

## Role of Subcutaneous Bilirubinometre in the Evaluation of Bilirubin Level in Neonatal Jaundice

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### ABSTRACT

**Objective:** To record the demographic features of neonates presenting with jaundice, identify their cause, and co-relate bilirubin levels obtained by subcutaneous bilirubinometre with a standard biochemical method.

**Study Design:** Cross-sectional study

**Place and Duration of Study:** Nursery of Combined Military Hospital, Malir Cantt Karachi, from Jul to Dec 2020.

**Methodology:** A total of 100 cases of neonatal jaundice were enrolled using a systematic random sampling technique. The demographic data of enrolled neonates and risk factors for jaundice were recorded. Their bilirubin levels were recorded using transcutaneous bilirubinometre (TCB) JH-2. Serum bilirubin levels were analyzed at the same time and recorded.

**Results:** Out of 100 neonates, 61(61 %) were male. Risk factors for jaundice included exaggerated physiological 70(70%), prematurity 11(11%), Rh incompatibility 9(9%), G6PD deficiency 5(5%). For all weight ranges, mean TCB values significantly correlated with mean serum bilirubin level ( $p$ -value <0.001) with a co-relation coefficient of 0.683 and device reliability of 74%.

**Conclusion:** Transcutaneous bilirubinometre can be considered a reliable tool to assess bilirubin for screening neonatal jaundice in term and pre-term neonates.

**Keywords:** Neonatal jaundice, Risk factors, Transcutaneous bilirubinometre.

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### INTRODUCTION

Neonatal jaundice is the common neonatal health problem affecting 60% of term and 80% of the pre-term neonates.<sup>1</sup> Although it is primarily a benign self-limiting condition yet bilirubin reaching a certain serum level can cross the blood-brain barrier, deposit in the basal ganglia of the brain and cause encephalopathy and kernicterus, which is the leading cause of neonatal jaundice-related deaths.<sup>2</sup> Pathological jaundice with serum bilirubin crossing certain pre-identified limits needs treatment with phototherapy or exchange transfusion (depending upon serum bilirubin level, underlying aetiology, body weight, age at presentation) to prevent bilirubin related toxic encephalopathy.<sup>3,4</sup> It all necessitates the frequent measurement of serum bilirubin levels, may require hospital admission, creates parental agony and puts an economic burden on them.<sup>5</sup>

Clinical estimation of the severity of jaundice is not a reliable method, especially in darkly pigmented neonates. The gold standard method for measuring serum bilirubin is biochemical testing based on the van den Bergh reaction.<sup>6</sup> Transcutaneous bilirubinometre is an easy, non-invasive, painless and time-saving

alternative to the conventional biochemical method of bilirubin level measurement.<sup>7</sup> Several studies have been conducted to validate its use. Some of them observe a good correlation between total serum bilirubin and transcutaneous bilirubin and advocates its use as a suitable substitute for standard method.<sup>8,9</sup> While in some studies, marked discrepancies were observed in bilirubin levels obtained by two methods.<sup>10</sup> The study objectives were to record the demographic features of neonates presenting with jaundice and identify the cause of jaundice in the study population, and to co-relate bilirubin levels obtained by subcutaneous bilirubinometre with a standard biochemical method.

### METHODOLOGY

The cross-sectional study was conducted at the Nursery of Combined Military Hospital, Malir Cantt from July 2020 to December 2020, after ethical approval from the Ethical Review Board (ERC approval certificate number 1440/2019/Trg/adm dated 31 Jan 2020). Sample size was calculated using formula  $n = [(Z\alpha + Z\beta)/C]^2 \pm 3$  where  $C = 0.5 \times \log [(1+r)/(1-r)]$ ,  $r =$  co-relation (taken as 0.82 with 95% confidence level and 80% power of test),  $Z\alpha = 95\%$  and  $Z\beta = 80\%$ .<sup>11</sup>

**Inclusion Criteria:** The cases of neonatal jaundice were enrolled irrespective of gestational age at birth and the cause of jaundice.

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**Exclusion Criteria:** Sick neonates and those having conjugated hyperbilirubinemia were excluded from the study.

Informed consent was taken from parents before the enrolment of their neonates. The study used the transcutaneous bilirubinometre (TCB) JH-2 of Zhengzhou Dison Instrument and Meter Co., Ltd. The site selected for transcutaneous bilirubin level recording was the sternum. The level was recorded by trained staff. Within five minutes of recording level, a venous blood sample of 1.5ml was taken with a disposable syringe by trained staff. It was immediately sent to a laboratory for serum analysis.

Statistical Package for Social Sciences (SPSS) version 21.0 was used for the data analysis. Data was analyzed using SPSS version 20. The comparison of variables was made using the chi-square test. The *p*-value of <0.05 was considered significant. Pearson correlation coefficient was also calculated.

**RESULTS**

A total of 100 neonates were enrolled in the study. About 40 neonates presented within the first three days of their life, while 60 neonates had ages between 4-7 days. Almost one third study population 36(36.0%) were low birth weight (1.5kg-2.5kg), while 39(39.0%) had between 2.6-3.0kg weight, 18(18.0%) had between 3.1-3.5kg and 7(7.0%) had weight between 3.6kg-4.5kg. The gestational age of the enrolled neonates is shown in Table-I, where 87% of neonates were born full term. The etiological distribution of jaundice is shown in Table-II, showing that exaggerated physiological jaundice was the most frequently identified aetiology.

