Evaluating the Phototherapy Practice and Adherence to Guideline in Managing Neonatal Hyperbilirubinemia in an Indonesian Tertiary Referral Hospital

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ABSTRAK

ABSTRACT

A guideline for the management of hyperbilirubinemia in infants has recently been established in Indonesia, but physician acceptance and adherence to these standards are unknown. The objective of this study was to assess the current state of phototherapy practice and to determine if this was in-line with the Indonesian Hyperbilirubinemia Guideline. The study was done in the neonatal care units of Dr. Soetomo Hospital in Surabaya, Indonesia. We evaluated all babies on phototherapy between September 2019 and September 2020. The conformity to core elements in the national guideline was assessed on hyperbilirubinemia management for 89 infants, two-third of these being preterm and low birth weight. One-third of infants were commenced on phototherapy just based on transcutaneous bilirubin measurement. A significant proportion of infants had phototherapy ceased without bilirubin level assessment or confirmation that jaundice had significantly resolved. Almost all (95.9%) of the phototherapy sessions did not conform to guidelines, with the most common being inadequate exposure of the body surface area to light. In spite of a guideline adapted to be pragmatic and applicable to the local setting, healthcare practitioners were not sufficiently aligned, thus an urgent reassessment of the implementation and adoption of the current hyperbilirubinemia guideline is required.

Keywords: Indonesia; intensive phototherapy; hyperbilirubinemia guideline; LMIC; neonatal mortality; non-conformity

INTRODUCTION

Neonatal hyperbilirubinemia is becoming one of the world’s top reasons for hospitalisation during the first week of life (Burke et al. 2009). It is estimated that over 400,000 newborn infants are affected by jaundice each year, with approximately three-quarters of them residing in South-East Asia, Sub-Saharan Africa and China (Bhutani et al. 2013a; Gourley et al. 2005; Yu et al. 2017). The incidence of severe hyperbilirubinemia, defined
as an increase in bilirubin levels over 340 mmol/L, is estimated to be approximately 6.8% in Indonesia, with a 2% incidence rate of Bilirubin-Induced Neurological Dysfunction (BIND) (Greco et al. 2016). Phototherapy (PT) is an established and effective treatment for neonatal hyperbilirubinemia. In a low and middle-income country (LMIC) setting, late detection or delayed therapy may be attributing factors to BIND (Olusanya et al. 2015). These may be associated with factors such as poor risk assessment, insufficient bilirubin testing and post PT follow-ups, improper use of PT lights and equipment maintenance (Greco et al. 2016; Olusanya et al. 2016; Sampurna et al. 2019). Many of these may be related to a lack of established protocols or guidelines (Olusanya et al. 2014).

Clinical practice guidelines are recommendations made in order to assist practitioner in the diagnosis and management of patients to maintain health care quality and reduce inappropriate interventions, such as in the care of neonatal hyperbilirubinemia (National Center for Complementary and Integrative Health 2022). Recognising the importance of guidelines, the Indonesian Pediatric Society (IPS) in collaboration with the Ministry of Health develop a standardised guideline for the care of hyperbilirubinemia in infants, including the use of PT (Menteri Kesehatan Republik Indonesia 2019). Despite the plethora of guidelines, concerns with physicians’ understanding of current standards as well as adhering to them in everyday practice remains questionable (Mateo et al. 2013). In a local survey done in 1998 regarding pediatricians’ awareness and attitudes toward the American Academy of Pediatrics “Practice Parameter for Hyperbilirubinemia in Newborns”, approximately two-third of Indonesian pediatricians were aware of it but only 28% changed their management according to this guideline (Christakis & Rivara 1998). Therefore, the objective of this study was to assess the current state of PT practice in a tertiary hospital in Indonesia and to determine if these were in-line with the newly formulated Indonesian Hyperbilirubinemia Guideline.

