ABSTRACT

Background: One of the greatest prevalent metabolic problems in newborns is hypoglycemia. Neonatal hypoglycemia may be both symptomatic and asymptomatic. Hypoglycemia has been linked to cognitive impairment and neuromotor developmental delay.

Aim of the study: The goal of the research was to discover the mean difference and correlation between capillary bedside glucose estimation by using glucometer in comparison venous sampling by using laboratory method.

Patients and Methods: This cross-sectional comparative prospective research was undertaken on 200 newborns that were admitted to special care baby unit at Al-Wahda teaching Hospital - Derna, Libya from March 2018 till March 2019.

Results: Agreement between blood sugar and glucometer blood sugar. Showing a significant agreement between venous blood sugar and glucometer blood sugar. Significant positive correlation between venous blood sugar and glucometer blood sugar.

Conclusion: Given the significance of blood sugar levels in the identification of hypoglycemia in the early hours of life, glucometer readings must be reliable. Furthermore, these glucose meters need skin breaking, which causes discomfort and the risk of infection. However, there are presently no painless and non-invasive procedures for precisely determining glucose levels in newborns. There is a demand for the creation of such gadgets for valid reasons.

Keywords: Blood glucose; Glucometer; Neonatal hypoglycemia; Screening.

INTRODUCTION

In the neonatal intensive care unit (NICU), bedside or point of care (POC) glucose measurement is often utilized to offer rapid treatment to the baby. Newborns are sensitive to glucose metabolism problems, especially hypoglycemia. With chronic hypoglycemia, both premature and mature newborns are at risks for negative neurodevelopment outcomes. As a result, precise and early detection of hypoglycemia, as well as prompt management, are critical for reducing neonatal sickness and death. 1

The most accurate approach for assessing blood glucose is laboratory estimate of plasma glucose. Although there is no internationally accepted reference approach for measuring blood glucose, the hexokinase approach is often used. The necessity for a bigger amount of blood and a delay in receiving findings for timely suitable management are the two key disadvantages of laboratory-based estimate. As a result, POC glucose testing devices are often used in NICUs. 2

A variety of glucometers are available to test glucose at the bedside. However, these glucometers were originally designed to measure glucose levels in adult diabetic patients. Glucometers, such as other medical equipment, have certain drawbacks. Environmental influences, operators' intervention, condition of the patient, medications, kind of sample utilized, blood glucose analytical approaches and numerous metabolic aspects all impact efficiency and accuracy of findings. 3

Various investigations have evaluated the performance of glucose meters from various manufacturers in newborn units with varying findings. However, assessing the function of glucometers in newborns is difficult because hemoglobin level and packed cell volume might alter test findings. Whole blood glucose concentrations are typically 10-15% lower than plasma glucose concentrations. 4

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In newborns, low blood glucose is a prevalent concern. 10% of regular neonates cannot sustain serum glucose level over 30 mg/dL (1.7 mmol/L) if their first feed is late for 3–6 hours after birth. 1 If hypoglycemia in a baby is not treated promptly, it might have negative consequences for neurodevelopment. Blood glucose measuring is required in neonates who are at potential for hypoglycemia, such as those born to diabetic moms, those who are tiny for gestational age, and preterm babies. However, owing to the long turnaround time, testing plasma glucose in the primary laboratory is typically not feasible. As a result, point-of-care (POC) glucometers are frequently utilized to guide therapy in nurseries and newborn critical care units. 5

The goal of this research was to investigate the mean difference and correlation between capillary bedside glucose estimation by using glucometer in comparison venous sampling by using laboratory method.

**PATIENTS AND METHODS**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Studied patients (n=200)</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sex</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>121</td>
<td>60.5%</td>
</tr>
<tr>
<td>Female</td>
<td>79</td>
<td>39.5%</td>
</tr>
<tr>
<td>GA</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Preterm</td>
<td>44</td>
<td>22%</td>
</tr>
<tr>
<td>Term</td>
<td>156</td>
<td>78%</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
<td></td>
</tr>
<tr>
<td>CS</td>
<td>118</td>
<td>59%</td>
</tr>
<tr>
<td>NVD</td>
<td>82</td>
<td>41%</td>
</tr>
<tr>
<td>Birth weight (gm)</td>
<td>Mean ±SD: 2896.93 ± 860.91</td>
<td>Median (Range): 3000 (600 – 5450)</td>
</tr>
</tbody>
</table>

**Table 1:** Basic patient characteristics. 60.5% of the patients were males and 22% of patients were preterm, moreover 59% were delivered by CS with mean weight was 2896.93 ± 860.91 gm.

This cross-sectional comparative prospective research was undertaken on 200 newborns that were admitted to special care baby unit at Al-Wahda teaching Hospital - Derna, Libya from March 2018 till March 2019. Consent was taken from the parents. A (1 ml) of venous blood was taken from the neonate by a trained nurse and sent for the laboratory, at the same time, a capillary blood sample obtained by a heel prick was spilled on a glucose strip and serum glucose level was tested using a glucometer. A glucometer (On Call Plus) was used in this study, the results were recorded.

