

# A Randomised Comparative Study Assessing Parental Anxiety Levels during Bilirubin Measurement in Neonatal Jaundice: A Comparison of Conventional Blood Taking and Transcutaneous Bilirubin Method

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Received: 03 Jul 2024 / Accepted: 30 Aug 2024

## ABSTRAK

Saringan jaundis neonatal adalah penting dalam mencegah perkembangan penyakit kernikterus dan morbiditinya. Bilirubinometer transkutaneus (TCB) adalah alat saringan jaundis neonatal yang berkost rendah, mudah dibawa, serta mempunyai ketepatan yang setara. Alat ini diterima secara baik oleh kebanyakan ibu bapa; namun, impaknya terhadap kegelisahan ibu bapa belum dibuktikan. Satu kajian rawak telah dijalankan di Jabatan Perubatan Kecemasan, Hospital Canselor Tuanku Muhriz (ED HCTM). Ibu bapa yang memerlukan ujian saringan jaundis neonatal telah dibahagikan secara rawak kepada kumpulan TCB atau kumpulan pengambilan darah konvensional (TSB). Skor kegelisahan trait diambil sebelum prosedur, manakala keadaan kegelisahan diukur selepasnya menggunakan soal selidik indeks trait kegelisahan Spielberger (STAI). Skor tersebut direkodkan dan dianalisis. Seramai 97 ibu bapa telah mengambil bahagian dalam kajian ini. Tiada perbezaan signifikan dalam trait kegelisahan antara kumpulan (skor min kumpulan transkutaneus = 39.24, SD = 7.385; skor min kumpulan konvensional = 36.44, SD = 10.173;  $p > 0.05$ ). Kumpulan TCB menunjukkan keadaan kegelisahan yang lebih rendah secara signifikan (skor min = 35.31, SD = 10.05) berbanding kumpulan TSB (skor min = 46.65, SD = 12.63;  $p = 0.000$ ). Keadaan kegelisahan yang signifikan secara klinikal lebih ketara dalam kalangan ibu bapa daripada kumpulan TSB (50%) berbanding kumpulan TCB (22.4%;  $p = 0.005$ ). TCB bukan sahaja mengurangkan keadaan kegelisahan berbanding pengambilan darah konvensional tetapi juga mengurangkan kegelisahan ibu bapa yang signifikan secara klinikal semasa ujian saringan jaundis neonatal. Oleh itu, TCB adalah alat saringan yang lebih baik apabila mengambil kira kegelisahan ibu bapa berbanding TSB.

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*Kata kunci: Jaundis neonatal; jumlah bilirubin dalam darah; keresahan ibubapa; pengesan bilirubin melalui kulit*

## ABSTRACT

Neonatal jaundice screening is important in preventing the progression of kernicterus and its morbidity. The transcutaneous bilirubinometer (TCB) regains popularity as a low-cost, portable neonatal jaundice screening tool whose accuracy is comparable. Its effects on parents are widely accepted as favourable; however, its impact on parental anxiety remains unproven. A randomised study was conducted at the Emergency Department of the Hospital Canselor Tuanku Muhriz (ED HCTM). Parents seeking neonatal jaundice screening were assigned randomly to the TCB or conventional blood-taking (TSB) groups. A trait anxiety score was taken before the procedure, while state anxiety was measured after, utilising Spielberger's state-trait anxiety index (STAI) questionnaire. The scores were recorded and statistically analysed. A total of 97 parents participated in the study. No significant difference in trait anxiety existed between groups (TCB group mean score = 39.24, SD = 7.385; TSB group mean score = 36.44, SD = 10.173;  $p > 0.05$ ). TCB group exhibited significantly lower state anxiety (mean score = 35.31, SD = 10.05) than TSB group (mean score = 46.65, SD = 12.63;  $p = 0.000$ ). Clinically significant state anxiety was more prevalent in parents from the TSB group (50%) than the TCB (22.4%;  $p = 0.005$ ). TCB is superior to TSB for parental anxiety.