**MATERIALS AND METHODS**

**Study Design and Participants**

This descriptive study was conducted at the Dr. Soetomo Hospital in Surabaya, Indonesia. The new Indonesian guideline was launched and promoted in this hospital on March 19, 2019 in a one-day workshop to all the pediatric division residents, trainees, and nurses. The new Indonesian Hyperbilirubinemia guideline was adopted from several guidelines, including the American Academy of Pediatrics (AAP) guideline, National Institute for Health and Care Excellence (NICE), and Dutch Guideline for hyperbilirubinemia, but then further adapted according to the resource limitation in Indonesia. It is the first guideline formulated to be used nationally by all health workers, including doctors, midwives, and nurses, in the management of neonatal
hyperbilirubinemia in Indonesia. The guideline was formulated by IPS which was then legitimised by the Ministry of Health of Indonesia. In the implementation, the Ministry of Health and local governments with the help of professional associations shall supervise and conduct training accordingly. The study was conducted about six months after this new guideline had been introduced, between September 2, 2019, and September 20, 2020. The patient inclusion criteria were; (i) infants admitted to or delivered at the Dr. Soetomo Hospital during the study period; (ii) having obtained informed consent from the parent/guardian; and (iii) infants undergoing PT. PT was prescribed by pediatric trainees under the supervision of neonatology consultants, and the PT was administered accordingly by the nurses. The protocol in this hospital regarding PT duration was solely based on the assessment and discretion of the attending pediatrician and prescribed based on a block of 24 or 48 hours, which had been predetermined before PT was commenced.

In studying the conformity to guidelines for hyperbilirubinemia management, seven factors were considered i.e. (i) the methods of bilirubin estimation used as the basis in initiating or ceasing PT; (ii) the traditional curtain-cover used to enhance PT; (iii) distance between the infant and the PT light source; (iv) the application of eye covering during PT; (v) the percentage of body surface area (BSA) exposed to PT light; (vi) PT light irradiance (µW/cm²/nm); and (vii) post-PT bilirubin level assessment. 

Study Materials

The collection of data was performed by the same investigator (MPM) in this study. A regularly calibrated Ohmeda BiliBlanketmeter™, an intensity meter was used to measure the irradiance of PT devices and a measuring tape was used to determine the distance between the light sources and the infants. The study was conducted at random times without prior notice to the attending staff. Throughout the study process, the investigator observed each of the ongoing PT practices on-site to determine whether the procedures were being conducted in adherence to the guidelines, including the use of appropriate eye coverings, placement of curtains over the incubators/cribs, the distance between the light source and the infants (in cm), percentage of body area exposed to the PT light and the measurement of irradiance using the above-mentioned intensity meter. Additionally, secondary descriptive data comprising birth weight, gestational age, risk factors, and bilirubin investigation results were obtained from the subjects' medical records. Classification of appropriateness in treatment was based on the BiliNorm, a web-based nomogram used as reference for PT in the Indonesian Hyperbilirubinemia Guideline (Sampurna et al. 2022), and post-PT serum bilirubin assessments were recorded. The treatment classification comprised prompt treatment, over-treatment, and inappropriate treatment. Over-treatment corresponded to infants who received PT despite having total
serum bilirubin (TSB) levels below the PT threshold. Prompt treatment was defined as accurate treatment given following the Indonesia hyperbilirubinemia guideline, while inappropriate treatment corresponded to PT practice not in accordance to the new Indonesian hyperbilirubinemia guideline. The pre-PT Transcutaneous Bilirubin (TcB) data were regrouped under infants with gestational age of ≥35 weeks or <35 weeks. The pre-PT TcB from infants with gestational age ≥35 weeks were plotted onto Maisels & Kring (2006) TcB nomogram, whereas the pre-PT TcB for infants <35 weeks were adjusted based on TcB + 50mmol/L >70% TSB cutoff (Oh et al. 2003). Resolution of jaundice was evaluated based on the post PT serum bilirubin level, in which infant with post PT TSB level below the PT threshold level was defined as having resolved jaundice.