**Inclusions criteria:** Neonates aged 1 – 28 days, term and preterm babies, high risk infants and symptoms suggestive of hypoglycemia.

**Exclusion criteria:** babies were age above 28 days

All data were collected; they were be analyzed by using IBM SPSS software version 20.
Table 2: Diagnosis distribution. The most prevalent diagnosis was RD (23%).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean ±SD</th>
<th>Median (Range)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Blood sugar “venous” (mg/dl)</td>
<td>83.72 ± 51.34</td>
<td>73.5 (28 – 672)</td>
</tr>
<tr>
<td>Blood sugar by glucometer (mg/dl)</td>
<td>88.73 ± 47.35</td>
<td>81 (36 – 352)</td>
</tr>
<tr>
<td>Difference</td>
<td>23.98 ± 29.72</td>
<td>---</td>
</tr>
</tbody>
</table>

Table 3: Blood sugar measurements.

Fig 1: Bland–Altman plot. Agreement between blood sugar and glucometer blood sugar. Showing a significant agreement between venous and glucometer blood sugar.

Fig 2: Blood sugar and glucometer blood sugar association, indicating a substantial positive correlation between venous blood sugar and glucometer blood sugar.

DISCUSSION

Glucose levels are checked regularly in hospital settings, especially in NICUs, and delivering a blood
sample to the laboratory for verification each time would be inconvenient and costly. POC testing glucometers are commonly employed as an early assessment instrument to determine plasma sugar level for quick evaluation and action while waiting for central laboratory results.  

Any analytical testing performed outside of a licensed laboratory facility is referred to as POC testing. It offers a number of benefits over standard laboratory-based testing, including a faster response time, lower blood volume needs, and clinical relevance. It is commonly known that today's glucometers were originally designed for glucose monitoring in adult diabetic patients, with findings that were well associated with gold standard laboratory testing in both normoglycemic and hyperglycemic sugar levels. However, we are concerned about the accuracy of data among infants with low sugar levels.  

As a consequence, the goal of this research was to investigate the mean difference and correlation between capillary bedside glucose estimation by using glucometer in comparison venous sampling by using laboratory method.  

This study was carried out on a 200 neonates; 60.5% of the patients were males and 22% of patients were preterm, moreover 59% were delivered by CS with mean weight was 2896.93 ± 860.91 gm.  

In comparison with the study of Nuntnarumit et al., 8 which reported that A total of 115 blood samples were collected from 111 newborns. The average (range) birth weight was 2195 (550–4360) g, and the gestational age was 35 (23–40) weeks. At the time of blood collection, the average (range) age and oxygen saturation were 5 (1–130) hours and 97 (88–100%), respectively.  

Another study of Torkaman et al., 9 which the research included 238 newborns with an average weight of 2869 ±821.9 g (range: 410–4900 g) who were included in order to find a cut-off value for plasma glucose level in glucometer findings. 94 (40.5%), 106 (45.7%), and 32 (13.8%) neonates, respectively, weighed less than 2500 g, between 2500 and 4000 g, and more than 4000 g.  

The advancements in obstetric practice regarding medical screening and monitoring, as well as greater neonatal expertise, have resulted in a dramatic decrease in newborn death rates over the last two decades. Respiratory tract infections, as well as sepsis and other infections, are the common causes of newborn illness and death. As a result, the duration of hospitalization, the expense of intensive care, and the load on the healthcare system have all grown. In the current study, the most prevalent diagnosis for NICU admission was RD (23%).  

In the study done by Al-Momani, 11 reported that Sepsis (27.3%), respiratory distress syndrome (RDS) (24.9%), and asphyxia (24.9%) were the most prevalent reasons for hospitalization (13.1 percent). The vast majority of newborns hospitalized survived (91.9%), with an overall death rate of 8.1 percent. According to the consequence death rate analysis, RDS was the most common reason of mortality (35.6 percent), accompanied by sepsis (27.7 percent).  

This discovery is similar to what was discovered in research done by Kanodia et al., 12 In a research, sepsis and prenatal asphyxia were also identified to be reasons for admittance to the NICU Gaucham et al., 13 In research done in Pakistan by Saboute et al., 14 The incidence of neonatal sepsis has been proven to be as low as 2% lesser than the rate reported in this research. This disparity might be the result of a distinct diagnostic method (therapeutically or by a lab culture test). In other research, RDS was the leading reason of newborn death in premature babies. The order in which these disorders appear as prevalent reasons of admission changes from research to study, Related to risk factors and clinical diagnosis that utilized.  

Over the last 40 years, many blood glucose measuring techniques have been suggested. Glucometer readings and regular laboratory testing are two popular ways for determining blood glucose levels. The enzymes glucose oxidase, glucose dehydrogenase, glucose hexokinase, and glucose6-phosphate dehydrogenase are all tested in the lab to determine blood glucose levels. 15  

In the present study, we found that blood sugar “venous” was 83.72 ± 51.34 mg/dl, Blood sugar by glucometer (mg/dl) 88.73 ± 47.35, with a Difference of 23.98 ± 29.72.  

