CLINICAL EVALUATION
JAUNDICE METER

Screening newborn babies for jaundice in the community setting using a transcutaneous bilirubinometer.

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Background:

The Paediatric Acute Response Team (PART) for Warrington & Halton Hospital Trust was commissioned by the Warrington CCG in October 2013. The service is run by experienced paediatric nurses and cares for children with self-limiting acute illness, to reduce the need for hospital admission. The team identified that clinical guidance from NICE (National Institute for Health & Care Excellence)[1] advised that babies exhibiting possible signs of jaundice from clinical examination should have a bilirubin test. They noted that the guidance included the use of transcutaneous measurement where appropriate and realised that this would offer a number of advantages in the community setting.

It is well established that transcutaneous jaundice meters do not give the precision of a serum bilirubin measurement, however the correlation for these types of devices is generally very good[2,3,4] and they offer significant advantages. Where the transcutaneous bilirubin value is borderline a serum bilirubin measurement is probably indicated, otherwise a non-invasive reading is typically acceptable.

Traditionally in our region midwives screened babies in the community using visual and clinical observations to determine if patients should be referred for testing. Using this practice a situation arose where the condition of two patients who were not referred for testing deteriorated, resulting in both meeting the criteria for exchange transfusion due to the late detection of hyperbilirubinaemia.

Following this it was noted that there was a significant over-referral level when comparing the outcome of Serum Bilirubin (SBr) testing. On occasions when this coincided with surges in bronchiolitis cases the Paediatric Department was unable to cope with the patient numbers. This could potentially have led to a need to refer patients to another hospital, adding significant cost to the paediatric care budget, and poor family experience.

The Paediatric Acute Response Team therefore proposed to instigate transcutaneous bilirubin measurement to screen in the community all patients who were identified as having clinical symptoms that could be related to high bilirubin levels. One of the barriers to this proposal was the ability to obtain budget for the equipment needed. Initially a transcutaneous bilirubinometer was borrowed from the hospital, and following early results it was agreed that the benefits justified the purchase of a device as the loan could not be continued indefinitely.

A jaundice meter (Beijing M&B Electronic Instruments Co., Ltd., model MBJ20) was selected for evaluation that was significantly lower cost than the product used on loan and had a number of other advantages in the community setting. The trial period was used to check it would give acceptable accuracy when compared to SBr values and that the perceived benefits over the hospital's device were realised in routine clinical practice. Following a successful evaluation the device was purchased,

however the team decided it would be prudent to carry out a more comprehensive verification that the transcutaneous measurements (TcB) were sufficiently accurate to rely on them on a routine basis.

Method:

The MBJ20 was used on all patients who would normally have been referred to hospital for SBr testing from clinical assessment. It was decided to set criteria based on NICE Guidance[1], but with a safety margin to remove the risk of missing any patient with hyperbilirubinaemia; for any TcB value within 50µmol/L of the NICE treatment threshold level the protocol required a SBr measurement. Where the TcB measurement was in this range a blood sample was taken and sent to the hospital for analysis and the patient was able to go home to await results and further advice. Patients falling outside this range were considered not at risk and no further action was indicated, although some borderline cases were asked to attend for repeat test in the following days.

The team set up a protocol to record the TcB readings in all cases where SBr measurement was indicated; these were then collated with the subsequent SBr value. The results were analysed to verify that the correlation was close enough to support the routine use of transcutaneous measurements.

Results:

This study was carried out over a period of 7 months between October 2016 and May 2017. Over this period approximately 465 patients were referred to our service, of which a total of 163 TcB measurements using the MBJ20 from 116 different patients indicated that a SBr test was required under our protocols. Patients tested had a mean age at testing of 6.8 days (min. 1, max. 38); gestation was not recorded but was used in determining the NICE threshold level.

Using this approach 11% (18/163) of the patients requiring a SBr measurement were found to fall within the NICE treatment threshold.

The correlation between TcB and SBr values is shown in Table 1 below:

Table 1	Transcutaneous	Serum Bilirubin	Difference
Mean	262.3 µmol/L	252.6 µmol/L	3.9%
Minimum	121.0 µmol/L	108.0 µmol/L	12.0%
Maximum	384.0 µmol/L	463.0 µmol/L	17.1%

The results indicate that overall there is a very good correlation between the transcutaneous measurements using MBJ20 and serum bilirubin analysis, with mean value difference of 3.9%. However, the higher difference for maximum and minimum values indicated that there could be significant variability so it was decided to analyse readings for each individual patient.