**Ethical Consideration**

All study protocols were approved by Ethical Committee of Clinical Research Unit Dr Soetomo General Hospital (IRB Number 1060/KEPK/III/2019). All methods were performed in accordance with guideline in the conduct and dissemination of observational studies. Informed consent was obtained from all subject’s parent/guardian.

**Statistical Analyses**

The collected data were analysed using the Statistical Program for Social Science software for Windows (version 21; IBM Corp., Armonk, N.Y., USA). All quantitative variables were estimated using the average of data distribution [median (range)]. The comparison between the 24 hours and 48 hours PT were done using Mann Whitney test (birth weight, gestation, post-natal age, pre-PT bilirubin level, post PT bilirubin level) and Pearson’s chi-square test (state of therapy, jaundice resolution). The difference in PT management between the preterm and term group were assessed using Mann Whitney test (birth weight, gestation, post-natal age, measured PT intensity, pre-PT bilirubin level, post PT bilirubin level) and Pearson’s chi-square test (PT duration, jaundice resolution). P-value <0.05 was considered statistically significant.

**RESULTS**

Only 99 of the jaundiced infants hospitalised during the research period were available and met the inclusion criteria of this study. Ten parents declined to participate in the research, the remaining 89 infants were then enrolled. In total there were 97 PT sessions observed. More than half of the infants in this study were female (56.2%), majority were preterm (64%) and had low birth weight (68.5%). Further characteristics of the infants in this study were in Table 1. Pre-PT bilirubin level as guide for the initiation of PT was predominantly based on TSB (n=62; 69.7%) whereas only one-third were based on TcB (n=27; 30.3%). Meanwhile, post-PT bilirubin level measurement was entirely based on TSB.

Among the 27 infants who started
their PT treatment based on TcB level, 15 infants had gestational ages of ≥35 weeks, meanwhile the remaining 12 infants were less than 35 weeks. Almost all (88.9%) TcB levels were above the cut-off level of 95th percentile, with the exception of 3 infants (Figure 1). Of note, more than one-third (37%) of the infants who underwent PT based on TcB level did not have post-PT bilirubin level follow-up. Majority (79.8%) of the infants in this study received only 24 hours PT. The reported rate of jaundice resolution was around 80% (Table 2). The 24 hours group was significantly older in postnatal age compared to the 48 hours group when starting the PT treatment (post-natal age 4 days vs 3 days; p value 0.028). Conversely, the 48 hours group had earlier onset and more severe jaundice, and less than three-quarter resolved despite this longer block of therapy and a tendency towards more intensive PT use. Even so, a significant proportion of infants had insufficient PT as treatment was ceased even without resolution or no bilirubin check was made to determine if PT was still indicated (Table 2). In reviewing the PT light efficiency, the overall median bilirubin

<table>
<thead>
<tr>
<th>TABLE 1: Demographic characteristics of the newborn infants that underwent PT</th>
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</thead>
<tbody>
<tr>
<td><strong>Total infants</strong></td>
</tr>
<tr>
<td>Gender, n (%)</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Gestation, weeks, median (Range)</td>
</tr>
<tr>
<td>Preterm, n (%)</td>
</tr>
<tr>
<td>Post-natal age at PT, days (Range)</td>
</tr>
<tr>
<td>Birth Weight, g, median (Range)</td>
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<tr>
<td>Low Birth Weight, n (%)</td>
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<tr>
<td>Pre-PT Bilirubin level, mmol/L TSB, median (Range) (n=62)</td>
</tr>
<tr>
<td>TCB, mean ± SD (n=27)</td>
</tr>
<tr>
<td>Post PT Bilirubin level, mmol/L TSB, median (Range) (n=74)</td>
</tr>
<tr>
<td>Infants receiving PT, n (%)</td>
</tr>
<tr>
<td>24 hours</td>
</tr>
<tr>
<td>48 hours</td>
</tr>
</tbody>
</table>

TSB= Total serum bilirubin; TCB= Transcutaneous bilirubin; PT= Phototherapy

FIGURE 1: Plotting of pre-PT TcB level of infants with gestational age ≥35 weeks based on Maisels & Kring (2006) TcB nomogram [63x39 mm (300 x 300 DPI)]
The decline rate in the first 24 hours was 3.5 mmol/L/hour. Intensive PT showed a remarkably more rapid bilirubin decline of 5.5 mmol/L/hour. PT lights that had subtherapeutic irradiance only achieved a median rate of bilirubin decline of 1.9 mmol/L/hour.

