positive correlation between both the methods. The Pearson correlation coefficient, denoted by the letter "R," in the case of blood sugar <40 mg/dL(hypoglycemia) showed positive correlation (R=0.985). A strong positive association between the mean glucometer value and the diagnosis of lab glucose method value with "R" value, 0.9715 with blood glucose >40 mg/dL as seen in **Table 3**

Table-4. Overall incidence of hypoglycemia

Methods	(N=100)
Glucometer	34
Lab Method	37

The present study showed that, out of 100 cases, 34% of cases were investigated for hypoglycemia by glucometer and 37% of cases were investigated with the laboratory oxidase method.

Table-5. Validity of glucometer

Validity of glucometer	Percentage
Sensitivity	94.20%
Specificity	97.30%
PPV	95.90%
NPV	91.80%
Accuracy	87.50%

For the diagnosis of hypoglycemia in neonates, showed an accuracy of around 87.50% when glucometer is compared with glucose oxidase methods. However, specificity, sensitivity, PPV and NPV were found to be 97.30%,94.20%, 95.90 % and 91.80% respectively as shown in Table-5

5. Discussion:

Glucose levels are closely monitored in hospital settings, particularly in NICUs. Point-of-Care (POC) testing glucometers are commonly employed as a preliminary tool to measure blood glucose levels prior to receiving central laboratory results. This allows for timely assessment and intervention.

Our study shows that 72% of the cases were primigravida and 22% were multigravida. InYogesh P. Mehta study 48.0% were primi and 52.0% of the cases were multigravida.[8]

57% of cases had normal vaginal delivery and 43% of cases had lower (uterine) segment caesarean section (LSCS) in our study. InYogesh P. Mehta study 18.0% had normal delivery,

7900

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 – 7903

Among the cases analyzed, 76.7% involved the use of LSCS, while 5.3% of the cases involved assisted delivery methods.[8]

The neonates admitted to the tertiary health care centre for various reasons, such as diabetic mother's infants (IDM), prematurity (PT), and intrauterine growth retardation (IUGR), were found to be 15%, 59%, and 19%, respectively in our study. InYogesh P. Mehta study, out of the 150 neonates included, 65 neonates (43.33%) were admitted as infants of diabetic mothers, 81 neonates (54%) were admitted due to prematurity, and 42 neonates (28%) were admitted because of IUGR.[8]

Our study shows that the mean and standard deviation of gestational age amongst neonates were 35.78 ± 2.93 weeks**.** The neonates' maternal age was 25.80 years, and neonates birth weight was approximately 2.03 ± 0.92 kilograms. Laboratory investigations, such as blood glucose level measurement using a glucometer and laboratory methods, revealed mean and standard deviation values of 51.16 ± 17.46 (mg/dl) and 50.84 ± 17.52 (mg/dl), respectively

In Yogesh P. Mehta study reported the mean gestational age in newborns was 36.09±3.34 weeks; maternal age was 22.73±4.18 years; birth weight was 2.53±0.71 kg and blood glucose as 62.87±23.19 and 59.71±25.73mg/dl by glucometer and laboratory methods respectively.[8]

In our study the mean diagnosed by using a glucometer was found to be 51.16 ± 17.46 and the mean diagnosed by the laboratory glucose method was found to be 50.84 ± 17.52 showing no major difference between the two methods. The Pearson correlation coefficient "R" which was 0.985 represents a positive correlation between both the methods. The Pearson correlation coefficient, "R," in the case of (40 mg/dL) hypoglycemia, showed positive correlation (R=0.985). Also there was a strong positive association between the mean glucometer value and the diagnosis of lab glucose method value with "R" value, 0.9715 as seen in glucose level >40 mg/dL

A study conducted by Sreenivasa B, involving 500 neonates admitted to the NICU, revealed a strong and statistically significant association between the measurements obtained using both the glucometer (Accu-chek advantage) and the laboratory technique utilizing the glucose oxidase method.[9]

In Naaz study it was reported that within the range of 45 mg/dl to 145 mg/dl, a robust correlation was observed between the two methodologies. The study also indicated that glucometers tend to exhibit inaccuracies at extremely high or very low glucose levels. Additionally, it was noted that bedside testing results may be influenced by various factors, such as hematocrit levels, altitude, surrounding temperature or humidity, and hypoxia.[4]

In Hwang JH, et al. study shows that the values obtained from the blood glucose self-monitoring were not markedly distinct from those obtained using the laboratory method.[10]

Our study assessed that, out of 100 cases, 34% of cases were investigated for hypoglycemia by glucometer and 37% of cases were investigated with the laboratory oxidase method.

