NON-INVASIVE, HAND HELD TRANSCUTANEOUS BILIRUBINOMETER

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EXECUTIVE SUMMARY

Introduction

Clinical evaluation of hyperbilirubineamia involves visual estimation of the yellowness of skin, known as jaundice. Quantification of total serum bilirubin based on visual assessment on the depth of jaundice is subjective and inaccurate which can be confounded by skin colour and haemoglobin. Various methods have been developed to aid non- invasive diagnosis of hyperbiliruneamia and total serum bilirubin. Transcutaneous bilirubinometer is hand held , non-invasive method that includes a few types such as Ingram Icterometer, Chromatic Colormate III ,Minolta AirShields Jaundice Meter and SpectRx Bilicheck. The SpectRx Bilicheck is a newer device which was claimed to have high accuracy and reproducibility across different ethnic groups as well as gestational age.

Aims/objectives

To assess the effectiveness and cost effectiveness of non-invasive hand held transcutaneous bilirubinometer for the diagnosis of neonates with hyperbilirubinaemia.

Methods

Literature were searched through electronic databases which included Medline, Cochrane Library, Science Direct and general databases such as Google and Yahoo. This review is done based on a Malaysian Health Technology Assessment report, a guidelines by NICE, 11 primary studies of prospective control design and cross sectional were selected to do this review.

Results and conclusion

There is sufficient evidence to show that trancutaneous bilirubinometer was effective in the estimation of serum bilirubin in term neonates. However, there was insufficient evidence to show the effectiveness of transcutaneous bilirubinomter in estimating serum bilirubin in preterm neonates. In addition, there was controversial evidence to show that trancutaneous bilirubinometers can be used in dark skin coloured term neonates.

There was fair evidence to show the effectiveness of transcutaneous serum bilirubinometer to estimate serum bilirubin of < 250 μmol/L. Most of the studies showed good correlation between trancutaneous serum bilirubin and total serum bilirubin (r= >0.8).

With regards to the site for using trancutaneous bilirubinometer, several studies showed that sternum readings were found to correlate better with total serum bilirubin values than forehead readings.

Recommendation

- Transutaneous Bilirubinometer can be recommended for use as a screening tool in term neonates to determine hyperbilirubineamia. Trancutaneous bilirubinometer application on dark skin coloured term neonates need to be cautioned.

- However, it should be emphasized that serum bilirubin levels estimated using transcutaneous bilirubinometer should be confirmed with chemistry analyser in the clinical laboratories.

NON-INVASIVE HANDHELD TRANSCUTANEOUS BILIRUBINOMETER

1. INTRODUCTION

Neonatal jaundice, or hyperbilirubinemia, is a common problem encountered in the newborn babies. It commonly occurs in approximately 65% of all full term babies with the peak bilirubin levels occurring on day 5 of life.[1] A total serum bilirubin levels above a define threshold warrants treatment to prevent the development of kernicterus. Usually, the clinical evaluation of hyperbilirubineamia involves visual estimation of the yellowness of skin, known as jaundice. However, quantification of total serum bilirubin based on visual assessment of the depth of jaundice is subjective and inaccurate and confounded by skin colour and haemoglobin. Various methods have been developed to aid non- invasive diagnosis of hyperbiliruneamia and total serum bilirubin. The non- invasive methods (transcutaneous bilirubinometer) includes Ingram Icterometer, Chromatic Colormate III, Minolta AirShields Jaundice Meter and SpectRx Bilicheck. The SpectRx Bilicheck is a newer device which was claimed to have high accuracy and reproducibility across different ethnic groups and gestational ages. [2]

This review was requested by a Family Health Officer from Terengganu State Health Department in order to reduce patients‟ waiting time as well as cost for consumables.

2. OBJECTIVES

To assess the effectiveness and cost effectiveness of non-invasive hand held transcutaneous bilirubinometer for the diagnosis of neonates with hyperbilirubinaemia.