There were two-fold more preterm infants receiving PT in this study than term infants. Overall, pre-PT TSB was significantly higher in the term infant but there was no significant difference in pre-PT TCB between the preterm and term infants. Preterm infants tended to receive PT with lights of significantly higher irradiance (Table 3).

### Conformity to Guideline in PT Practice

Almost all (95.9%) of the PT sessions observed in this study was non-conforming, with only 4 (4.1%) adhered to the current Indonesian Hyperbilirubinemia Guideline. Out of 93 cases of non-conforming PT practice, the most common non-conformity determinant was failure to expose up to 80% of the infant’s surface.
area to the PT light (91 cases, 97.8%), followed by curtain-cover usage to enhance PT (58 cases, 62.3%), and starting treatment when bilirubin level was below the therapeutic threshold for PT (43 cases, 46.2%). Almost one-fifth (16.1%) of the PT session was started without complete jaundice risk factor assessment. A small proportion (7.5%) of the PT light used had irradiance below the therapeutic irradiance. More than 1 in every 10 infants (16.1%) did not have post-PT bilirubin check to confirm jaundice resolution (Figure 2).

**DISCUSSION**

The population studied here were largely lower risk groups with a milder form of hyperbilirubinemia (average peak SB of less than 250 mmol/L) at the age of onset of day 4 of life. Consequently, this might explain jaundice resolution in the majority of cases who only received 24 hours of PT. The PT light intensity

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**TABLE 3: Comparison of PT treatment between term and preterm infants**

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Preterm (n=57)</th>
<th>Term (n=32)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Birth weight, g, median (Range)</td>
<td>1800 (900 – 3200)</td>
<td>2900 (1700 – 4100)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Gestation, weeks, median (Range)</td>
<td>34 (30 – 36)</td>
<td>38 (37 – 41)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Post-natal age at PT, day, median (Range)</td>
<td>4 (0 – 21)</td>
<td>4 (0 – 9)</td>
<td>0.651</td>
</tr>
</tbody>
</table>

Pre-PT Bilirubin level, mmol/L

<table>
<thead>
<tr>
<th>TSB</th>
<th>n (%)</th>
<th>median (Range)</th>
<th>n (%)</th>
<th>median (Range)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSB</td>
<td>37 (64.9)</td>
<td>216.8 (160.4 – 480.9)</td>
<td>25 (78.1)</td>
<td>259 (171 – 477.1)</td>
<td>0.041</td>
</tr>
</tbody>
</table>

Post PT Bilirubin level, mmol/L

<table>
<thead>
<tr>
<th>TSB</th>
<th>n (%)</th>
<th>median (Range)</th>
<th>n (%)</th>
<th>median (Range)</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td>TSB</td>
<td>46 (80.7)</td>
<td>155.1 (57.6 – 354)</td>
<td>28 (87.5)</td>
<td>165.3 (42.4 – 418.1)</td>
<td>0.660</td>
</tr>
</tbody>
</table>

PT duration, n (%) 24 hours 45 (78.9) 26 (81.3) 0.795

Measured intensity of PT light used, median (Range) 26.7 (6.2 – 82.3) 16 (7.8 – 79.9) 0.042

Irradiance intensity >30 µW/cm²/ nm, n(%) 23 (40.4) 10 (31.3) 0.394

Jaundice Resolution, n (%)

| Resolved jaundice* | 41 (71.9) † | 26 (81.3) ‡ |
| No post-PT follow up | 11 (19.3) | 4 (12.5) |
| Unresolved jaundice | 5 (8.8) § | 2 (6.3) | 0.694 |