**Table-I: Gestational age of Study Population (n=100)**

Gestational Age	Frequency
28 to 32 weeks	3
33 to 36 weeks	10
37 to 40 weeks	87
Total	100

**Table-II: Risk factors for Jaundice in Study Population (n=100)**

Risk Factors for Jaundice	Frequency
Rh incompatibility	9
ABO incompatibility	3
Physiological/exaggerated physiological	70
G6PD deficiency	5
Prematurity	11
Cephalhematoma	2
Total	100

The mean serum bilirubin level of the neonates was 12.54±2.72 (range 8-18mg/dl ), and the mean transcutaneous bilirubin value was 13.16±2.53 (range 8-20mg/dl). There was a positive correlation between

mean serum bilirubin and mean TCB value with a Karl Pearson correlation coefficient of 0.683 and *p*-value <0.001 (Table-III).

**Table-III: Serum Bilirubin Levels with Transcutaneous Bilirubinometre Values for Different Weight Ranges (n=100)**

Weight Range	Study Groups		<i>p</i> -value
	Group A (Seum Bilirubin Levels) n=100	Group B (Transcutaneous Bilirubinometer Value) n=100	
1.5-2.5kg (Mean±S.D)	12.39±1.517	13.08±2.034	0.003
2.6-3kg (Mean±S.D)	12.33±3.303	13.10±2.532	0.001
3.1-3.5kg (Mean±S.D)	13.28±3.196	13.44±3.451	<0.001
3.6-4.5kg (Mean±S.D)	12.57±2.936	13.14±2.610	0.009

**DISCUSSION**

As neonatal jaundice is a common neonatal health issue so, considering the disease burden, a lot of research work has been carried out to seek possible ways for the correct clinical assessment of jaundice (which sometimes is confusing with a high probability of inaccuracy) and to devise alternative ways for the reliable judgment of bilirubin levels. TCB was invented in 1980 as a suitable alternative to conventional laboratory methods, was tested for precision and accuracy, and its use was suggested for jaundice screening.<sup>11</sup> With advancing technology, gradually, better and more accurate models of TCBs are becoming available. Currently, TCB is in common practice worldwide since its reliability and co-relation with the gold standard method have been tested positively in many studies. It is an easy bedside procedure, giving immediate results, saving time, economy and prick-related complications. Different types of TCBs are in use in different neonatal setups in Pakistan. One of them is JH-2 which is used in our nursery. The recording technique is simple, easy to understand and reasonably practicable.<sup>10,11</sup>

Our study found a significant correlation between serum bilirubin levels and bilirubin values obtained by TCB. Comparable results were obtained in recent local and international studies. Saeed *et al.* found a significant positive correlation between the bilirubin levels obtained by the two methods.<sup>12</sup> In Agha Khan Hospital Karachi, Hussain *et al.* conducted a study to introduce TCB readings nomogram after validating its accuracy.<sup>13</sup> Anum and Hafeez proved TCB accuracy in a study conducted in Lahore only in term neonates.<sup>14</sup> However, in our study, bilirubin levels obtained by the

two methods also showed significant positive correlation in pre-term neonates. The same positive correlation was found in another study, where study population comprised only pre-term neonates.<sup>15</sup> Therefore, in most of the recent studies, values of the TCB significantly co-related with serum bilirubin levels as with advancement in technology TCBs with gradually improving efficacy are now available.

Most of our study population (87%) delivered full-term, although neonatal jaundice is more common in pre-term neonates, a fact that is well-proven in literature and clinical practice. In our study, 33% of the jaundiced neonates were delivered through the vaginal route. Rest 67% of cases were delivered through caesarean section. This ratio of delivery routes could be just by chance, and our study was not aimed at finding the association of the mode of delivery with the risk of neonatal jaundice. However, the vaginal delivery route was considered a risk factor for developing neonatal jaundice in an African study.<sup>16</sup> Frequency table for risk factors for jaundice in our study results showed that exaggerated physiological jaundice was the most commonly observed aetiology of jaundice in otherwise healthy neonates (observed in 70% of cases) followed by prematurity (observed in 11% of cases). Rhesus incompatibility as a sole risk factor was observed in 9% of cases. Numerous studies have been conducted to see the prevalence of risk factors for neonatal jaundice. Meena *et al.* identified ABO incompatibility as the common risk factor, followed by prematurity and sepsis.<sup>17</sup> Sample size of that study was sufficient (>500), and several risk factors were studied. While Scafford *et al.* observed male gender, high birth weight, feeding difficulties, prolonged labour, primiparity, oil massage and ethnicity as significant risk factors.<sup>18</sup> G6PD deficiency, prematurity, infections and ABO incompatibility were found to be significantly responsible for neonatal jaundice in an African study.<sup>19</sup> We excluded sick neonates from our study. For this reason, some important risk factors like neonatal sepsis and birth asphyxia could have been missed for evaluation.

Many neonatal set-ups have replaced conventional serum bilirubin measurement with TCB use. For screening purposes, it is a good alternative. However, for neonates who are candidates for exchange transfusion, still, more studies are required to evaluate this replacement. Moreover, the decision for replacement can be individualized based on the accuracy of the available device. Establishing a normogram based on

TCB readings is a better idea to justify the replacement of serum bilirubin measurement with TCB use alone.

### CONCLUSION

TCB is a reliable tool for neonatal screening since its readings co-related well with serum bilirubin levels in patients of neonatal jaundice independent of age, body weight and gestational age at delivery. Neonatal jaundice is more frequent in male neonates and those delivered through cesarean section. Physiological/exaggerated physiological jaundice is the most common aetiology of neonatal jaundice among healthy neonates.

**Conflict of Interest:** None.

### Authors Contribution

Following authors have made substantial contributions to the manuscript as under:

AM: & STHZ: Data acquisition, data analysis, drafting the manuscript, approval of the final version to be published.

AS: & WS: Study design, drafting the manuscript, data interpretation, critical review, approval of the final version to be published.

BF: & BR: Critical review, concept, data acquisition, drafting the manuscript, approval of the final version to be published.

Authors agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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