**A NOVEL SCORING SYSTEM FOR TERM EQUIVALENT AGE CRANIAL ULTRASOUND IN EXTREMELY PRETERM INFANTS**

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**ABSTRACT**

The role of term equivalent age (TEA) cranial ultrasound (cUS) for predicting outcome in preterm infants is increasingly recognized. However, a detailed quantitative scoring system that allows comparison of groups and comparison to TEA magnetic resonance imaging (MRI) scoring systems is lacking. Eighty-four extremely preterm infants underwent cUS and MRI at TEA. cUS was evaluated using a novel detailed cUS scoring system. Agreement between cUS and MRI scores was good. Outcome at 30 months corrected was assessed in 66 of the 84 preterm and in 85 term-born infants. Sensitivity for prediction of cerebral palsy and severe cognitive delay was the same with cUS and MRI, while specificity was slightly higher for MRI. Prediction of severe language and motor delay remains difficult irrespective of imaging modality. The proposed novel cUS scoring system is a helpful tool to quantitatively assess cUS at term age and to predict outcome at 30 months.

**KEY WORDS**: brain injury, cerebral palsy, magnetic resonance imaging, neonate, neurodevelopmental outcome, white matter abnormalities, prognosis

**INTRODUCTION**

Extremely preterm infants (EPT) are at high risk of brain injury and subsequent neurodevelopmental impairments (Serenius et al. 2016, Pierat et al 2017). Early prediction of long-term outcome remains a challenging task, despite the increased use of neonatal neuroimaging (Janvier et al. 2012; van’t Hooft et al. 2015).

Serial cranial ultrasound (cUS) scans in the first weeks of life are the gold standard for bedside detection of the most important prematurity related brain lesions such as germinal matrix – intraventricular haemorrhages (GMH-IVH), periventricular haemorrhagic infarctions (PHI), posthaemorrhagic ventricular dilatation (PHVD), and cystic white matter injury (WMI). When high-resolution cUS is repeated frequently from the first week of life until term equivalent age (TEA) it is a very sensitive tool to predict cerebral palsy (CP) with specificity reaching 95% and sensitivity 76% (de Vries et al. 2004). Recently, the value of term/ near- term cUS for prediction of outcome has been highlighted in two large studies (Hintz et al. 2015, Edwards et al. 2017). In both these studies the definition of an abnormal late cUS was limited to the presence of cystic WMI, porencephalic cysts, or ventriculomegaly whereas more subtle abnormalities like thinning of corpus callosum and delay in cortical folding that are evaluated in the most commonly used magnetic resonance imaging (MRI) scoring systems were not taken into account. Making fair comparisons between imaging modalities is difficult, because a corresponding validated quantitative scoring system for TEA cUS is lacking.

In the present study, we have elaborated on our previous work in which we reported good agreement between tentative cUS scoring and an established MRI scoring system in extremely preterm infants (Horsch et al. 2010). We now present a novel quantitative scoring system for cUS at TEA that accounts for all relevant prematurity related forms of brain injury. Westudied its value for prediction of outcome in a population-based cohort of extremely preterm infants, in particular, with regards to CP and severe cognitive, language and motor developmental delay, and compared it to cranial MRI performed on the same day.

**MATERIALS AND METHODS**

**Participants**

The regional ethical review board in Stockholm approved the study and informed consent was obtained from every participating family. All infants born in Stockholm between August 2004 and April 2007 with agestational age (GA) of <27 weeks + 0 days were eligible for inclusion. Perinatal data were collected prospectively.

**cUS at TEA**

cUS was performed at TEA (38-41 weeks GA), on the same day as the MRI. Infants were scanned by one of two examiners (BS or SH) using an ACUSON Sequoia ultrasound system (Siemens Medical Solutions, Germany) with a multifrequency sector transducer (5-8 MHz). The imaging protocol consisted of the standard projections according to Levene in coronal and sagittal/parasagittal planes through the anterior fontanelle (Levene et al. 1985).

cUS images were stored digitally and analysed off-line by three independent observers (BS, SH, MB; blinded to the clinical course, MRI findings and outcome), with interobserver agreement of 98%.The cUS scoring system consists of in total 10 items (table 1); five items are subjectively *scored* (cysts, cortical and deep grey matter abnormalities, maturation of gyral folding and cerebellar abnormalities) and five are *measured* (size of frontal horns, ventricular mid body, subarachnoidal space, interhemispheric fissure and corpus callosum), see figure 1. The possible scores differ between items and reflect the clinical relevance for outcome. The composite cUS scores (sum of all 10 items) were categorized into 4 severity groups:

1 - normal: composite score (CS) ≤10; 2 - mild abnormalities: CS 11-14;
3 - moderate abnormalities CS 15-20; 4 - severe abnormalities CS >20.