* when the measured TSB level post PT is below the PT threshold
† N=2 had jaundice resolution after another round of PT (n=1, 24 hours; n=1, 48 hours)
‡ N=3 had an additional round of PT despite bilirubin levels below the threshold for PT
§ N=1 after two rounds of 24 hours PT; N= 2 cases with significant rebound jaundice
TSB= Total serum bilirubin; TCB= Transcutaneous bilirubin; PT= Phototherapy
used in treating the preterm infant was significantly higher compared to the PT for term infants in this study (median of 26.7 µW/cm²/nm vs 16 µW/cm²/nm; p 0.042), although there was no disparity in the pre-PT bilirubin levels of the two groups. Moreover, the proportion of preterm infants who received longer PT duration (48 hours block) appeared higher and were possibly overtreated when compared to the term infants. This practice may have evolved based on the attending, recognising that the preterm and lower birth weight infants are at a greater risk of hyperbilirubinemia and predisposed to BIND if not aggressively treated. The results of our study also suggested a tendency towards a “prophylactic” PT approach. The inclination towards a more aggressive PT approach, may also be reflected in the modified Bhutani nomogram in this modified local guideline (Figure 3), in which the

FIGURE 2: Non-conformity determinants in phototherapy practice based on Indonesian Hyperbilirubinemia Guideline (Menteri Kesehatan Republik Indonesia 2019)

FIGURE 3: Modified TSB phototherapy nomogram for infants with gestational age ≥35 weeks based on the current Indonesian Hyperbilirubinemia Guideline (Menteri Kesehatan Republik Indonesia 2019)
threshold for PT become lower even for the low risk infant group (Menteri Kesehatan Republik Indonesia 2019). In general, the side effects of PT may be low and this therapy, overall is considered to be safe, but there are several potentially serious and perhaps under-reported long-term consequences, especially in low-birth-weight infants (Faulhaber et al. 2019; Morris et al. 2008; Tyson et al. 2012; Wang et al. 2021).

The present study also showed a substantial use (27%) of TcB as a less invasive alternative method to TSB in determining initiation of PT for jaundiced infants. Of the 27 infants that had TcB pre-PT checks, only three term infants were under the cut off value for PT. Several studies have shown the promising potential with TcB measurement in the management of hyperbilirubinemia, especially in LMICs with limited resources (Cat et al. 2021; Olusanya & Emokpae 2017; Taylor et al. 2016). There are known limitations with TcB whereby, at TSB level of more than 200 mmol/L and in infants with low birth weight, TcB tends to underestimate TSB value (Mohamed et al. 2022; Taylor et al. 2015). It is also important to note that there is still insufficient population data regarding which TcB nomogram is appropriate and applicable to the Indonesian infant population with variable degree of skin pigmentation. Although TcB is a rapid and less invasive detection method compared to TSB measurement, physicians need to be cautious when using TcB to determine the severity of hyperbilirubinemia to initiate PT. Currently, most units in developed countries favour the use of TcB only to monitor the trend of bilirubin levels before ceasing PT and to screen if the infant is safe for discharge. In our study, the use of TcB should at least be applied to the approximately one-third of infants who did not have TSB-check when PT was ceased and whose jaundice may have yet to resolve fully. Some studies have shown that repeated TcB measurement during the first 8 hours of treatment and around 24 hours post treatment combined with visual inspection is more accurate than visual inspection only as a guide in deciding if PT were to continue or safely ceased (Ansong-Assoku et al. 2022; Grabenhenrich et al. 2014; Kaplan et al. 2008).