3. TECHNICAL FEATURES

source : http://www.technomedica.com/Neo-Site-TM_verx.jpg

Transcutaneous Bilirubinometry works by directing light into the skin of neonate and measures the intensity of specific wavelength that is returned. The number of wavelengths, used is variable in different transcutaneous bilirubinometers. The meter analyzes the spectrum of optical signal reflected from the neonate‟s subcutaneous tissues. These optical signals are converted to electrical signal by a photocell. These are analyzed by a microprocessor to generate a serum bilirubin value. The major skin components, which

impart the spectral reflectance in neonate, are melanin, dermal maturity, hemoglobin and bilirubin.

Common transcutaneous bilirubinometer available in the market includes the Airsheild‟s-Minolta, Bilitest, BiliCheck. These which can be divided into 2 categories:

(i) Multi wavelength Spectral Reflectance meters (Bilicheck™)
(ii) Two-wavelength (460 nm, 540 nm) Spectral Reflectance meters (Minolta, Bili-test) [3]

Site of measurement

The commonly used sites for measurement are the forehead and the upper end of sternum. The meter readings for each site should be compared with the actual Total Serum Bilirubin (TSB) levels before a particular site is chosen. Hyperemia at the test site may affect the results. Measurements against bruises, birthmarks and subcutaneous hematoma should be avoided.

All transcutaneous bilirubinometers are spectrophotometric instruments that operate in the following manner:

Step One: A pressure-sensitive probe is activated when pressed on the infant‟s skin. This illuminates a light-generating tube (Xenon in the Minolta Air-Shields instrument) to produce a bright strobe light.

Step Two: This bright light travels for a short distance through the skin (where the pressure-probe is applied) and transilluminates the underlying subcutaneous tissue.

Step Three: The resultant scatter of light is then channeled through fiber optic filaments to a spectrophotometric module.

Step Four: In the spectrophotometric module, a dichromic mirror splits the reflected light into two component spectra that pass respectively through green (with maximum absorption at wavelength 550nm) and blue (with maximum absorption at wavelength 460nm) light filters. The difference between the optical densities of the beams traversing through the two filters indirectly indicates the intensity of yellow colour of the reflected beam and therefore, of the dermis of the infant.

Step Five: The instrument translates this yellow colour intensity to an arbitrary displayed number; the higher the number, the higher the intensity of yellow colour. The instrument is calibrated to read white light as zero. During regular use, the instrument is calibrated against glass standards (with specific colour intensities) and the coefficient of variation for successive readings in a particular subject should not exceed 5% (manufacturers‟ recommendations).[4]
Level II-2

4. METHODOLOGY

4.1 SEARCH METHODS

Literature were searched through electronic databases which included Medline, PubMed, Cochrane Database for Systematic Review, EBM Review HTA Database, INAHTA database and general databases such as Google and Yahoo.

The search strategy used the terms, which were either used singly or in various combinations: "transcutaneous bilirubinometer*", bilirubinometer*, "transcutaneous bilirubinometry". The search was limited to articles on human. There was no language limitation applied in the search.

4.1.1 SELECTION OF STUDIES INCLUDED /EXCLUDED

All the studies pertaining to effectiveness and cost effectiveness of handheld transcutaneous bilirubinometer were included in this review.

A critical appraisal of all relevant literature was performed using Critical Appraisal Skills Program (CASP) checklists and the evidence graded according to the US/Canadian Preventive Services Task Force (Appendix 1)

Data were extracted and summarized in evidence table as in Appendix 2. The data were not pooled and only qualitative analysis was carried out.

5. RESULTS AND DISCUSSION

This review was based on a Health Tchnology Assessment report (HTA) on Management of Neonatal Hyperbilirubinemia which was done in 2002, a draft clinical practice guidelines (NICE 2009), 11 primary studies of prospective control and cross sectional designs were selected for this review.