The variability was analysed by taking the difference between transcutaneous and SBr values for each patient and the results are shown in Table 2 below:

Table 2	Difference between TcB & SBr	
Mean	26.6 µmol/L	10.5%
Minimum	0.0 µmol/L	
Maximum	115.0 µmol/L	

These results indicate that there is generally very good correlation even when looking at individual patients, with mean differences of 10.5%. The mean difference of 26.6µmol/L is very close to the specified accuracy of most transcutaneous jaundice meters (25.5µmol/L).

However, it was decided that a more formal statistical approach should be considered and so a Bland-Altman analysis was carried out to quantify the variability between readings. It was decided that the use of percentage difference in readings as suggested by Altman & Bland[5]. The plot is in Figure 1, showing the difference in individual measurements, adjusted so that the mean of all differences is set as the zero line. Further lines are shown at ±1.96 S.D. from the Mean.

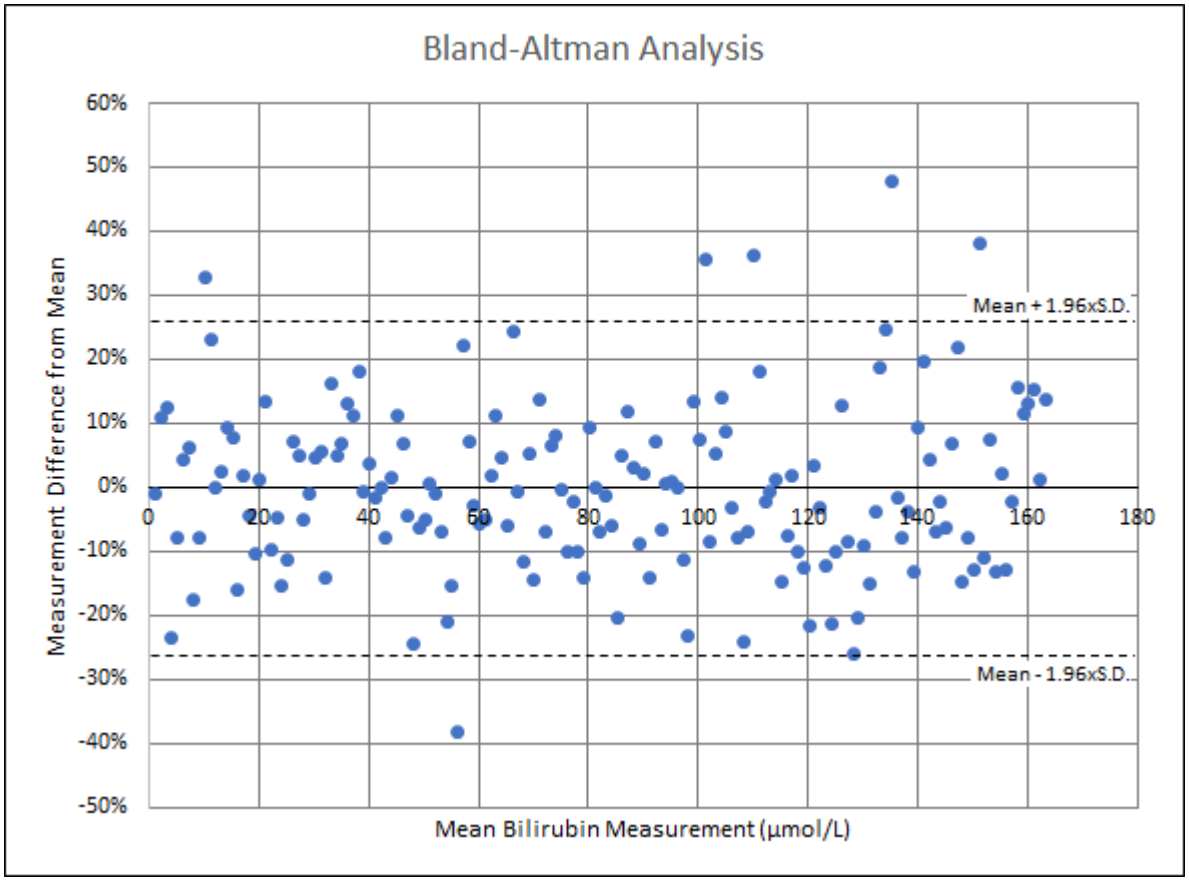

Figure 1

The Bland-Altman plot shows that there are 6 of 163 data points outside the 2 S.D. limits, representing 3.7% of the total. This means 96.3% are inside with the target for well correlated measurement methods being considered to be 95% or more.