**Magnetic Resonance Imaging at TEA**

All scans were performed at TEA on a Philips Intera 1.5 Tesla scanner (Philips International, Amsterdam) at Astrid Lindgren Children’s Hospital in Stockholm, as previously described (Skiöld et al. 2010; Skiöld et al 2012). Conventional MR images were evaluated by four independent observers (MM, MB, BS/SH, BH/UÅ; blinded to the clinical course, cUS findings and outcome), using a scoring system for structural brain abnormalities (Woodward et al. 2006; Inder et al. 2003). Five white matter (WM) items are graded from 1 (normal) to 3 (severe): abnormal WM signal, reduction in WM volume, cystic changes, myelination/ thinning of the corpus callosum, and ventricular dilatation, resulting in a total score between 5 and 15. According to these composite scores, data sets are categorised into four groups: ”no WM abnormalities” (5-6), ”mild” (7-9), ”moderate” (10-12) or ”severe WM abnormalities” (13-15). For the grey matter (GM), three items are graded from 1 (normal) to 3 (severe): abnormal signal in the cortical or deep GM, enlargement of the subarachnoid spaces, and delay in gyral maturation. Data sets are then categorised as “normal GM” (3-5) and “abnormal GM” (6-9). The interobserver agreement for group assignment was 98%, and consensus was reached after discussion when opinions differed.

**Follow-up at age 30 months**

Follow-up was performed at 30 months corrected age within the framework of the EXPRESS project (Serenius et al. 2013). A control group of 85 term-born infants with similar age and sex distribution underwent the same follow-up assessments. For preterm children who did not attend the research follow up (n=18/84), medical records from routine clinical follow-up (performed by either a neonatologist or a paediatric neurologist) were reviewed for information regarding neurological status.

Neurological status (movements, posture, reflexes, and muscular tone) was assessed by a paediatric neurologist (BV) and categorized as “normal” or “abnormal” if neurological signs of cerebral palsy (CP) were present (SCPE-working-group. 2000). A third category comprised children with “unspecific signs” , for example, mild muscular hypotonia, brisk reflexes, but not fulfilling the Surveillance of Cerebral Palsy criteria for diagnosis of CP (reference). The Bayley Scales of Infant and Toddler Development- III (BSITD-III) were performed on the same day as the neurological examination, assessing cognitive, language and motor development. The cut off level for severe delay (< -2 SD) was applied to the mean values of the regional term-born control group who had a mean cognitive composite score of 104 (SD ± 9.6, i.e. severe delay <85), a mean language composite score of 108 (SD ± 11.7, i.e. severe delay <85), and mean motor composite score of 117 (SD ±14.7, i.e. severe delay <88 (Skiöld et al. 2012).

**Statistics**

Statistical analysis was performed with PASW Statistics® software 21.0 (SPSS Inc, Chicago, IL). Infants were divided based on the MRI scoring categories for WM and GM. Similarly, infants were categorized based on cUS scoring groups. Furthermore, infants were grouped based on neurological status (normal, abnormal or unspecific signs) and developmental outcomes (no or severe delay: i.e. a composite score more than 2SD below the mean of the control group).

The Student t-test was used for continuous variables, the Pearson Chi-2 and Fisher’s Exact tests were used for dichotomous data. Nonparametric tests were used for ranked data and unequal group sizes. Spearman’s rank coefficient was used to assess correlations between the composite scores of the two scoring systems. A p-value of < 0.05 was chosen as the cut off level for significance.**RESULTS**

Eighty-four preterm infants were included in the study. Patient characteristics and perinatal factors are presented in table 2.

**Neuroimaging at TEA**

Brain abnormalities on MRI and cUS in the sample of the current study did not differ from data previously reported for the whole Stockholm cohort (Horsch et al. 2010; Skiöld et al 2010; Skiöld et al 2012). Incidences of brain abnormalities on cUS and WM injury on MRI are detailed in figure 2. Grey matter abnormalities on MRI were seen in 4 patients.

There was overall good agreement between the composite scores on cUS and MRI, both between total cUS score and WM abnormality score (Spearman’s rho= 0.51, p<0.001) and total cUS and GM abnormality score (Spearman’s rho= 0.58, p<0.001). Of the 34 infants with an entirely normal cUS, 68% (23/34) had normal, and 32% (11/34) had mild WM abnormalities on MRI, none had moderate or severe WM abnormalities, and none had abnormal GM. The two infants with severe WM abnormalities on MRI were identified as having moderate or severe abnormalities on cUS.

