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Improved growth, tolerance and intake with an extensively hydrolysed peptide feed in infants with complex disease

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SUMMARY

Background & aims: Infants with complex medical conditions often display faltering growth due to elevated nutritional requirements, poor intake and intolerance of feeding with malabsorption and maldigestion. As a result their nutritional management can be extremely challenging and enteral nutritional support is required. This study aimed to investigate the effectiveness, tolerance and acceptability of nutritional support with a specially formulated, paediatric peptide feed in infants with complex disease and signs of growth faltering with their current nutritional management.

Methods: This prospective intervention study investigated gastrointestinal (GI) tolerance, nutritional intake and compliance with feeding, anthropometry and growth in 18 infants (mean age 6.11 months \pm 4.69, mean weight 4.97 kg \pm 1.71) during 28 days of enteral nutritional support with a paediatric (1 kcal/ml) peptide feed.

Results: GI tolerance to nutritional support with a peptide enteral feed was good and either improved or remained stable over the study. Compliance was excellent (94.0% \pm 12.6), total energy intake improved ($+23 \pm 42$ kcal/kg, $p = 0.037$) and mean weight (0.61 kg \pm 0.31, $p = 0.0001$), length (1.89 \pm 1.77 cm, $p = 0.0001$), head circumference (1.33 \pm 1.29 cm, $p = 0.001$), weight for length Z score ($p < 0.05$), and weight for age Z score ($p < 0.05$) significantly improved. Sixty one percent ($n = 11$) of the infants showed signs of increased growth velocity, moving upwards in terms of their centiles. All 18 infants continued with the paediatric, peptide enteral feed once the study was complete.

Conclusions: This prospective study showed that nutrition support with a specially formulated, paediatric peptide feed was well tolerated, helped to promote growth, and can be considered suitable for use in infants with complex disease and faltering growth who are unable to tolerate a whole protein feed.

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1. Introduction

In infants with complex medical conditions involving multiple organ systems, faltering growth is common [1–4] and associated with poorer outcomes [3–7]. The causes of faltering growth are typically multifactorial and often include severe malabsorption and maldigestion of nutrients (including protein and fat) and an

inability to take or tolerate an oral diet or enteral nutritional support with standard whole protein feeds [8]. In these situations nutritional support with enteral feeds that contain pre-digested sources of protein and readily absorbed fat are often indicated. In some circumstances failure to achieve tolerance and growth with enteral feeding may also necessitate involvement of parenteral nutrition (e.g. in total gut failure), which, although lifesaving in one respect can itself be associated with further and often significant complications [9,10]. Very few trials of enteral nutritional support have been published in this patient group [4,11–13], especially in young infants with complex diseases, and therefore nutritional management decisions in clinical practice are often based on expert clinical opinion and experience.

Special consideration should also be given to nutritional requirements, as these infants with multiple, complex diseases may have an increased requirement for both energy and protein [14] as well as micronutrients. Our understanding of requirements in infants and particularly those with complex disease is limited and the calculation of these requirements can be challenging and prone to error [15]. However there is guidance available on protein requirements and more specifically the protein energy ratio required to achieve the correct rate of growth, and to ensure that the weight gain is of the desired composition [16,17]. In recent years specialist, ready to use, paediatric enteral formulae have been developed with a protein:energy ratio in line with these recommendations to support adequate growth in infants who require nutritional support. However, traditionally, these formulas were based on whole protein and long chain triglyceride fat sources which can be unsuitable for managing patients with severe maldigestion and malabsorption. The lack of readymade, high energy, peptide and medium chain triglyceride (MCT) containing formulae has also meant that dietitians and other clinicians have had to adapt powdered peptide formulas to meet the nutritional needs of infants with complex disease which, in itself carries a risk of microbial contamination and error in reconstitution [18–20]. Consequently, a ready to use high energy, high protein feed based on peptides and MCT has been developed in line with nutritional guidelines, to help clinicians improve the effectiveness of the nutritional support to infants with complex medical problems who have maldigestion and malabsorption and increased nutritional requirements. However, research is required to investigate the effect of this type of enteral nutritional support in this patient group.

