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Transcutaneous screening for hyperbilirubinemia in neonates

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ABSTRACT

This is the protocol for a review and there is no abstract. The objectives are as follows:

To evaluate to the effects of transcutaneous screening for hyperbilirubinemia to prevent the readmission of neonates for phototherapy.

BACKGROUND

Description of the condition

Hyperbilirubinemia is a term used to describe elevated levels of bilirubin in the blood. In newborns, hyperbilirubinemia becomes clinically apparent as jaundice, a yellow coloration of the skin and the sclera, at serum bilirubin levels > 5 mg/dL (Porter 2002). Hyperbilirubinemia is very common in both term and preterm newborn infants (occurring in around 60% of newborns) and results from a predisposition to produce bilirubin and the newborn's limited ability to excrete it (Lauer 2011). Jaundice or hyperbilirubinemia is the most common cause of hospital readmission in the neonatal period (Soskolne 1996; Maisels 1998; Escobar 2005). Most cases of newborn jaundice are mild and self limited. However, in rare cases, infants can have very high levels of bilirubin that can lead to bilirubin encephalopathy and kernicterus (Newman 2006). The threshold concentration of bilirubin and/or the duration of hyperbilirubinemia responsible for causing kernicterus in-

jury in newborn infants is not known (Dennerly 2004). Low concentrations of bilirubin may have some antioxidant benefits, suggesting that bilirubin should not be completely eliminated. Studies from developed countries estimate the incidence of kernicterus to range from about 0.4 to 2 per 100,000 (Sgro 2006; Manning 2007; Burke 2009). However, studies from developing countries suggest that the incidence may be much higher (Nair 2003; Owa 2009).

The acute phase signs of kernicterus are poor feeding, lethargy, high-pitched cry, hypertonia or hypotonia, opisthotonos and seizures. The chronic manifestations include athetoid cerebral palsy, motor delay, gaze palsy, dental dysplasia, mental retardation and sensorineural hearing loss (AAP 2004). Current treatments for hyperbilirubinemia include phototherapy and exchange transfusion (usually reserved for severe cases of hyperbilirubinemia) (NICE 2010).

Description of the intervention

Transcutaneous bilirubin (TcB) measurement devices are used for the rapid and noninvasive measurement of bilirubin levels in the skin. Transcutaneous bilirubinometry works by directing light into the skin of the neonate and measuring the intensity of the specific wavelength of light returned. The measurement is usually taken by gently pressing the meter against the sternum. Findings from many studies suggest that the accuracy and precision of TcB measurements are correlated with standard laboratory total serum bilirubin (T_sB) (Rubaltelli 2001; Engle 2002; Maisels 2004; Slusher 2004; Jangaard 2006). Other studies suggest that TcB measurements do not correlate with T_sB measurements in preterm newborn (Knupfer 2001; Karoly 2004). TcB screening involves the measurement of bilirubin in every newborn in whom clinical jaundice is not present or observed, prior to discharge.

How the intervention might work

The practice of early discharge (< 72 hours of age) of healthy term newborns is growing worldwide. Because peak serum bilirubin levels usually occur on postnatal days three to five, an effective means of screening for the onset of hyperbilirubinemia could enhance the safety of the early discharge of newborns.

The clinical evaluation of hyperbilirubinemia involves the visual assessment of jaundice. However, this method can be affected by the newborn's skin color and does not provide a quantification of the T_sB level. Current, more-objective methods of assessing hyperbilirubinemia include the use of T_sB measurements from blood sampling and noninvasive methods, such as TcB measurement with a handheld bilirubinometer. To aid in identifying newborns with a significant risk of hyperbilirubinemia and its consequences, TcB and other screening strategies for hyperbilirubinemia prior to the discharge of newborns have been advocated (Bhutani 1999; Alpay 2000; Newman 2000; Stevenson 2001). Transcutaneous screening for hyperbilirubinemia is used to identify newborns with bilirubin levels greater than the 75th percentile for age in hours and to track those with rapid rates of bilirubin rise (> 0.2 mg per 100 mL per hour). Bhutani 1999 proposed an on-the-hour-specific bilirubin nomogram as an approach to pre-discharge screening for hyperbilirubinemia. However, Fay 2009 have highlighted multiple methodologic flaws in the methods used to create the hour-specific total bilirubin nomogram.