5.1 EFFECTIVENESS

Transcutaneous bilirubinometers have been approved by the U.S. Food and Drug Administration (FDA). Those devices include the BiliChekTM, Colormate IIITM and JM-102TM, SpectRx Air Shields. Approval to market BiliChekTM and JM- 102TM in Canada was in 1998 and 2001, respectively. [5 level III]

a) Reliability and accuracy of transcutaneous bilirubinometers

A study by Tyommy SK in 2005, which investigated the trancutaneous blirubin using the paired transcutaneous bilirubin measurements by the JM-103 Minolta and the total serum bilirubin measurement by a direct spectrophotometric method in the laboratory. The mean age of the 113 neonates at the time of data collection was five days (range = 3-7 days and >30 weeks of gestational age). Transcutaneous bilirubin showed a good correlation with total serum bilirubin; the highest correlation coefficient was 0.83 ($P<0.001$). Transcutaneous bilirubin cutoff values of 230 μmol/L and 298 μmol/L could have 100% sensitivity and specificity respectively, to predict a total serum bilirubin level of higher than 250 μmol/L (the accepted threshold for treatment). However, when the mean difference between transcutaneous and total serum bilirubin was 14 μmol/L (standard deviation, 28 μmol/L; $P<0.001$); the JM-103 tended to overestimate total serum bilirubin. The 95% limits of agreement were between 40 and 69 μmol/L. The author concluded that the JM-103 (as a point-of-care screening device) can be used safely in the Emergency Departments (AED) or Maternal and Child Health Centres (MCHC) for healthy-looking neonates aged 3 to 7 days; a transutaneous bilirubin (maxTcB) of less than 230 μmol/L can be used to let the patient return home for follow-up.

The study also suggested that admitting those with a maxTcB of greater than 298 μmol/L to hospital, for treatment without the need to perform TSB laboratory blood assay in an AED. However, the study found that a serum bilirubin assay still appears necessary for neonates with a maxTcB within the „grey" zone (230-298 μmol/L). [6 Level II-2 8]

In another study, a new transcutaneous bilirubinometer (JM-103 Minolta Airshields) for detection of hyperbilirubinaemia in term or near-term healthy Chinese newborn was evaluated. The transcutaneous bilirubin (TcB) was used to screen for severe hyperbilirubinaemia in newborn infants. Blood was taken for total serum bilirubin (TSB) measurement if the initial TcB level was higher than the 40th centile in Bhutani"s nomogram. Paired TcB and TSB results were then reviewed over 6 months. The clinical application of TcB with Bhutani"s nomogram in the prediction of severe hyperbilirubinaemia in low-risk, medium-risk and high-risk thresholds for phototherapy was also analysed. Nine hundred and ninety seven paired TcB and TSB measurements were evaluated in term or near-term newborns. TcB was significantly correlated with TSB, with a correlation coefficient of 0.83 ($p= 0.001$). Their mean difference was 21.7 mmol/l (SD 21.2, $p=0.001$), with the 95% limits of agreement between 219.9 and 263.3 mmol/ l. In both low-risk and medium-risk thresholds for phototherapy, using the 75th centile of Bhutani"s nomogram as threshold, TcB could identify all cases. It had a sensitivity and negative predictive value of 100% each, a specificity of 56% and positive predictive value of 23% for high-risk cases, using the 75th percentile as cut-off, the

sensitivity and negative predictive value were reduced to 86.7% and 97.0%, respectively. An accurate point-of-care bilirubin analyser facilitates bilirubin screening and avoids unnecessary blood tests. Although using the transcutaneous bilirubinometer JM-103 might result in a significant difference between TcB and TSB measured in Chinese newborns, combining the use of TcB and the 75th percentile in Bhutani‟s nomogram as the cut-off level can identify all cases of significant hyperbilirubinaemia. [7] Level II-2

