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Implementation and validating transcutaneous bilirubinometry for neonates

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ABSTRACT

During the first week of life all newborns have increased bilirubin levels by adult standards, with approximately 60% of term babies and 85% of preterm having visible jaundice. A significant reduction in serum bilirubin analysis which is traumatic and painful, could be achieved after implementation of transcutaneous bilirubin (TCB) measurements in preterm babies. Measurements made on the forehead and sternum have the best correlation with TSB.

Objectives: Is to evaluate the use of non-invasive transcutaneous spectrophotometer, its efficiency and the influence of the site of measurement of transcutaneous bilirubin (forehead and sternum) on the accuracy of bilirubin levels.

Subjects and methods: This study was conducted on 316 clinically jaundiced neonates in NICU and postnatal clinics of Ain-Shams University Hospital, El Monira Governmental Public Hospital and El Amreky Private Hospital. Neonates of both sexes and gestational age $\geqslant$30 weeks were included, with no hemolytic disease, no known skin disorders or receiving phototherapy or exchange transfusions. Transcutaneous bilirubin using Minolta JM-103 probe from sternum and forehead was measured and compared to serum bilirubin levels.

Results: There was statistically significant correlation between TSB and TCB in all the groups of studied cases, but was slightly higher in the cases with bilirubin measured in postnatal age of $\leqslant$3 days. In preterm newborns, measurement of TCB from forehead was less accurate than from sternum.

Conclusion: Noninvasive TCB measurement by Minolta JM-103 has demonstrated significant accuracy compared to TSB measured by clinical laboratory methods in all cases with better accuracy in cases of IHB. TCB measurement over sternum is more accurate than forehead.

Introduction

Jaundice (icterus) is the most common condition that requires medical attention in neonates.[1,2] Neonatal serum bilirubin (SB) concentrations typically increase until 3 or 4 days after birth, and, ultimately, up to 60% of healthy neonates will have hyperbilirubinemia in the first week of life. As such jaundice has been the most common cause for readmission after early discharge.[3,4]

Once bilirubin levels are more than 15 mg/dl, it results in staining of soles and palms.[5] For most neonates, this is a benign occurrence; however, the neonates with the highest bilirubin values are at increased risk for developing kernicterus.[4,6] Early recognition of hyperbilirubinemia is cardinal significance and requires evaluation in the form of non-invasive screening.[1,7]

SB measurements that are compared with an age-specific normogram are the standard for identifying neonates at an increased risk for kernicterus.[4,8]

For newborns, the majority of the samples are taken by heelstick, which can be painful and involves other potential complications of blood collection, including infection and possibly osteomyelitis.[9]

Bilirubin levels can also be measured transcutaneously by a transcutaneous bilirubinometer. Transcutaneous bilirubin (TCB) level measurements may be accurate when a photo-opaque patch is applied to the baby's skin (normally the forehead) whilst the baby is receiving light bank phototherapy and the transcutaneous bilirubin level measurement is performed on the skin that has not been exposed to phototherapy.[10]

Transcutaneous bilirubin (TCB) measurements have demonstrated linear correlation with SBRs and several investigators have

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recommended their use as a screening device to detect clinically significant jaundice and thus decrease the need for frequent blood sampling in the well term infant.[11] The forehead is the most frequent site of transcutaneous bilirubin measurement in clinical practice.[1]

The potential harms associated with under diagnosis of moderate to severe jaundice include; sensorineural hearing loss. bilirubin encephalopathy (hypertonia, arching, opisthotonos, high pitched cry) and kernicterus.[12]

Subjects and methods

This study was carried out on 316 clinically jaundiced neonates in NICU and post-natal clinics of Ain-Shams University Hospital, El Monira Governmental public Hospital and El Amreky Private Hospital.

Neonates of both sexes and of any skin color with gestational age $\geqslant$30 weeks, with no hemolytic disease, no skin disorders, not receiving phototherapy or exchange transfusions were included in the study. Also neonates with major congenital anomalies at forehead or skin were excluded.