**Neurodevelopmental outcome**

At age 30 months, 79% (66/84) of the preterm born children attended follow-up. Of these, seven had incomplete BSITD-III assessments. For 18 children (21%), information regarding neurological status was obtained from medical records (mean age at follow-up 24 months, SD ±8 range 11-36). This group did not differ from the group of children that did attend follow-up with regards to perinatal characteristics, neuroimaging or neurological status (table 2).

On the BSITD-III, the mean cognitive composite score of the preterm study sample was 95 (SD ± 8.3; range 65-120), the mean language composite score was 97 (SD ± 14; range 53-124), and the mean motor composite score was 104 (SD ± 17; range 45-130). Two children (3%) had severe cognitive delay, eight children (13%) had severe language delay, and eight children (13%) had severe motor delay (table 3). Four infants (6%) fulfilled the criteria for CP (table 3 and 4).

**Associations between cUS scoring groups and outcome**

For infants with either moderate or severe abnormalities on cUS, associations were seen with CP (Fisher’s Exact test, p=0.007) and with severe cognitive delay (Fisher’s Exact test, p=0.015), while other investigated associations (unspecific signs and BSITD-III language and motor composite score) were not significant (table 5). Of the four infants with severe abnormalities, two developed CP and one severe cognitive delay. When investigating individual cUS items, cysts were associated with unspecific neurological signs, CP, and severe cognitive delay (Pearson Chi-square, p<0.001); parieto-occipital WM loss was associated with severe cognitive delay (Pearson Chi-square, p<0.001). The negative predictive value of a normal or mildly abnormal TEA cUS regarding normal neurological status and cognitive outcome was 98% and 100%, respectively (table 6). One infant that developed CP had a normal CUS and MRI.

**Associations between MRI scoring groups and outcome**

For infants with either moderate or severe WM abnormalities on MRI, associations were seen both with CP (Fisher’s Exact test, p=0.001) and severe cognitive delay (Fisher’s Exact test, p=0.005), while other investigated associations (unspecific neurological signs and BSITD-III language and motor composite score) were not significant (table 4), previously published (Skiöld et al 2012). Both infants with severe WM abnormalities developed CP and severe cognitive delay. When infants with mild and moderate WM abnormalities were pooled together, no associations with neurological status or developmental outcome were seen.

Abnormal GM (irrespective of WM abnormalities) was not associated with CP or severe developmental delay. Adding ‘abnormal GM’ to the pooled analyses of infants with moderate and severe WM abnormalities on MRI did not alter the associations with outcome. When investigating individual scoring items, WM reduction, delayed myelination, and cysts were associated with unspecific neurological signs, CP, and severe cognitive delay (Pearson Chi-square, p<0.001). Abnormal signal in the cortical or deep GM was associated with severe cognitive delay (Pearson Chi-square, p<0.001).

The diagnostic accuracy of both scoring systems is compared in table 5.

**Cerebellar haemorrhages**

Six infants had small cerebellar haemorrhages. All six were only detected on MRI.

**Discussion**

We present a novel comprehensive scoring system for cUS at TEA that allows quantification of overall brain injury comparable to established MRI scoring systems. This cUS scoring covers the most relevant prematurity related brain injuries such as residuals and sequelae of haemorrhages, periventricular infarctions, posthaemorrhagic hydrocephalus, white matter injury and brain atrophy. The TEA cUS scores showed good agreement with TEA MRI scores and reached similar predictive values for severe impairments.

MRI and cUS are the two most important neuroimaging modalities in newborn infants. Neonatal MRI has been increasingly used in the last two decades and has tremendously enhanced our understanding of neonatal brain development and injury (Inder et al. 2003; Woodward et al. 2006, Keunen et al. 2016). Nevertheless, MRI remains an expensive method that is time- and manpower consuming. Access to MRI is limited in many countries and centres, therefore patients who undergo MRI need to be carefully selected. The increasing use of MRI at term age for screening of extremely preterm infants remains controversial. In 2015, the American Academy of Pediatrics’ (AAP) section on Neonatal Perinatal Medicine undertook an expert consensus building process to identify “use of unnecessary tests and treatments that contribute to health care waste“ as part of the AAP Choosing Wisely**®** campaign. The authors concluded that routine screening with TEA MRIs in preterm infants is related to, but not proven to improve outcomes (Ho et al. 2015). This was in brief supported by a recent randomized trial by Edwards and colleagues investigating predictive power, maternal anxiety and costs of TEA neuroimaging (cUS and MRI), concluding that MRI “increased costs and provided only modest benefits”. On the other hand, experts have opposed to the AAP Choosing Wisely**®** statement (Cheong et al. 2018). This controversy underlines the need for thorough research in this field and careful assessment of cost effective alternatives to routine TEA MRI in preterm infants.