A study by Suwinol et al. had compared the accuracy of two transcutaneous bilirubinometer (Minolto AirShields Jaundice Meter, JM103 (JM) and SpectRx, Bilicheck (BC) in estimating total serum bilirubin (TSB) level and also assessed the predictive ability of transcutaneous bilirubin in relation to specific selected TSB levels. A total of 154 measurements of TcB, using JM and BC, and TSB were recruited from 134 term and near-term infants. Postnatal ages ranged from 19 to 160 hours (SD = 25.6). TSB levels ranged from 4.5 to 17.5 mg/dl (76.95-229.25 µmol/L). The correlation coefficients between TcB (JM and BC) and TSB measurements were significant and similar (r 0.80 and 0.82, respectively). The errors of distribution were, for TSB and TcB-JM, the mean difference of 0.7 mg/dl (11.9µmol/L) [SD 1.6 mg/dl and 95% confidence interval of the mean (CI) 0.4 and 1.0]; and for TSB and TcB-BC, the mean difference of -0.6 mg/dl (SD 1.5 mg/dl [25.7µmol/L] and 95% CI -0.4 and -0.8). TcB-JM had a tendency to underestimate TSB levels, and TcB-BC had a tendency to overestimate TSB levels. The sensitivity of BC was higher, but specificity was lower, than JM in corresponding to different TSB levels, except at a TSB level of 15 mg/dl (256.5µmol/L) when both instruments yielded 100% sensitivity. The accuracy of JM in predicting TSB was higher than BC at all TSB levels. Operating the JM was simple and uncomplicated. It would be suitable for clinical use when a number of personnel perform the measurement. Comparison between transcutaneous bilirubin measured by JM and BC had similar correlation to TSB. The TcB-JM has a tendency to underestimate TSB levels, and TcB, BC had a tendency to overestimate TSB levels. Accuracy in predicting TSB at specific levels for JM was higher than BC. [8] Level II-2

In another prospective double-blind study which compared two devices, the BiliCheck (BC) and BiliMed (BM), the accuracy of those devices were evaluated against total serum bilirubin (TSB) measurements. A total of 686 healthy newborns (gestational age >34 weeks measurement of their bilirubin were estimated over a 4-months period. Serum and transcutaneous bilirubin measurements were taken with both devices within 15 minutes. The study found that BM is significantly less accurate than BC and showed tendency of underestimates serum bilirubin levels.

The linear regression analysis showed a better correlation between BiliCheck and serum bilurubin (r=0.75) than between BiliMed and serum (r=0.45). The ROC curves for both devices with target TSB values > 205.2 µmol/l or > 239.4 µmol/l showed that area under the curve for BC was significantly wider than those for BM (p>0.001). The study suggested that the transcutaneous bilirubinometry can be useful for neonatal hyperbilirubinaemia management but new studies are needed to develop and validate the mentioned non-invasive devices. BiliCheck is considered to be a significant improvement

over the older devices. The limitation of this study was it did not compare the result with the standard used method HPLC. [9] Level II-2

In another prospective descriptive study which estimated serum bilirubin, as measured using the BiliCheck, were compared with serum bilirubin concentration measured by direct spectrophotometry in neonates at Songklanagarind Hospital. Transcutaneous bilirubinometer readings were taken on the forehead. Eighty-two newborns were enrolled in the study. The means and standard deviations of serum bilirubin concentration and transcutaneous bilirubinometer index were 11.96 (204.5 μmol/L) + 2.98 and 11.61 (198.5 μmol/L) + 2.93 mg/dl, respectively. There was no statistically significant difference (p = 0.44, paired t-test). The correlation coefficient between total serum bilirubin and BiliCheck index was 0.95 with the linear regression equation of Y= 0.99 x + 0.4. The study concluded that serum bilirubin can be accurately measured by the transcutaneous bilirubinometer index in full term newborn infants prior to any intervention modalities. [10] Level II-2

A study evaluated the Minolta/Hill-Rom Air-Shields Transcutaneous Jaundice Meter model JM-103 in 849 newborns more than 35 weeks of gestation in 3 hospitals (Beaumont, Advanced Instruments Bilirubinometer; Hutzel, Dupont Dimension XL and Jefferson Beckman LX20). These infants had total serum bilirubin (TSB) levels measured on clinical indication, and transcutaneous bilirubin (TcB) levels were obtained within one hour of the Total Serum Bilirubin (TSB) levels. The population was 59.2% white, 29.8% black, 4.5% East Asian, 3.8% Middle Eastern, 1.6% Indian/Pakistani, and 1.1% Hispanic.