All cases were subjected to the following: Thorough history taking laying stress on:

- Gestational age, postnatal age, mode of delivery, Maternal illnesses; DM, HTN, UTI.
- Factors that might lead to sepsis: as premature rupture of membranes, maternal fever, vaginal discharge.
- Scanty breast milk & delayed passage of meconium.
- Family history of jaundice in a previous sibling.

The following investigations were done to all neonates: Measuring transcutaneous bilirubin (TCB) level using the *Konica Minolta/Air Shields JM 103, Jaundice Meter (JM103).*

- Measuring Serum bilirubin (Total & direct fractions) in laboratory using the method of direct spectrophotometry.
- In this study, the Minolta JM-103 probe was placed against the forehead (halfway between the headline and the glabella, making consecutive determinations, one-centimeter apart) and sternum (five measurements, from the suprasternal notch to the xiphoid process, one-centimeter apart) of the infant in a supine position. Then a computerized average of three consecutive readings over each measurement site was displayed as the transcutaneous bilirubin (TCB) level in mg/dl.
- Blood samples were drawn from a peripheral vein for serum bilirubin (SB) within 10 min of transcutaneous measurement.

A difference of greater than 5% between serum and transcutaneous was considered significant to account for the fact that there is a small analytic variation in any laboratory measure.

Ethical approval of studies

Written informed consent was obtained from the parents or guardians of the neonates who served as subjects in the study.

- The studied cases were classified into groups according to type of hyperbilirubinemia, skin color, gestational age, bodyweight and postnatal age:

According to type of hyperbilirubinemia
they were classified into two groups;

1. Group of indirect hyperbilirubinemia: included 282 neonates with elevated serum unconjugated bilirubin.
2. Group of direct hyperbilirubinemia: included 34 neonates with elevated serum conjugated bilirubin.

According to skin color
They were classified into two groups;

1. Group of white skin color: included 234 neonates with white skin color.
2. Group of brown skin color: included 82 neonates with brown skin color (relatively darker than the other.

According to gestational age
They were classified into two groups;

1. Group of preterm neonates: included 46 neonates with gestational ages of less than 37 weeks.
2. Group of full-term neonates: included 270 neonates with gestational ages of more than 37 weeks.

According to bodyweight
They were classified into two groups;

1. Group of bodyweight of $\leqslant$2 kg: included 76 neonates.
2. Group of bodyweight of >2 kg: included 240 neonates.

According to postnatal age
They were classified into three groups;

1. Group of $\leqslant$3 days postnatal age: included 97 neonates with bilirubin measured at age of $\leqslant$3 days of life.
2. Group of 3 to 7 days postnatal age: included 127 neonates with bilirubin measured at age of 3 to 7 days of life.
3. Group of >7days postnatal age: included 92 neonates with bilirubin measured at age of >7 days of life.

Statistical methodology

Statistical analysis of data was done by IBM computer using SPSS (Statistical program for social science) as follows:

- Description of quantitative variables as mean, SD and range.
- Description of qualitative variables as no (numbers) and % (percents).
- Chi-square test was used to compare two independent groups as regard a quantitative variable.
- Paired *t*-test was used to compare quantitative variable in the same group.
- Correlation coefficient test was used to rank different variables against each other's positively or negatively.
- *The results were considered to be*: Statistically significant at P value <0.05, Highly significant at P value <0.001, Insignificant at P value >0.05.

Results

- 316 neonates were included in the study. They were 160 females (50.6%) and 156 males (49.3%) with a female to male ratio 1.03:1. Their postnatal ages ranged from 24 h to 15 days with a mean of 7.1 ± 6.3 days. Their gestational age ranged from 32 to 42 weeks with a mean of 38.2 ± 1.8 weeks. Their body weight ranged from 1290 g to 4600 g with mean 2954.8 ± 100 g.

In the present study, 168 neonates (53%) were delivered by ceserian section and 148 (46.8%) neonates came from vaginal