

Which infants in a neonatal unit are at most risk of feeding difficulties?

Background

It is known that the incidence of feeding problems is high in neonatal populations and certain patient groups appear to be particularly at risk. It is not yet known which infant groups admitted to Level 3 Neonatal Units are at most risk of feeding problems and in need of specialist feeding assessment and interventions. While many studies have examined the impact of prematurity and comorbidities on feeding outcomes, most studies to date are limited to sub-populations, and/or do not investigate how best to identify the babies who are at most risk of feeding difficulties. Neonatal Speech and Language Therapists require information about feeding risks and outcomes for the neonatal population as a whole for caseload prioritisation and to target populations most in need of specialist feeding interventions.

Babies born extremely preterm (before 28 weeks gestational age) and very low birth weight (less than 1500g at birth) have been identified as slower to achieve full oral feeding than those born at an older gestational age and higher birth weight (Jackson, Kelly, McCann, & Purdy, 2016; Gianni et al., 2015; Park, Knafel, Thoyre, & Brandon, 2015; Hwang, Ma, Tseng, & Tsai, 2013; Jadcherla et al., 2010). Moderate to late preterms (those born at 32-36 weeks gestational age) are also more prone to feeding problems than term infants (Jackson et al., 2016; Celik, Demirel, Canpolat, & Dilmen, 2013) although severity and duration of these problems is generally not reported. Certain comorbidities have been found to correlate with feeding outcomes in preterms. Impaired respiratory function, gastrointestinal complications, neurological involvement, and cardiac defects have all been associated with delayed feeding progression and poor feeding outcomes (Park et al., 2015; Malkar, Gardner, Welty, & Jadcherla, 2015; Gianni et al., 2015; Hwang et al., 2013; Jadcherla et al., 2010). Prematurity has also been found to increase the severity of feeding problems caused by congenital abnormalities, such as laryngomalacia (Durvasula, Lawson, Bower, & Richter, 2014).

Studies of preterm infants do not always agree on which comorbidities are significant for feeding outcomes. For example, in extremely preterm infants, severe intraventricular haemorrhage (IVH, grades 3-4) has been reported as both significantly associated with achievement of feeding milestones (Park et al., 2015) and as not predictive of feeding outcome (Malkar, et al., 2015). These varied findings appear to be due to differences in the outcomes measured and the specific population studied. Park et al. (2015) studied a general population of extremely preterm infants and identified the factors associated with days to achieving specified feeding milestones. 9.6% of the sample were discharged on gastrostomy feeds but this was not a study outcome and comorbidities related to discharge with gastrostomy were not reported. Malkar et al. (2015) focused on a sub-population of extremely preterm infants with prolonged mechanical ventilation. This study reported significant predictors of gastrostomy placement during initial hospitalisation and, unsurprisingly, findings differed from those of Park et al. (2015).

In order to study the effect of prematurity, many studies exclude infants with conditions that could be considered 'confounding variables'. For example, White-Traut et al. (2013) excluded infants with congenital abnormalities, necrotizing enterocolitis, positive findings on head

scan, chronic lung disease, prenatal drug exposure, and those receiving ventilatory support. While these studies provide valuable information on the effect of prematurity on feeding, it also results in the exclusion of those infants who are most likely to have feeding difficulties. It is also important to note that not all infants with feeding problems on a neonatal unit are premature. Children who underwent cardiac surgery and gastrointestinal surgery in the neonatal period often experience significant feeding problems requiring long term tube feeding (Ricci et al., 2016; Pierog et al., 2014; Sables-Baus, Kaufman, Cook, & da Cruz, 2012; Emil, Canvasser, Chen, Friedrich, & Su, 2012). Infants with neurological impairment frequently experience feeding problems (Colombo et al., 2015; Martinez-Biarge et al., 2012; Barkat-Masih, Saha, Hamby, Ofner, & Golomb, 2010;) although this is not found in all studies (Ou-Yang et al., 2010). Feeding problems are also common in children with congenital abnormalities of the aerodigestive tract, such as those found in Pierre Robin sequence (Daniel et al., 2013; Al-Samkari, Kane, Molter, & Vachharajani, 2010).