**Keywords:** Neonatal jaundice; parental anxiety; serum bilirubin; transcutaneous bilirubinometer

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## INTRODUCTION

Parental anxiety can be characterised as excessive worry by parents concerning the safety and well-being of their children; being afraid of something going wrong, especially matters concerning major events such as medical procedures. To highlight the prevalence of this, a recent study managed to show significant levels of anxiety were detected in 74.2% of parents of children that were about to undergo surgery (Ayenew et al. 2020). If not addressed, it may make it more difficult for the parents to handle new or stressful events (Franck & Spencer 2005). Furthermore, these fears may end up

being externalised through physical or verbal cues, which may be sensed by the child, causing an increase in their anxious state (Bearden et al. 2012), especially when they lack the maturity to understand what is happening. This can lead to poorer compliance and outcomes for both the parent and the child. Measures to allay such anxiety would be beneficial by resulting in boosted parental confidence in the procedure, leading to better care and outcomes in addressing the medical outcomes of their child. For instance, epileptic children with anxious parents were found to have a lower quality of life and care when compared to less anxious

parents. This could further boost parents' confidence and subsequently lead to better care for the child. In the long run, more motivated and confident parents could improve the quality of life for their children. Addressing parental anxiety is crucial, as it can have a direct effect on the child's level of anxiety during the procedure. Moreover, a higher level of confidence among parents towards a procedure or treatment could lead to better care as well as an improved quality of life in the long run. For instance, it has been shown that anxious parents had a lower quality of life care for children with poorly controlled epilepsy compared to parents who were not anxious (Williams et al. 2003). Additionally, less anxious parents and patients would result in reduced stress on the medical practitioners, further contributing to the smoothness of the procedure.

Neonatal jaundice (NNJ) is common among neonates. It affects term and preterm infants, usually for as long as 14 days in term infants and 21 days in preterm infants (Porter & Dennis 2002). It is clinically diagnosed when the serum bilirubin reaches 85 mmol/L or 5 mg/dL (American Academy of Pediatrics Subcommittee on Hyperbilirubinemia 2004). The conventional and gold standard method used for measuring bilirubin levels is total serum bilirubin (TSB). A transcutaneous bilirubinometer (TCB) can reliably screen NNJ up to 205 mmol/L (Romagnoli et al. 2012), although other studies have suggested and accepted levels up to 20 mg/dL or 342 mmol/L (Mussavi et al. 2013).

The choice of screening tool must minimise the psychological impact on the young parent and be more cost-effective

without impacting accuracy. Universal screening for NNJ is important to prevent acute or chronic bilirubin encephalopathy (Bhardwaj et al. 2017). One solution for this is the introduction of the TCB method at the Emergency Department (ED) and primary clinics. Although it is relatively reliable and painless, there is a lack of evidence regarding its effect on parental anxiety.

Based on the above, the current study aimed to determine the effect of TCB on parental anxiety in comparison to the more conventional venepuncture method. Additionally, the study also sought to examine factors that were associated with levels of parental anxiety during the procedure. The findings of this study hold the potential to guide clinical practices towards allaying parental anxiety during NNJ procedures, thereby enhancing both the procedural experience and the overall well-being of families.

## MATERIALS AND METHODS

### Study Design and Population

This was a randomised observational study conducted at the ED of Hospital Canselor Tuanku Muhriz (HCTM). Ethical clearance was obtained from the Research Ethics Committee, at the National University of Malaysia with the research code number UKM PPI.800-1/1/5/JEP-2019-497. This survey included parents of neonates aged less than 14 days of life undergoing NNJ screening at the study centre from the 1st of September 2019 to the 31st of December 2019. Exclusion criteria were transcutaneous bilirubin or capillary bilirubin results that had been obtained from primary care on the same day,

abnormal skin pigmentation such as a café au lait spot, a large mole at the sternum, or any sternal deformity, as well as neonates presented with additional symptoms requiring immediate intervention. Parents with underlying psychiatric illnesses were also excluded from the study.