In the previous study of Reddy et al., 6 When compared to plasma glucose levels (76.95 + 45.99) determined in central laboratory and HemoCue glucose 201+ analyser (82.9 + 51.4), median blood glucose values (100.2 + 48.4) with B Braun glucometer were substantially greater (p=0.003). The HemoCue glucose 201+ analyser and central laboratory tests did not demonstrate a substantial variation (p=0.463). The capillary and venous samples assessed in both devices had no substantial difference.  

While, Torkaman et al., 9 this research recruited there were 238 newborns in all, with a median weight of 2869±821.9 grams. The median (SD) blood sugar levels were 65.1± 22.9, 82.9± 24.7, and 84.4± 24.8 mg/dl, respectively, according to the standard laboratory technique, glucometer reads of venous blood samples, and glucometer reads of heel-stick capillary serum sample.  

Furthermore, Torkaman et al., 9 reported that the median blood glucose level indicated by the laboratory evaluation differed substantially from the glucose levels detected by the glucometer (P=0.045), whereas the average value computed by the glucometer was not (P=0.67). According to test findings, 45 patients (19.4%) exhibited hypoglycemia, with 39 cases being asymptomatic and just six babies displaying clinical hypoglycemia symptoms (P <0.05).
On the other hand, Nuntnarumit et al. 8 showed that the reference technique found plasma glucose concentrations ranging from 12 to 371 mg/dL, with a mean (interquartile range; IQR) of 81 (65–104) mg/dL. Twenty-one specimens (19%) had glucose content below 45 mg/dL. There were no discrepancies in glucose findings between the Statstrip® and the Accu-Check® and serum glucose levels (reference process), with an average bias (95 percent CI) of 2.8 (6.2, 12.4) mg/dL for the Statstrip® and 1.8 (6.7, 10.3) mg/dL for the Accu-Check®, respectively.

When the two averages are compared, there is a statistically significant enhance in plasma glucose levels assessed with a glucometer (117.76+39.01) compared to venous blood samples levels recorded with a semi autoanalyzer (108.78+39.05), but no statistical relevance (P>0.05). Individual patients’ blood glucose levels varied by 2 percent to 15% when measured using two different methodologies.

In the normoglycaemic and hyperglycaemic ranges, POC devices have a good correlation with laboratory data, although accuracy is reduced at low glucose concentrations, with differences from real values ranging from 10 to 20 mg/dL (0.55 to 1.11 mmol/L). The precision of these devices reaches its limit at the glucose level that triggers changes in neonatal clinical treatment. As a result, although such devices are helpful for screening, they cannot be used to accurately diagnose newborn hypoglycemia. 2

Hypoglycemia has been linked to cognitive impairment and neuromotor developmental delay. The glucose oxidase technique for detecting blood glucose levels in the laboratory is exact and specific for glucose. The findings are not accessible soon enough for timely suitable treatment since it is generally conducted in the main laboratory. In the NICU, glucometers are usually employed to estimate blood glucose levels. Many investigations have demonstrated that their findings in the normoglycemic and hyperglycemic ranges correlate well with laboratory determined glucose levels, but not in the lower range. 16

In the study on our hands, Agreement between blood sugar and glucometer blood sugar. Showing a significant agreement between venous blood sugar and glucometer blood sugar. Significant positive correlation between venous blood sugar and glucometer blood sugar.

Nuntnarumit et al., 8 reported that Plotted against the means of the two readings is the variance between the glucometer reads (Statstrip®) and the plasma glucose level obtained by the reference technique. The average and agreement limits (±2SD) were 2.8 (−14.1 to 19.7) mg/dL. Plotted against the mean of the two reads is the variance between the glucometer reads (Accu-Check®) and the plasma glucose level determined by the reference technique. The median and agreement limits (±2SD) were 1.8 (−21.3 to 24.9) mg/dL.

Similarly, Reddy et al., 6 reported that When compared to median blood glucose readings (41.8 + 5.4) determined by auto analyzer in central laboratory, B Braun's average value (66.33 + 21.6) was substantially higher (p=0.03).

Finally. We propose that all test instruments be subjected to periodical quality reviews. Weekly quality control may be done using the manufacturer's and laboratory's quality control materials, and comparative studies can be done twice a year. This would enhance patient care in general. More research is needed that compares capillary and venous blood, as well as one with a bigger sample size and one that completely explores all of the procedures involved in using the glucometer and the laboratory.

CONCLUSION

The median glucose level in capillary blood samples measured with a glucometer are greater than those measured using a conventional technique in venous plasma samples, although the difference is statistically significant. As a result, glucometers cannot be utilized at the bedside as a better option for out-of-hospital identification or in emergency scenarios. Capillary blood glucose measured using a glucometer is acceptable, but venous plasma glucose levels should be validated for diabetes mellitus diagnosis and monitoring.

REFERENCES