One study that reported on the feeding outcomes of a neonatal population as a whole utilised a screening method to identify neonates with dysphagia (Lee, Kim et al., 2011). The authors studied 142 infants admitted to a neonatal unit, including term and preterm infants. Feeding was observed after 36 weeks postmenstrual age and assessed for the following signs during the feed: cyanosis, coughing, vomiting, nasal regurgitation, drooling, voice change, or crying while feeding. 37 infants (26%) showed signs of dysphagia and underwent videofluoroscopy. 22 of these 37 showed abnormalities on videofluoroscopy (15.5% of all infants studied). Cyanosis was significantly associated with aspiration and all infants presenting with both coughing and cyanosis were found to aspirate on videofluoroscopy. The study did not attempt to determine the presence or absence of dysphagia without clinical signs or determine the infant and medical characteristics associated with poor feeding outcomes. However, these findings demonstrate that the incidence of dysphagia is high among neonatal populations and that clinical signs of dysphagia should be investigated. Interestingly, in this study there was no significant correlation between gestational age at birth and abnormal videofluoroscopy findings. This suggests that the exclusion of subpopulations from other studies of neonatal feeding may result in a disproportionate emphasis on prematurity.

Aim

This study aims to answer the following questions:

1. Is gestational age or medical status the better indicator of risk of feeding difficulties in infants admitted to a Level 3 Neonatal Unit?
2. Is gestational age or medical status the better indicator of risk of slow attainment of slow oral feeding among preterm infants admitted to a Level 3 Neonatal Unit?
3. Are certain types and combinations of medical problems a better indicator of risk for feeding difficulties among infants admitted to a Level 3 Neonatal Unit than others?

Objectives

1. Collect anonymised data on gestational age at birth, medical status, and feeding outcomes for infants admitted to the Royal Preston Neonatal Unit in 2015.
2. Determine the feeding outcomes of babies in each of the gestational age categories
3. Determine the feeding outcomes of babies in each of the medical status categories
4. Conduct statistical analysis to determine which category type is most associated with:
 - Slow attainment of full oral feeding (preterms only)
 - Feeding difficulties (all gestational age categories)
5. Analyse the gestational age and medical features of babies with slow attainment of full oral feeding and feeding difficulties

Methods

Design

Prognostic study using retrospective case note analysis.

Setting

A Level 3 Neonatal Unit (including intensive care, high dependency, and special care) at the Royal Preston Hospital.

Sample

Inclusion criteria:

Data will be collected for all babies admitted to the Neonatal Unit at Royal Preston Hospital in 2015 (approximately 500 infants).

Exclusion criteria:

Babies will be excluded if all data regarding their gestational age, medical status, and feeding outcome is not available.

Procedure

A retrospective analysis of routinely collected data will be undertaken. The BadgerNet patient record management system is updated daily for all babies in neonatal units around the country. Data will be collected from the BadgerNet daily notes and discharge summary and added to a bespoke spreadsheet prior to statistical analysis.

Data Collection and Storage

Data from the BadgerNet system will be collected by Sarah Edney, a member of the Royal Preston Hospital Neonatal Unit clinical team. Data for each participant will be inputted directly into a spreadsheet of coded variables. No patient identifiable data will be collected to ensure complete anonymity. This spreadsheet will be stored on the Lancashire Hospitals T-Drive in a password protected folder accessible only to Sarah Edney and Helene Thygesen (Lecturer in Health Statistics at University of Central Lancashire, Lancashire Clinical Trials Unit and advising statistician at Lancashire Teaching Hospitals NHS Trust).

If it is necessary to move the spreadsheet to the UCLan computer system for statistical analysis, it will be emailed securely/encrypted from sarah.edney@LTHTR.nhs.uk to sedney@uclan.ac.uk then saved on a networked university computer, on a restricted drive, in a password protected folder that will only be accessible by Sarah Edney and Helene Thygesen.

Information to be included on spreadsheet includes:

- Gestational age category (coded 1-4)
- Medical status – number of systems involved (coded 1-5) and types (coded 1-27)
- Full oral feeding by 37 weeks and 40 weeks (coded 1-3/1-4)

All data collected will be stored securely for a minimum of 10 years.