There was a close correlation between TSB and TcB values in all of the population groups: white (n= 503, r=0.949); black (n = 253, r=0.822); and East Asian, Indian/Pakistani, and Hispanic (n = 93, r= 0.926). In the black population, the correlation was less close than in the other groups, and differences between the TcB and TSB measurements tended to increase with rising TSB values. JM-103 values differed from TSB values by 3 mg/dL or more in 2% of white, 3.2% of other, and 17.4% of black infants. In these black infants, the JM-103 value was always greater than the TSB value. The correlation in black infants was not as close as in other groups, but there was a tendency in blacks was for the JM-103 to overestimate serum bilirubin levels. However, the author revealed that the measurement technique was rapid and simple, and it was easy to perform repeated measurements over time, thus reducing the likelihood of error. Serum bilirubin measurements are still required when treatment with phototherapy or exchange transfusion is being considered. [11] Level II-2

b) Site of measurement for transcutaneous bilirubinometers

In terms of the site of reading taken, the HTA report revealed that sternal readings were found to correlate better with serum bilirubin values than the forehead readings. It has also been demonstrated that averaging forehead and sternal readings provides better correlation with serum bilirubin than either reading individually. [4] level II-2

In a cross sectional study, a total of 210 newborn infants of gestational age ≤ 36 weeks ([19.8%] and >36 weeks [80.2%]), were studied. Thirty-five infants were from six

different European hospitals. The study group consisted of 140 white, 31 Asian, 14 Hispanic, 9 African, and another 16 newborns of different races. Blood collection for total serum bilirubin (TSB) and transcutaneous bilirubin (TcB) using BiliCheck (BC) were performed. The measurement of trancutaneous bilirubin was obtained from the forehead (BCF) and sternum (BCS). TSB levels were determined by the serum bilirubin method in use at each site, and all the readings were tested via HPLC-B determinations at the same time, in an independent laboratory.

The correlation coefficient (*r*) between BCF and high-pressure liquid chromatography (HPLC-B) was 0.890 (95% confidence interval 0.858–0.915). BCF and BCS generated similar results (*r* value of 0.890 for BCF and 0.881 for BCS) even if BCS slightly overestimated (mean error = -0.04 mg/dL [-0.68 µmol/L] and BCF slightly underestimated (mean error= 0.96 mg/dL [16.5 µmol/L]) in comparison with HPLC-B. Analysis of covariance demonstrated that BiliChek (BC) accuracy was independent of race, birth weight, gestational age, and postnatal age of the newborn, with the use of a cutoff point for HPLC-B of 13 mg/dL (equivalent to 222.3 µmol/L) and a cutoff of 11 mg/dL (equivalent to 218.1µmol/L) on the BCF. The accuracy and the precision of the transcutaneous bilirubin measurement in this study were observed to be comparable to the test in standard of care laboratory. The correlation coefficient for HPLC-B and BCF is very similar to that found for HPLC-B and laboratory TSB. Therefore the author concluded that BC not only could be used as a screening device but also as a reliable substitute of TSB determination in very low birth weight neonates. [12] Level II-2

Another cross sectional study by Gagan et al., which was undertaken from April 2002 to March 2003 to find out the correlation of transcutaneous bilirubinometer index (TcBI) with serum bilirubin levels in term, pre-term, small for gestation age babies, with and without phototherapy in neonates with jaundice. Another aim was to evaluate the transcutaneous bilirubinometer as a screening device for neonatal hyperbilirubinemia by finding the action levels for TcBI at forehead and sternum at which sample for serum bilirubin estimation should be taken. A total of 104 neonates were studied. The mean serum bilirubin was 16.6 mg/dL ± 6.1 (283.9 µmol/L) (SD) range (7.0-34.0), the mean transcutaneous bilirubin index reading over forehead was 22.7 mg/dL ±4.999 (388 µmol/L), (SD) range (14.0-37.0) and sternum was 21.2 mg/dL ±4.9 (363.5 µmol/L), (SD) range (12.0-36). Overall correlation coefficient of 0.878 at forehead and 0.859 at sternum was observed. On excluding infants receiving phototherapy, coefficients of 0.900 at forehead and 0.908 at sternum were noted. Correlation coefficient over forehead and sternum was found to drop from 0.85 to as low as 0.33 with duration of phototherapy exceeding 48 hrs. [13] level II-2