Early studies that compared MRI and cUS in the prediction of outcome of extremely preterm infants found TEA MRI to be superior to cUS (Maalouf et al. 2001; Woodward et al. 2006; Mirmiran et al. 2004). In many of these studies cUS was performed during the first weeks after birth and not at term age, using a variety of cUS diagnosis (IVH, PHVD, periventricular leukomalacia (PVL)) to be compared to data from complex MRI scorings systems. Later studies have shown improved accuracy of cUS in the prediction of outcome, using serial cUS including term or near-term data in comparison to TEA MRI (de Vries et al. 2004). For example, Hintz et al demonstrated that late (but not early) adverse cUS findings, defined as cPVL, porencephalic cyst, or moderate-to-severe ventricular enlargement or shunt, were associated with outcomes at 18-22 months corrected age (Hintz et al. 2015). Interestingly, although a detailed MRI scoring system that was developed for white and grey matter abnormalities has been widely used, refined and up-dated over the years (Inder et al. 2003, Woodward et al. 2006, Kidokoro et al.2013), no detailed or systematic scoring system for cUS images has, to our knowledge, yet been published.

The aim of the proposed cUS scoring was to create a quantitative assessment tool that reliably detects clinically relevant sequelae of preterm brain injury and impaired brain development at TEA. The examination does not differ significantly from a clinical routine scan (usually takes approximately 10 minutes for an experienced user) as only standard projections according to Levene (Levene et al 1985) are used. cUS images are stored and scoring may be performed on a later occasion, i.e. not interfering with clinical work on the ward, which also facilitates training of less experienced cUS users. The interobserver agreement in the present study was high. Similarl to the updated MRI scoring system by Kidokoro et al., the present cUS scoring includes a combination of subjectively scored items and objective metrics, resulting in a composite (‘global’) brain abnormality score. With this novel scoring system not only the adverse findings but also a normal TEA cUS and mild abnormalities are clearly defined and easily reproducible for users. This is important as the negative predictive values regarding all investigated outcomes were high when TEA cUS scoring was normal or showed only mild abnormalities. This underlines the value of TEA cUS to screen for infants that highly unlikely will profit from further investigation with MRI. We believe that this proposed cUS scoring system can be integrated into clinical routine, but also enables uniform structured assessment of brain injuries in the research setting such as comparison across cohorts.

The low rates of severe brain abnormalities and severe impairments in our cohort are important limitations to this study. Although it is of course gratifying that the cohort is doing well, it restricts the prognostic value of the tool, a problem experienced by others in similar settings (Brouwer et al. 2017). Therefore, validation of the presented cUS scoring system in a cohort with higher incidences of both brain injury and impaired outcomes is warranted. Another limitation is that cUS images were only acquired via the anterior fontanel, which resulted in a low detection rate of cerebellar injury. In future studies additional views through the mastoid window should be added to increase the sensitivity for cerebellar injury.

Moreover, a comparison with the revised version of the Inder-Kidokoro MRI scoring system (Kidokoro et al. 2013) would also be of great interest. Another major limitation is the relatively short time of follow up, which might naturally underestimate more subtle, later emerging cognitive impairments.

We believe that the major strength of the present scoring system is that it assesses the full spectrum of prematurity related brain injury, and uses weighted subscores that reflect the relevance for outcome of each item. Moreover, the cUS scoring is clearly structured and easy to use also for non-experts. The population-based design is another strength of our study, along with the large sample size of infants with a gestational age at birth below 27 weeks. In addition, to increase accuracy of the outcome comparisons, we used a regional control group of term born infants, since the third edition of the Bayley Scales has been shown to underestimate developmental delay (Anderson et al. 2010; Vohr et al 2012),

**Conclusion**

The present study describes a novel comprehensive scoring system for cUS at TEA allowing quantification of preterm brain injury comparable to established MRI scoring systems. It may thus enable uniform structured assessment of brain injuries in the research setting such as comparison across cohorts. Moreover, we believe this cUS scoring may be integrated into study protocols and clinical routine. The negative predictive values regarding all investigated outcomes were high, i.e the cUS scoring may potentially be used to screen for infants that is unlikely will profit from further investigation with MRI.

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