Transcutaneous screening for hyperbilirubinemia, the characterization of bilirubin levels by risk, with selective follow up of at-risk infants and timely intervention in infants at risk of hyperbilirubinemia, could lead to a reduction in the number of newborns with severe hyperbilirubinemia and a reduction in the number of newborns readmitted to the hospital for phototherapy or exchange transfusion. If hyperbilirubinemia is identified early, effective interventions such as phototherapy can be initiated to reduce the risk bilirubin encephalopathy. However, TcB screening could also

lead to unnecessary readmissions, prolonged hospitalization, excess laboratory tests and increased costs.

Why it is important to do this review

The American Academy of Pediatrics (AAP) and the Canadian Pediatric Society both recommend the use of either pre-discharge serum bilirubin or TcB measurements as appropriate screening options for identifying infants at risk of neonatal hyperbilirubinemia (AAP 2004; CPS 2007). In contrast, however, according to the US Preventive Services Task Force, "there is insufficient evidence to make a recommendation on screening infants for hyperbilirubinemia to prevent chronic bilirubin encephalopathy" (USPSTF 2009). There is conflicting evidence for, and recommendations on, the usefulness of pre-discharge bilirubin screening in newborns. Without proof of efficacy, universal screening of newborns for hyperbilirubinemia can result in the waste of healthcare resources and the unnecessary testing of many newborns.

We aim to evaluate all the relevant available evidence to assess the effects of transcutaneous screening for hyperbilirubinemia in newborn infants before discharge from hospital.

OBJECTIVES

To evaluate the effects of transcutaneous screening for hyperbilirubinemia to prevent the readmission of neonates for phototherapy.

METHODS

Criteria for considering studies for this review

Types of studies

We will include randomized controlled trials, quasirandomized controlled trials, cluster randomized trials and other prospective study designs (e.g. cohort studies).

Types of participants

- Well newborns, of gestational age 35 weeks or more and weighing 1800 g or more, being discharged from the newborn nursery (in the first week of life)

We will not include infants admitted to, or being discharged from, the neonatal intensive care unit.

Types of interventions

1. TcB screening (alone or combined with any other method, e.g. visual assessment) compared to no screening or visual inspection for hyperbilirubinemia before discharge from hospital
2. TcB screening versus serum bilirubin screening before discharge from hospital
3. Closer follow up or home nursing visits based on TcB screening results versus postdischarge follow up or treatment decisions based on visual inspection

Types of outcome measures

Primary outcomes

- Readmission for phototherapy or home phototherapy for hyperbilirubinemia
- Exchange transfusion

Secondary outcomes

- Phototherapy before hospital discharge
- Peak bilirubin levels
- Acute bilirubin encephalopathy
- Chronic bilirubin encephalopathy
- Hearing loss
- Length of stay (days)
- Cost of care

Search methods for identification of studies

We will use the standard search strategy of the Cochrane Neonatal Review Group to identify all relevant studies regardless of language or publication status (published, unpublished, in press and in progress).

Electronic searches

We will search the following electronic databases: the Cochrane Central Register of Controlled Trials (CENTRAL, *The Cochrane Library* - current), MEDLINE (1950 to current), EMBASE (1980 to current) and CINAHL (1982 to current). We will search MEDLINE, EMBASE and CINAHL for relevant articles using the search terms: [Infant OR Newborn (explode) [MeSH heading] AND transcutaneous (explode) [MeSH heading] OR screening AND [hyperbilirubinaemia OR hyperbilirubinemia OR jaundice (explode) [MeSH heading]]. We will search clinical trial registries for any ongoing trials (www.clinicaltrials.gov; www.controlled-trials.com/ and www.who.int/ictrp).

Searching other resources

We will attempt to contact experts and organizations or manufacturers of bilirubinometers for information on any relevant study. We will scan through the reference lists of all relevant studies. We will search any previous reviews, including cross-references and abstracts, and conference and symposia proceedings of the Perinatal Society of Australia and New Zealand and the Paediatric Academic Societies (American Pediatric Society, Society for Pediatric Research and European Society for Paediatric Research).