A prospective study had compared transcutaneous bilirubin using BiliCheck and Minolta bilirubin meter measurements with serum using on term and near-term babies with gestation age above 32 weeks in a Chinese population. Transcutaneous measurements of serum bilirubin were obtained from the forehead and the sternum with two instruments: BiliCheck and Minolta Airshields JM 102. The correlations between serum bilirubin and transcutaneousbilirubin measurements of the two devices at the two sites were high, with a coefficient of 0.718 (95% CI, 0.610-0.800; n=100) for forehead measurements, and

0.814 (95% CI, 0.740-0.870; n=99) for sternum using the Minolta Airshields JM 102; and a coefficient of 0.757 (95% CI, 0.657-0.827; n=98) for forehead measurements, and 0.794 (95% CI, 0.700-0.862; n=92) for sternum using the BiliCheck. For BiliCheck, a cut-off point of 250 micromol/L at the forehead and 260 mol/L at the sternum had a specificity of 61.9% and 70.0% respectively with a sensitivity of 100% for the detection of serum bilirubin concentrations of 250 µmol/L or higher. Whereas for Minolta Airshield JM 102, a cutoff point of 20 at the forehead and 21 at sternum produced a specificity of 50% and 78%, respectively with a sensitivity of 100%. Serum bilirubin had higher correlations with TcB at the sternum than at the forehead. [14] Level II-2

c) Level of transcutaneous bilirubinometers

A draft National Institute for Clinical Excellence (NICE) guidelines has indicated that there was good evidence to show transcutaneous bilirubinometer is reliable in neonates whose serum bilirubin level was below 250 µmol/L. There was lack of data on the reliability of transcutaneous estimation of bilirubin at levels above 250 µmol/L. [15] Level II-2

In a study by William et al. in 2002, which estimated the serum bilirubin by a transcutaneous device BiliCheck **(**BC) with laboratory-measured total serum bilirubin (TSB) in a predominately Hispanic population in which a significant number of TSB values were estimated around >15 mg/dL (256.5 µmol/L) . A total of 248 Hispanic and 56 non-Hispanic neonates (neonates <28 days and >30 weeks‟ gestational age) were studied.

Predictive indices for TSB >10 mg/dL (171 µmol/L) of cut off value and >15 mg/dL (256.5 µmol/L) were determined using various BC cutoff values (predictive indices of different BC cutoff values for TSB >10mg/dl was ranged from >5- >11mg/dL and for TSB> 15 mg/dL the range was >5 to >15 mg/dL). TSB was >15 mg/dL (256.5 µmol/L) in 31% of the Hispanic neonates. BC generally tended to underestimate TSB determinations, and this trend was more pronounced when TSB was >10 mg/dL (171 µmol/L). Very high sensitivities were observed only when relatively low BC cutoff values were used to predict TSB >10 mg/dL (171µmol/L) or >15 mg/L (256.5µmol/L). Relatively small numbers of infants had BC values in these low ranges. The tendency of BC to underestimate TSB limited its usefulness in neonates with relatively high TSB. In this population, most infants would have required additional evaluation to ensure that TSB was not >10 mg/dL or >15 mg/dL(> 171µmol/L or >256.5µmol/L). [16] Level II-2

d) Color of the Skin

In term of skin pigmentation, HTA report revealed that there is continued reliability of transcutaneous bilirubinometry in infants from multi-ethnic societies with varying intensities of skin pigmentation. In infants of Malay, Chinese and Indian ethnicities from Singapore a uniform correlation was found between transcutaneous bilirubinometry and serum bilirubin despite varying skin pigmentation. In contrast, a local study encountered poor correlation with serum bilirubin levels in 30 Indian babies, but good correlation for babies of Malay and Chinese ethnicity. It has also been suggested that individualised correlation curves for various ethnic groups were more reliable. [4] Level II-2

A new transcutaneous bilirubinometer, which uses multiple wavelength analysis of reflectance data BC (BiliCheck system), and the commonly used two - wavelength bilirubinometer JM (Jaundice Meter JM - 102) to estimate serum bilirubin were compared. Jaundiced newborn term infants (n= 101 babies) had transcutaneous bilirubinometry (TCB) using each bilirubinometer, a determination of skin color using a skin color chart, and a total serum bilirubin determination BC meter readings. With the BC meter readings, the skin color was not statistically significant (p=0.890) in predicting the total serum bilirubin (TSB). With the JM meter readings, the skin color was statistically significant (p=0.002) in predicting the TSB.