Coding

Gestational age category:

- 1) Extremely preterm: <28 weeks
- 2) Very preterm: 28-31+6 weeks
- 3) Moderate to late preterm: 32-36+6 weeks
- 4) Term: 37 weeks+

Medical status – number of systems involved:

- 1) None
- 2) 1
- 3) 2
- 4) 3
- 5) 4 or more

Medical status – types and combinations:

- 1) No involvement in any of the specified systems
- 2) Neurological only
- 3) Respiratory only
- 4) Gastrointestinal only
- 5) Cardiac only
- 6) Craniofacial only
- 7) Neuro + respiratory
- 8) Neuro + gastrointestinal
- 9) Neuro + cardiac
- 10) Neuro + craniofacial
- 11) Respiratory + gastrointestinal
- 12) Respiratory + cardiac
- 13) Respiratory + craniofacial
- 14) Gastrointestinal + cardiac
- 15) Gastrointestinal + craniofacial

- 16) Cardiac + craniofacial
- 17) Neuro + respiratory + gastrointestinal
- 18) Neuro + respiratory + cardiac
- 19) Neuro + respiratory + craniofacial
- 20) Neuro + gastrointestinal + cardiac
- 21) Neuro + gastrointestinal + craniofacial
- 22) Neuro + cardiac + craniofacial
- 23) Respiratory + gastrointestinal + cardiac
- 24) Respiratory + gastrointestinal + craniofacial
- 25) Respiratory + cardiac + craniofacial
- 26) Gastrointestinal + cardiac + craniofacial
- 27) 4 or more systems

Slow attainment of full oral feeding (preterms only):

- 1) Yes
- 2) No
- 3) Information not available (exclude from analysis)

Feeding difficulty (all babies):

- 1) Yes – achieved oral feeding after 40 weeks but before discharge
- 2) Yes – discharged home tube feeding
- 3) No
- 4) Information not available (exclude from analysis)

Operational Definitions

Gestational age groups are based on the categories used by the World Health Organisation:

- Extremely preterm: <28 weeks
- Very preterm: 28-31+6 weeks
- Moderate to late preterm: 32-36+6 weeks
- Term: 37 weeks+

Medical status will be categorised by the number of impaired body systems from the following list: neurological, respiratory, gastrointestinal, cardiac, and craniofacial. Following a thorough literature review, these five systems are the most commonly related to feeding difficulties.

Presence/absence of involvement of these systems will be determined by the patients discharge letter on BadgerNet. This letter is completed by a medical doctor and includes a section for each of the listed systems. If a problem is listed under any of these system headings it will be recorded as a positive, regardless of severity or duration. Exceptions to this include the following: retinopathy of prematurity, transient tachypnea of the newborn, intraventricular haemorrhage grades 1-2, and brachial plexus injury with no respiratory compromise.

Slow attainment of full oral feeding is defined as inability to achieve full oral feeding by:

- 37 weeks post-menstrual age (full term)
- Discharge home (if earlier than 37 weeks) or
- One week chronological age if born at or over 36 weeks

Feeding difficulty is defined as inability to achieve full oral feeding by:

- 40 weeks post-menstrual age (due date)
- Discharge home if earlier than 40 weeks, or
- One-week chronological age if born at or over 39 weeks.

Analysis

Descriptive statistics and appropriate statistical tests will be used to determine the presence or absence of correlation between variables. Outcomes with the strongest correlation will be identified and analysed using a logistic regression model. A member of University of Central Lancashire staff (Helene Thygesen, Lecturer in Health Statistics, Lancashire Clinical Trials Unit and advising statistician at Lancashire Teaching Hospitals NHS Trust) will assist in conducting statistical analysis.

Ethical and Research Governance considerations

Patient/Guardian consent will not be sought for this study for reasons of practicality. The data to be utilised is routinely collected at Lancashire Teaching Hospitals and will be gathered retrospectively and anonymously by the clinical researcher who is a member of the clinical team (Sarah Edney). Anonymised data will be stored securely with access only for Sarah Edney and Helene Thygesen. Findings from the study will be used to identify correlations only. No new treatment methods will be suggested or recommended as a result of this study.

Timeline

Task	Mar	Apr	May	June	July	Aug	Sept
Learning agreement	✓						
Literature review	✓						
Finalise methods		✓					
UCLan ethics			x				
Develop spreadsheet			x				
R&D approval				Early June			
Data collection				Late June			
Analysis					Early July		
Write up results					Late July		
Write up discussion						Early Aug	
Produce poster						Late Aug	
Complete final report							

Outputs

Findings from this study will be submitted for presentation at the NHS Research & Development North West Annual Conference 2016 and for publication in an academic peer-reviewed journal. Findings will also be presented in a final report.

Costings

This project is taking place as part of a Clinical Academic Internship funded by Health Education England. The funding covers the project co-ordinators time, ensuring that for the host trust the project is cost neutral.

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