As infants with complex, multiple system diseases are a particularly sensitive and vulnerable patient group, a study was designed and undertaken in a way to ensure the continued appropriate clinical care for the infants with as little disturbance as possible. Therefore a prospective, single arm, longitudinal, interventional, 4 week multi-centre study was undertaken to investigate the tolerance, and effectiveness of nutritional support with a ready to use, liquid peptide and MCT based enteral feed in infants who are unable to tolerate a whole protein feed.

2. Methods

2.1. Patient population

Dietitians from nine hospitals across the UK (Royal Alexandra Children's Hospital, Brighton; The Great North Children's Hospital, Newcastle; Bristol Royal Hospital for Children, Bristol; Great Ormond Street Hospital, London; Nottingham Children's Hospital, Nottingham; Royal Hospital for Sick Children, Edinburgh; Addenbrooke's Hospital, Cambridge, St Georges Hospital, London; Royal Hospital for Sick Children (Yorkhill), Glasgow) took part in the trial. Infants were included if they were aged 0–18 months and/or up to 8 kg in body weight, had signs of growth faltering (identified

individually by the dietitian, using assessment of weight for length, weight for age, length for age and or head circumference for age (see Table 1), growth on inappropriate centiles for age or a dropping off and crossing of growth centiles (UK – WHO Neonatal and Infant Close Monitoring Charts) [21,22], also a medical picture of concern and the dietitian's clinical experience) and requiring a peptide feed (the infant had been unable to tolerate or grow adequately on a whole protein feed or alternative enteral regimen) to promote growth. All alternative feeding options had been considered by the recruiting dietitians. The infants had to be receiving at least 30% of their total energy intake from enteral feeding and written informed consent had to be provided by their parents or legal guardian. Infants were excluded if they were receiving parenteral nutrition providing in excess of 70% of their total energy requirements; had confirmed cow's milk protein allergy, major hepatic or renal dysfunction, galactosaemia or severe lactose intolerance, or had participated in other studies within 2 weeks prior to entry of this study; were being exclusively breast fed or if the investigator had a concern around the willingness or ability of the parents/carers to comply with protocol requirements.

Due to the limited number of infants estimated to require this type of enteral feed in the UK (approximately 200), the aim was to recruit 20 participants (10%) in total to the study, a sample size similar to other studies in complex paediatric patients [11–13] and considered adequate to meet the objectives of the study. Between July 2011 and September 2012, sixty two infants were screened for participation in the trial by the recruiting dietitians, 40 infants were found to be either unsuitable or their parents declined to participate details of which are shown in Fig. 1. Twenty two infants with complex disease and documented concerns regarding gastrointestinal intolerance and growth faltering were recruited. Eighteen infants completed the 4 week study (10 males (55.6%), 8 females (44.4%)) with a mean age of 6.1 ± 4.7 months. Four infants did not complete the study; parents of 3 infants withdrew consent within the first 48 h of the study due to concerns with initial tolerance (the decision to withdraw was independent of any discussion with the investigating dietitian at the study sites) and 1 of the infants had to be withdrawn halfway through the study because of complications with their stoma site, and required total parenteral nutrition in order for the site to heal. The baseline characteristics of the 18 infants who completed the trial are shown in Table 1. Seventeen of these infants were receiving enteral nutritional support, whilst 1 was receiving a mixture of enteral and parenteral nutritional support.

The 18 infants completing the study had complex medical diagnoses, often with multiple unresolved problems impacting their nutritional status, see Table 2.

Table 1
Baseline characteristics of the infants completing the study, n = 18.

Characteristic, measure	Mean \pm standard deviation (range)
Age, months	6.11 \pm 4.69 (2–14)
Period of growth failure prior to baseline, days	96.70 \pm 85.19 (30–330)
Baseline energy requirements, kcal/kg	118.47 \pm 21.27 (77–166)
Baseline protein requirements, g/day	11.84 \pm 4.55 (6.3–24.2)
Percent energy to be provided by enteral feed, %	74.78 \pm 25.38 (34–100)
Weight on day 1, kg	4.97 \pm 1.71 (2.31–7.7)
Length on day 1, cm	59.16 \pm 8.03 (42.9–73)
Head circumference on day 1, cm*	39.23 \pm 3.75 (33.1–45.2)
Weight for length, Z score**	-1.54 \pm 1.47
Weight for age, Z score	-2.67 \pm 1.10
Length for age, Z score	-2.14 \pm 1.84
Head circumference for age, Z score*	-1.90 \pm 1.08

*n = 16, **n = 17.

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