Harish J et al. study conducted on 250 neonates revealed that 103 cases (41.2%) were identified as hypoglycemic based on laboratory values, whereas 52 cases (20.8%) were determined to be hypoglycemic using the glucometer.[3]

Our study for the diagnosis of hypoglycemia in neonates, showed an accuracy of around 87.50% when glucometer is compared with glucose oxidase methods. However, specificity,

7901

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 − 7903

sensitivity, PPV and NPV were found to be 97.30%,94.20%, 95.90 % and 91.80% respectively

In Naaz study reported sensitivity64.40%, Specificity98.20%, PPV95%, NPV83.84%, Accuracy 86.47%.[4]

6. Limitations of study:

Considering the high specificity of the glucometer observed in our study, it is possible that a few infants were mistakenly identified as hypoglycemic when tested with the glucometer. Therefore, we conclude that if a clinician suspects hypoglycemia in a neonate but the glucometer indicates normal values, it is advisable to confirm the blood sugar levels using the glucose oxidase method as the definitive diagnostic approach before initiating treatment.

7. Conclusion:

This study provides evidence that the blood glucose estimation using a glucometer is an effective method for assessing neonatal hypoglycemia. Consistent with previous research, it can be concluded that glucose reagent strips should be regarded solely as convenient, rapid, point-of-care tests and screening tools, rather than diagnostic tests, due to their questionable reliability.

Declaration -

- Ethics approval and consent to participate – Patients consent was taken completely.
- Consent for publication – All authors give permission for the publication
- Availability of data and materials – Data was made available by the corresponding author.
- Competing interests – No competing interest was recorded.
- Funding – There is no funding for the research.
- Authors' contributions - 1. Dr. Pankaj Barabde: Conceptualization, formal analysis, resources, Methodology

2. Dr. Aditi Ravindranath Katkar: Validation, Writing - Review

3. Dr. Ninad Chaudhari: Writing original Draft, Data curation, Methodology

4. Dr. Rakesh Nasna: Resources, Formal analysis

References

1. Abramowski A, Ward R, Hamdan AH. Neonatal Hypoglycemia. [Updated 2022 Sep 5]. In: StatPearls [Internet]. Treasure Island (FL): StatPearls Publishing; 2023 Jan-. Available from: https://www.ncbi.nlm.nih.gov/books/NBK537105/
2. Abdullatif M. , Balsam A. , Lena E.. Neonatal Blood Glucose Assessment (Glucometer Vs Serum). AIMJ. 2022; Vol.3-Issue7 .7-13
3. McMillin JM. Blood Glucose. In: Walker HK, Hall WD, Hurst JW, editors. Clinical Methods: The History, Physical, and Laboratory Examinations. 3rd edition. Boston:

7902

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 – 7903

Butterworths; 1990. Chapter 141. Available from: https://www.ncbi.nlm.nih.gov/books/NBK248/

4. Patel P, Gogoi PR, Deb S, Paul P, Yesmin S, et al. (2020) Hypoglycemia in Exclusively Breastfed High-Risk Neonates - A Hospital-Based Study. Int J Pediatr Res 6:066. doi.org/10.23937/2469-5769/1510066

5. J Harish and A SrinivasH. and Ayyappankalathil Soumya, Comparative study of glucometer and laboratory glucose oxidase method for the estimation of blood glucose levels in neonates},Journal of Evolution of medical and Dental Sciences},2015,04:2652-2663

6. Naaz F, Gulati R.K. Comparative study of glucometer and laboratory glucose oxidase method for the estimation of blood glucose levels in neonates. Int J Pediatr Res. 2019;6(03):113-117.doi:10.17511/ijpr.2019.i03.02

7. Ho HT, Yeung WK, Young BW. Evaluation of "point of care" devices in the measurement of low blood glucose in neonatal practice. Arch Dis Child Fetal Neonatal Ed. 2004 Jul;89(4):F356-9. doi: 10.1136/adc.2003.033548. PMID: 15210675; PMCID: PMC1721720.

8. Mehta YP, Munde BP.Study of blood sugar levels in high risk neonates using glucometer method and laboratory glucose oxidase peroxidase method. Int J Contemp Pediatr 2017;4:1185-92.

9. Sreenivasa B1 , Kumar GV2 , Sreenivasa B Comparative study of blood glucose levels in neonates using glucometer and laboratory glucose oxidase method. Curr Pediatr Res 2015; 19 (1 & 2): 29-32

10. Hwang JH, Sohn YH, Chang SS, Kim SY. Evaluation of three glucometers for whole blood glucose measurements at the point of care in preterm or low-birth-weight infants. Korean J Pediatr. 2015 Aug;58(8):301-8. doi: 10.3345/kjp.2015.58.8.301. Epub 2015 Aug 21. PMID: 26388895; PMCID: PMC4573444.

7903

Eur. Chem. Bull. 2023,12(Special Issue 7), 7896 – 7903