The present study showed that the management of neonatal hyperbilirubinemia in a tertiary referral hospital in Indonesia is predominantly physician-centred rather than evidence-based following the new guideline. Prior to the formulation of the new guideline, there were several differing hyperbilirubinemia guidelines in Indonesia which had been followed by these pediatricians (Menteri Kesehatan Republik Indonesia 2019). These may have dictated the way they practise for the many preceding years prior to the implementation of the current harmonised new guideline. This could be the reason for the low adherence rate observed in this study (4.1%). This result is consistent with other studies regarding physician adherence to hyperbilirubinemia guidelines (Hameed et al. 2020; Sampurna et al. 2018). A majority of the PT session in this study failed to
provide adequate exposure to PT light, perhaps due to nursing care attention to keep the babies dry on diapers. This may impede the bilirubin decline in severe hyperbilirubinemia and prevent earlier recovery for discharge. Arnolda et al. (2018) in their study have shown the benefit of increasing surface area to PT by using double-sided PT, which was not readily available in Indonesia. A meta-analysis regarding the usage of reflective curtain in PT showed a favourable greater decrease in the TSB, shorter duration of PT and hospital length-of-stay (Van-Rostenberghe et al. 2020). A substantial proportion in the usage of curtain-cover during PT in this study may be influenced by a locally conducted study (Sampurna et al. 2019). The use of curtain-cover to enhance PT has not been incorporated into the Indonesian guideline, but a review may be necessary if this measure merits to be implemented in the local context. Although the patients in this study did not appear to have severe hyperbilirubinemia, it is of concern that many PT sessions were started without proper risk factor assessment, especially to rule out the presence of hemolytic disease and glucose-6-phosphate dehydrogenase (G6PD) deficiency. These were often grouped as jaundiced infants with unknown risk factors (Bhutani et al. 2013b; Erdeve et al. 2018; Pahlavanzadeh et al. 2013). It is important to note that G6PD deficiency is a recognised cause of severe hyperbilirubinemia of rapid onset, and is a significant risk for BIND and kernicterus (Cunningham et al. 2016; Lee et al. 2022).

The present study had some limitations. Firstly, the results from this hospital in East Java limited the generalisation of our findings to the whole of Indonesia. The results may be an overestimation because the study was conducted in a teaching hospital with a different patient population, and resources such as staffing, experienced specialist care and equipment. We suspected that other hospitals may have a different conformity pattern to PT guidelines depending on various differing local circumstances. Secondly, the PT devices used in our study were heterogenous, varying between fluorescent light tubes and light emission diodes (LED), which could be a major confounding factor in the effectiveness of PT on bilirubin clearance. Even so, this variability in the type of PT devices actually reflect the real situation in PT practices in Indonesia as a resource-limited LMIC. Thirdly, we had no follow-up data of the proportion of infants after 24 or 48 hours PT, the rate of rebound hyperbilirubinemia and re-admission for further PT due to inconsistent patient records and traceability. To our knowledge, this was the first study to review the PT practice in accordance to the latest Indonesian Hyperbilirubinemia guideline. It also reported the actual current status of a core treatment outcome in the NICU of a referral hospital in Indonesia and how this may compare against the global standards of care.

CONCLUSION

The present study has revealed a high non-adherence rate to the latest
Indonesian Hyperbilirubinemia Guidelines introduced in 2019. There appeared to be a very presumptive and prophylactic approach in initiating PT without referring to standard nomogram and proper evaluation of risk factors. On cessation of therapy, there was also no prior assessment and efforts in follow-up review. If time and resources are the main limitations, TcB may be a simple diagnostic and rapid monitoring tool recommended for use to guide in the proper PT management of neonates with hyperbilirubinemia in this country. In quality improvement, we recommend further research on the current PT recommendations based on the Indonesian Hyperbilirubinemia Guideline and if there is a need for modifications especially focusing on reviewing the practicality in adoption of modifiable factors that could increase adherence and uptake. The lack of attention and adoption of the guidelines may be the result of unfamiliarity or failure to recognise certain important aspects such as total exposure of the body to lights. In this instance, simple measures such as the use of reflective curtains may increase irradiance when insufficient total body surface area is exposed during PT. Ultimately, regular frequent workshops to educate and raise awareness on these guidelines to all healthcare providers, emphasising on the pitfalls and highlighting the tips to successful implementation, need to be carried out with the support of the government and all hospitals nationwide.

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