The plot does not show any obvious bias of outlying data points towards either extreme of mean bilirubin measurement values. This indicates that there is no systematic inaccuracy related to the measured bilirubin level.

During the study staff had identified that the cases where there was a significant difference between TcB and SBr almost always related to patients of Afro-Caribbean skin type and that TcB measurement on this population is known to be less accurate. If the latter patient population had been excluded then we believe the correlation would have been significantly closer.

In all cases where the SBr indicated that the patient was above the NICE treatment threshold the TcB had also indicated treatment using our protocol.

Conclusions:

The results obtained indicate that there is a good statistical correlation between the use of transcutaneous measurements with the chosen device (MBJ20 from Delta Medical International) and serum bilirubin tests. The Bland-Altman analysis in particular confirms that more than 95% of the difference values fall within 2SD of the mean difference.

The referral process before this service was initiated involved patients being admitted to the hospital Paediatric department. Admission involved assessment by a qualified member of nursing staff and review by a doctor. Full blood screening would be performed, with up to 6 hour wait for SBr results to return from the Lab. After this screening was completed a decision would be made to discharge home, detain for further test later or commence phototherapy treatment. The typical cost of this pathway, prior to any treatment, was £400 - £700 per patient. The whole process was very upsetting for the parents of a new baby and often stretched the resources of a department already working close to its capacity.

Our protocol is that patients are now referred by the outside healthcare professional (Midwife, Health Visitor or Neonatal Outreach team) to attend a community clinic in their own time on weekdays and Saturday mornings. Normal clinical observations are made, along with discussion on feeding pattern, complications associated with jaundice and monitoring for sepsis. A transcutaneous measurement is taken and this informs the decision to carry out a SBr test or not.

If SBr test is indicated then the infant and parents can go home to await blood results. If no further action is required parents are called to advise SBr is normal and if further investigation is indicated then the parents will be asked to go straight to the Paediatric ward, where they can be admitted. The cost to be seen by the PART service is around £18 -20 per patient and the clinic sees on average 5 patients per day for testing. The PART team will also see babies who have been discharged from hospital after phototherapy treatment; SBr is checked before discharge and they are referred to the PART clinic 24 hours after light therapy was concluded for subsequent TcB check to ensure rebound of jaundice is not occurring.

Since initiating the screening programme the protocols resulted in only 18 patients meeting admission criteria under NICE guidance, thus saving 96% of admissions that would have arisen before our service came into effect. This has significantly reduced the burden on the Paediatric department and has probably saved well in excess of £200k annually in admission costs alone. In addition, the number of SBr tests that would have been carried out has reduced by 65%.

The use of a transcutaneous jaundice meter for screening has saved the need to carry out well over 500 SBr tests per year. A conservative analysis for our Trust, based on the cost to us of SBr testing alone, would recover the cost of a jaundice meter in less than 6 months. Where total costs of admissions are taken into account the case is so compelling it could justify every community midwife having a transcutaneous jaundice meter.

The PART service and its function has also impacted on the care of the babies and on their families, providing easier access to care and preventing unnecessary admission to hospital. The new approach helps infant maternal bonding to continue in the home environment and reduces the stress on new families. The use of a Transcutaneous Jaundice Meter impacts on the infant as

the non-invasive test avoids babies being subjected to painful stimuli, which can have a negative effect on their neurodevelopment.

On the basis of our study and our subsequent experience we would highly recommend community testing of patients with clinical signs that might indicate hyperbilirubinaemia. There are clear and significant benefits to hospitals, patients and parents. We would recommend adopting some degree of "safety margin" over the NICE clinical guidance treatment levels, as we have done, and caution when testing patients with Afro-Caribbean skin type.

References:

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