These results demonstrated that the BC meter is superior to the JM meter in predicting TSB. This is probably related in part to the lack of effect of skin color on the BC meter readings. The BC meter uses multiple wavelengths to determine correction factors for the effect of melanin and hemoglobin on the bilirubin estimation. The BC meter correctly identified 44 of 49 patients at higher risk (90%), whereas the JM meter correctly identified 38 (78%). The BC meter correctly identified 37 of 49 patients at lower risk (76%), whereas the JM meter correctly identified 33 (67%). The transformed JM meter values were obtained from the regression model for these data which provide estimates closer to the actual TSB values than would an objective transformation not obtained from the data. Using the JM meter, approximately 10% more babies will be erroneously judged to not require follow -up and about 10% more babies erroneously judged to require follow -up for hyperbilirubineamia. The study indicated that the JM meter would require approximately 12% more infants having a follow -up to equal the performance of the BC meter. [17] Level II-2

e) Gestational age of neonates

A systematic review by the Malaysian Health Technology Assessment section which was done in 2001 indicated that there were several factors that could influence the reliability of the transcutaneous bilirubinometers. One of the factors includes the gestational age of infant. Transcutaneuos bilirubinometers correlates well with serum bilirubin measurements over the ranges of bilirubin that are considered significant to initiate phototherapy (i.e., between 170 – 225 μmol/L), and is thus an effective screening tool in determining significant neonatal jaundice. However, transcutaneous bilirubinometry is unreliable in predicting serum bilirubin levels in preterm infants. This has been attributed to the increased intrinsic dermal yellowness of preterm neonates which confounded transcutaneous readings. Further, preterm neonates often have coexistent illnesses (anemia, respiratory distress syndrome, sepsis, acidosis) that appear to decrease the reliability of dermal spectral reflectance. [4] level II-2

Similarly a draft National Institute for Clinical Excellence (NICE) guidelines also indicated that that there was insufficient evidence to show the effectiveness of transcutaneous bilirubinometers, were useful in preterm neonates. [15] Level II-2

5.2 COST EFFECTIVENESS

There are two types of transcutaneous bilirubinometers (JM and BiliCheck meter) that are commonly used for estimation of serum bilirubin in neonates. The direct cost for the JM meter costs about [redacted] and requires no additional supplies. The BiliCheck meter costs [redacted] and each patient use requires a BiliCal cap costing [redacted]. Both meters are relatively easy to use. If we consider screening 1000 babies a year, the cost, using the BC meter, is about [redacted]. Using the JM meter, the increased variability would require follow -up for consideration of jaundice of about 120 more infants than when using the BC meter. [17 Level II-2]

6. CONCLUSION

There is sufficient evidence to show that trancutaneous bilirubinometer was effective in the estimation of serum bilirubin in term neonates. However, there was insufficient evidence to show the effectiveness of transcutaneous bilirubinomter in estimating serum bilirubin in preterm neonates. In addition, there was controversial evidence to show that trancutaneous bilirubinometers can be used in dark skin coloured term neonates.

There was fair evidence to show the effectiveness of transcutaneous serum bilirubinometer to estimate serum bilirubin of < 250 µmol/L. Most of the studies showed good correlation between trancutaneous serum bilirubin and total serum bilirubin (r= >0.8).

With regards to the site for using trancutaneous bilirubinometer, several studies showed that sternum readings were found to correlate better with total serum bilirubin values than forehead readings.

[redacted].

7. RECOMMENDATION

Transutaneous Bilirubinometer can be recommended for use as a screening tool in term neonates to determine hyperbilirubineamia. Trancutaneous bilirubinometer application on dark skin coloured term neonates need to be cautioned.

However, it should be emphasized that serum bilirubin levels estimated using transcutaneous bilirubinometer should be confirmed with chemistry analyser in the clinical laboratories.

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