### **Measurement**

The Spielberger state and trait anxiety (STAI) test, which has proven reliability (Julian 2011) and was previously validated in English (Vitasari et al. 2011) and Malay (Embong et al. 2018), was chosen to measure parental anxiety in this study using either English or Malay version of STAI. The psychological inventory was administered in the form of a questionnaire with two parts: the first, STAI Y-1, consisted of 20 Likert-style questionnaires measuring trait anxiety, while the next portion, STAI Y-2, consisted of another 20 Likert-style questionnaires measuring state anxiety. While the state anxiety score measures the current anxiety state, which is how respondents feel “right now,” using items that measure subjective feelings of apprehension, tension, nervousness, worry and activation or arousal of the autonomic nervous system, the trait anxiety score evaluates relatively stable aspects of “anxiety proneness,” including general states of calmness, confidence, and security (Julian 2011). With a possible score between 20 and 80, the higher score indicated a higher state of anxiety, particularly the score of 40 or higher (Addolorato et al. 1999; Knight et al. 1983). In this study, differences between trait and state anxiety scores were used to gauge changes in anxiety state from baseline trait anxiety. State anxiety scores of 30

suggest moderate anxiety, and scores of 45 suggest severe anxiety (Bunevicius et al. 2013). Clinically significant anxiety in this study was defined as an STAI Y-2 score of 45 or more.

### **Study Protocol**

All parents who presented to the ED at HCTM were screened using the inclusion and exclusion criteria. Parents who satisfied inclusion criteria and had been excluded using exclusion criteria were recruited into the study, and their consents were obtained after an explanation of the study, its benefits, and its risks. Parents were randomised into the conventional TSB group and the TCB screening group using simple randomisation. A software-generated random sequence was generated, and the subsequent procedure was written on top of the questionnaire. Consented parents took a quick questionnaire regarding demography, underlying illnesses, and their pre-test trait anxiety score (STAI form Y-2) while preparing for bilirubin sampling. The type of method was then revealed, and prior consent was obtained before sampling (nonblinding). Venepuncture for TSB sampling was done in the conventional TSB group, and TCB screening was done in the TCB screening group. A post-test state anxiety score (STAI form Y-1) was done after the procedure. The questionnaire was completed in around 5 to 10 minutes. For parents with an infant whose TCB score was more than 250 moles/L, subsequent TSB blood collection was done to maintain the accuracy of the results. Parental anxiety scores would not be recorded after the blood collection in this category, and treatment would not

be delayed as this study only took a few minutes to complete.

### Sample Size Calculation

Based on a recent study on parental anxiety in the ED at the same centre, it was measured that the prevalence (P) of parents coming to the ED for the treatment of their children found to be clinically anxious with an STAI score of more than 49 was 65.7% (Embong et al. 2020). We estimated the population size of 180 parents coming for the screening of jaundice throughout the study based on the number of NNJ cases in the ED from May to July 2018. Using a confidence interval of 95% with a Z value of 1.96, a margin of error (d) of 5%, and a tested population of 180 (N), the sample size (n) was calculated using the formula below (Naing et al. 2006).

$$n = \frac{\frac{Z^2 P(1 - P)}{d^2}}{1 + \frac{Z^2 P(1 - P)}{d^2 N}}$$

$$n = \frac{\frac{1.96 \times 0.657(1 - 0.657)}{0.05^2}}{1 + \frac{1.96 \times 0.657(1 - 0.657)}{0.05^2 \times 180}}$$

$$n = 89.16$$

For this randomised controlled trial (RCT), the minimum calculated sample size necessary to achieve statistically significant results and reliable conclusions was determined to be 90 participants.

### Data Analysis

All statistical analyses were conducted

using SPSS version 23.0 (IBM Corp., Armonk, NY, USA). The independent T-test was used to compare the actual state and trait score, while the Chi Square ( $\chi^2$ ) compared clinically significant state and trait score and their associated factors. A p-value of 0.05 was considered to be statistically significant.

## RESULTS

We managed to recruit 97 parents. They were randomised into the TSB and TCB groups, where the pre- and post-procedure questionnaires were conducted. Demographic data were shown in Table 1.