Data collection and analysis

We will use the standard methods of the Cochrane Neonatal Review Group.

Selection of studies

The first two review authors will independently scan through the titles and abstracts of the search output to identify potentially eligible studies. Discrepancies will be resolved through discussion or, if required, we will consult the third author. We will obtain full text articles of all selected abstracts to formally assess eligibility using the prespecified eligibility criteria. We will summarize the reasons for exclusion of any potentially eligible study in the 'Characteristics of excluded studies' table.

Data extraction and management

We will design a data extraction form for the extraction of data. Two review authors will independently extract data from all included studies using the data extraction form. We will resolve discrepancies through discussion or, if required, we will consult the third review author. We will enter data into the latest version of Review Manager ([RevMan 2011](#)) and check them for accuracy. We will contact authors of the studies identified via email or telephone to provide more information, if necessary.

Study information that will be extracted will include:

- study details: citation, start and end dates, location and study design;
- participant details: study population eligibility (inclusion and exclusion) criteria, gestational age, sex, sample size and attrition rate;
- details about the interventions: type of transcutaneous bilirubin meter used and any other method used for screening for hyperbilirubinemia
- outcome details: readmission rates for phototherapy, exchange transfusion, acute bilirubin encephalopathy, chronic bilirubin encephalopathy and adverse effects.

For each dichotomous outcome, we will extract information on the number of participants experiencing the event and the number of participants randomized to each treatment group. For each continuous outcome we will extract the means or geometric means and standard deviations (or information to estimate the standard deviations) for each treatment group, together with the numbers of participants in each group. Medians and ranges will also be extracted if these are reported in place of means and standard deviations.

Assessment of risk of bias in included studies

The first two review authors will independently assess the risk of bias in each study using the criteria outlined in the *Cochrane Handbook for Systematic Reviews of Interventions* (Higgins 2011). We will resolve any disagreement by discussion or by consulting the third review author.

(1) Sequence generation (checking for possible selection bias)

We will describe for each included study the method used to generate the allocation sequence in sufficient detail to allow an assessment of whether it should produce comparable groups. We will assess the method as:

- adequate (any truly random process, e.g. random number table; computer random number generator);
- inadequate (any non-random process, e.g. odd or even date of birth; hospital or clinic record number);
- unclear (if we do not find enough information to make a judgment).

(2) Allocation concealment (checking for possible selection bias)

We will describe for each included study the method used to conceal the allocation sequence in sufficient detail and determine whether intervention allocation could have been foreseen in advance of or during recruitment, or changed after assignment. We will assess the methods as:

- adequate (e.g. telephone or central randomization; consecutively numbered sealed opaque envelopes);
- inadequate (open random allocation; unsealed or nonopaque envelopes; alternation; date of birth);
- unclear (if we do not find enough information to make a judgment).

(3) Blinding (checking for possible performance bias)

We will describe for each included study the methods used, if any, to blind study participants and personnel from knowledge of which intervention a participant received. We will judge studies to be at low risk of bias if they were blinded, or if we judge that the lack of blinding could not have affected the results. We will assess blinding separately for different outcomes or classes of outcomes. We will assess the methods as:

- adequate, inadequate or unclear for participants;

- adequate, inadequate or unclear for personnel;
- adequate, inadequate or unclear for outcome assessors.

(4) Incomplete outcome data (checking for possible attrition bias through withdrawals, dropouts, protocol deviations)

We will describe for each included study, and for each outcome or class of outcomes, the completeness of data, including attrition and exclusions from the analysis. We will state whether attrition and exclusions were reported, the numbers included in the analysis at each stage (compared with the total numbers of randomized participants), reasons for attrition or exclusion where reported, and whether missing data were balanced across groups or were related to outcomes. Where sufficient information is reported, or can be supplied by the trial authors, we will reinstate missing data in the analyses that we undertake. We will assess methods as:

- adequate (where fewer than 20% of data are missing);
- inadequate (where more than 20% of the data are missing);
- unclear (if we do not find enough information to make a judgment).