The analysis showed that the mean score for baseline (trait) anxiety was not significant between the two groups (p-value = 0.117) (Table 2). The mean score for state anxiety post-procedure was significantly higher (M = 46.65, SD = 12.6, p = 0.000).

Based on Table 3, there was no significant difference in baseline anxiety severity between two groups (p = 0.760). More parents in the conventional TSB group had clinically significant state anxiety, with 24 out of 48 (50%) compared to 11 out of 49 (22.4%) of parents in the other group (p = 0.005).

A sub-analysis of the demographic data showed lower parental anxiety levels in higher-educated parents (p = 0.039), parents who worked as civil servants (p = 0.009), and parents with second-born children onward (p = 0.013) (Table 4).

## DISCUSSION

This was the first study in Malaysia to objectively measure the parental anxiety impact of using a transcutaneous

TABLE 1: Demographic data

Group	Total	Conventional blood taking, TSB (n = 48)		Transcutaneous bilirubinometer, TCB (n = 49)	
		Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)
Age (mean)		33.4 (SD 4.1)		32.7 (SD 5.0)	
Gender					
Male	58	29	50.0	29	50.0
Female	39	19	48.7	20	51.3
Race					
Malay	77	41	53.2	36	46.8
Non-Malay	20	7	35.0	13	65.0
Education					
High school or below	42	26	61.9	16	38.1
Diploma or above	55	22	40.0	33	60.0
Income bracket					
< MYR 58200 / year	69	36	52.2	33	47.8
≥ MYR 58200 / year	28	12	42.9	16	57.1
Employer type					
Public Sector	53	27	50.9	26	49.1
Private or self-employed	44	21	47.7	23	52.3
Spouse employment					
Spouse working	74	39	52.7	35	47.3
Spouse not working	23	9	39.1	14	60.9
Previous child with jaundice					
No	23	15	45.5	18	54.5
Yes	64	33	51.6	31	48.4
Firstborn					
Yes	27	13	48.1	14	51.9
No	70	35	50.0	35	50.0

TABLE 2: The mean trait anxiety score and state anxiety score between the conventional blood-taking (TSB) group and the transcutaneous bilirubinometer (TCB) group

	Procedure	N	Mean	Std Deviation	Independent Sample t-test	95% CI	
						Lower	Upper
Pre-procedural Trait Anxiety	TSB	48	36.44	10.173	P = 0.117	-6.426	0.730
	TCB	49	39.29	7.385			
Post-procedural State Anxiety	TSB	48	46.65	12.630	P = 0.000*	6.744	15.936
	TCB	49	35.31	10.050			

\*P-value <0.05

TABLE 3: The number of clinically significant anxiety levels between the conventional blood-taking (TSB) group and the transcutaneous bilirubinometer (TCB) group

	Procedure	STAI Score <45	STAI Score ≥45	Total	Chi Square (χ <sup>2</sup> )
Pre-procedural Trait Anxiety	TSB	38	10	48	P = 0.760
	TCB	40	9	49	
Post-procedural State Anxiety	TSB	24	24	48	P = 0.005*
	TCB	38	11	49	

\*P-value <0.05

TABLE 4: Tabulation and statistical analysis of clinically significant state anxiety scores and non-clinically significant state anxiety scores versus demographic data and the risk factor for parental anxiety

Group	Non-clinically significant state anxiety, state STAI < 45 (n = 62)		Clinically significant state anxiety, state STAI ≥ 45 (n = 35)		P-value
	Frequency (n)	Percentage (%)	Frequency (n)	Percentage (%)	
Gender					
Male	36	62.1	22	37.9	P = 0.644
Female	26	66.7	13	33.3	
Education					
High school or below	22	52.4	20	47.6	P = 0.039*
Diploma or above	40	72.7	15	27.3	
Income					
<MYR 58200 / year	43	62.3	26	37.7	P = 0.607
≥MYR 58200 / year	19	67.9	9	32.1	
Employer type					
Private Sector	40	75.5	13	24.5	P = 0.009*
Private or self-employed	22	50.0	22	50.0	
Spouse employment					
Spouse working	46	62.2	28	37.8	P = 0.518
Spouse not working	16	69.6	7	30.4	
Prev child with jaundice					
No	17	51.5	16	48.5	
Yes	45	70.3	19	29.7	
Firstborn					
Yes	12	44.4	15	55.6	P = 0.013*
No	50	71.4	20	28.6	
Age (mean)	33.5 (SD 4.4)		32.29 (SD 4.8)		P = 0.221

\*P-value <0.05

bilirubinometer over conventional blood taking in NNJ screening.