(5) Selective reporting bias

We will describe for each included study how we investigated the possibility of selective outcome reporting bias and what we found. We will assess the methods as:

- adequate (where it is clear that all of the study's prespecified outcomes and all expected outcomes of interest to the review have been reported);
- inadequate (where not all the study's prespecified outcomes have been reported; one or more reported primary outcomes were not prespecified; outcomes of interest are reported incompletely and so cannot be used; study fails to include results of a key outcome that would have been expected to have been reported);
- unclear (if we do not find enough information to make a judgment).

(6) Other sources of bias

We will describe for each included study any important concerns we have about other possible sources of bias. We will assess whether each study was free of other problems that could put it at risk of bias as: yes, no or unclear.

Measures of treatment effect

We will present results for dichotomous outcomes as summary risk ratios (RRs) with 95% confidence intervals (CIs) and absolute risk differences with 95% CIs. Continuous outcomes will be presented using the mean difference (MD), if outcomes are measured using the same scale in trials, or using the standardized mean difference when the outcome is measured using different scales. The summary effect measures will be presented with 95% CIs. If the RR is statistically significant, the number needed to treat to for an

additional beneficial outcome (NNTB) or an additional harmful outcome (NNTH) will be calculated.

Unit of analysis issues

We will note the unit of analysis at the level of randomization (individual or group) and analyze the data accordingly. We will include cluster randomized trials in the analyses along with individually randomized trials. For cluster randomized trials, we will adjust the sample sizes using the methods described in the *Cochrane Handbook for Systematic Reviews of Interventions*, Section 16.3.4 or 16.3.6 (Higgins 2011) using an estimate of the intracluster correlation coefficient (ICC) derived from the trial (if possible) or from another source.

Dealing with missing data

We will attempt to contact authors if there are missing or unclear data. We will also note levels of attrition in each of the included studies. For all outcomes we will carry out an intention-to-treat analysis. For outcomes in which the results have been pooled in meta-analysis, we will explore the impact of including studies with significant loss to follow up in the overall assessment of treatment effect by using sensitivity analyses.

Assessment of heterogeneity

We will assess statistical heterogeneity by visually inspecting the forest plots to detect overlapping CIs, applying the χ^2 test (P value < 0.10 considered statistically significant) and also using the I^2 statistic, where an I^2 of less than 25% will be considered as unimportant, 25% to 49% will be considered to suggest low heterogeneity, 50% to 74% will be considered to suggest moderate heterogeneity, and 75% or greater will be considered to indicate high heterogeneity.

Assessment of reporting biases

If we have 10 or more studies, we will explore the likelihood of reporting bias or publication bias for each outcome using funnel plots.

Data synthesis

We will analyze the data using Review Manager 5.2.7. Where possible, we will adjust for the effect of clustering in cluster randomized trials and combine the results with results from individually randomized studies in meta-analysis. We will use a random-effect model for any meta-analyses.

Quality of evidence

The quality of evidence across each outcome measure will be assessed using the GRADE approach. GRADE defines the quality of evidence as the confidence we have in the estimate of effect for an outcome (Atkins 2004). The quality rating across studies has four levels: high, moderate, low or very low. Randomized trials are categorized as high quality, but can be downgraded. Some of the factors that would impact on the quality of evidence are the risk of bias in included studies, the presence of unexplained heterogeneity or inconsistency, the imprecision of results, indirectness of the evidence and publication bias (Balslem 2011).

Subgroup analysis and investigation of heterogeneity

We plan to carry out subgroup analyses based on gestation age (preterm versus term newborns); the presence of jaundice (versus no jaundice) in newborns; birth weight (<2500g versus > 2500g); and the presence of any comorbid conditions (e.g. hemolytic disease or other conditions known to exacerbate jaundice); mode of delivery (spontaneous vertex delivery or delivery by caesarean section).

Sensitivity analysis

Depending on the number of included studies, we plan to conduct sensitivity analyses on the robustness of the methods used regarding allocation concealment and losses to follow up in the analysis, and we will report the impact of the sensitivity analyses on the quantitative results from the meta-analysis.

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* *Indicates the major publication for the study*

CONTRIBUTIONS OF AUTHORS

Charles Okwundu conceptualized and wrote the draft protocol. Olalekan A Uthman and Johan Smith contributed to various sections of the protocol.

DECLARATIONS OF INTEREST

None

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