NNJ is a common problem during the neonatal period. Although in most cases jaundice is harmless, the need to monitor bilirubin levels with repeated visits requiring blood draws and occasionally re-admitting infants to the hospital for phototherapy may cause parental anxiety and adversely affect the parent-infant relationship (Kemper et al. 1990; Matthew 1971). Thus, a less painful and distressing procedure should be opted for, especially for NNJ screening to reduce parental anxiety. However, TCB would be much better suited as a first-line screening method due to its high negative predictive value when dealing with NNJ.

In this study, there was a relationship between parents' demography and a higher anxiety response towards blood taking for TSB. Parents with a higher level of education tend to be less anxious. Almost half of the parents (48%) with high school education and below had significant anxiety, compared to 27.3% of parents with higher levels of education. This was consistent with a Greek study showed that parental anxiety was negatively associated with health literacy and parental educational level during paediatric surgery (Kampourglou et al. 2020). Higher-educated parents tend to have higher health literacy and seek further information regarding their children's condition, the procedures involved, and their expectations of the intervention.

Civil servants were shown to be less anxious compared to their peers working in the private sector or self-employed. This was not related to the income group, as shown in the same table. This might be due to the fact that there are more benefits

to the subsidised free treatment option for civil servants through the Guarantee Letter (GL) system, the familiarity with the civil service bureaucracy, and lower expectations of service. Average working hours for government servants in Malaysia are limited to 45 hours per week according to government guidelines and are largely shift-based or normal office hours-based. In the private sector, working hours usually exceed 45 hours per week. A Portuguese study showed that shift work, a full-time job, and working >40 hours per week significantly increase work-family conflict but not anxiety and depression (Moreira et al. 2019). In contrast, our study found that parents with almost similar working conditions have higher levels of anxiety.

Experienced parents had lower anxiety compared to their less experienced counterparts. This was observed through the higher levels of anxiety among the firstborn's parents. First-time moms had a rise in role distinction and declines in role satisfaction throughout the transition, whereas second-time mothers' reports were largely steady, even though both groups experience equal levels of stress (Krieg 2007). Parental overconcern and protectiveness may predispose their firstborns to interpret illnesses and discomforts as more distressing compared to their siblings. This could lead to heightened concerns regarding their physical welfare (Kushnir 1984).

Limitations include the fact that the study was done in an already high-stress environment, such as ED. A similar study should be replicated in the primary care setting and community health centres to further explore our findings.

The parents' state of mind might also be affected by the time taken to fill out



the form for newborns and postpartum mothers. To improve this, their time and comfort in filling out the form should be improved. Suggestions such as using their phone and scanning a QR code to fill out the form online should be investigated, but some parents might have trouble with internet access, so a backup plan should be constituted.

## CONCLUSION

Parental anxiety should be reduced whenever possible, especially when involving noxious procedures. In this study, we investigated the relationship between parental anxiety and the method of investigation in NNJ. Our finding showed that TCB has a lower state anxiety score than the TSB method and reduces clinically significant state anxiety in parents who came for NNJ screening in the ED. However, other factors such as parental employer type, parental educational level and firstborn child also influence the state of anxiety among these parents. Despite being slightly costlier, it is outweighed by the benefits of reducing lab workload and lab run-time, reagent costs and parents' waiting time in the ED. For that reason, a transcutaneous bilirubinometer is a better screening tool compared to conventional blood collection in terms of parental anxiety. Although the present findings do provide significant insights into the benefits of TCB from a parental point of view, it would be interesting to replicate the study for a wider population through primary care and community health centres. This would allow for a wider demographic scope, especially when comparing the anxiety levels of urban and rural parents.

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