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Tube feeding and quality of life in children with severe neurological impairment

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ABSTRACT

Objective: To assess the quality of life (QOL) of neurologically impaired children before and after gastrostomy (G) and gastrojejunostomy (GJ) tube insertion. **Design:** This was a prospective longitudinal study of children with severe neurological impairment who underwent G or GJ tube insertion. At baseline, and at 6 and 12 months after tube insertion, parents rated (1) global QOL and health-related quality of life (HRQOL) using 10 cm visual analogue scales, with 10 representing maximal QOL and (2) HR-QOL using a questionnaire-based measure.

Results: Fifty patients, 45 and five of whom underwent G and GJ tube insertion, respectively, were enrolled with a median age of 591 days. Forty-two had a static neurological disorder, and eight had a progressive neurological disorder. The mean weight for age z score increased significantly over time: -2.8 at baseline and -1.8 at 12 months. The mean QOL and HR-QOL scores at baseline were 5.5 and 5.6 out of 10, respectively. There was no significant change in these scores at 6 and 12 months post-tube insertion. Children with a progressive versus a static neurological disorder had a significantly lower QOL over time. Ease of medication administration as well as feeding showed a significant improvement in scores from baseline to 12 months. Parents felt that the G and GJ tube had a positive impact on their child's health at 6 months (86%) and 12 months (84%).

Conclusion: QOL as rated by parents did not increase following insertion of a G or GJ tube in neurologically impaired children. However, parents felt that the tube had a positive impact on their child's health, particularly with regards to feeding and administration of medications.

Tube feeding has become the standard of care for nutritional rehabilitation in children with severe neurological impairment who may suffer from swallowing dysfunction and/or undernutrition.12 With new image-guided techniques that facilitate safe enteral access for long-term tube feeding in medically fragile children,^{3 4} this technology has been widely applied based on the assumption that this intervention has a positive effect on the general health and quality of life (QOL) of the child. Studies have shown that tube feeding results in improvements in weight for age.^{5 6} One recent prospective cohort study demonstrated that tube feeding resulted in reduced need for treatment of respiratory infections, reduced hospitalisation and improved the health of care givers.78 However, systematic reviews of the literature have shown that the impact of tube feeding on outcomes such as QOL has been inadequately studied.^{5 6} The objective of our study was to describe the QOL

What is already known about this topic

Children with severe neurological impairment often have feeding difficulties and are undernourished. Tube feeding is helpful for nutritional rehabilitation, but its impact on quality of life has not been well studied.

What this study adds

► In children with severe neurological impairment, gastrostomy and gastrojejunostomy tube insertion resulted in weight gain. Quality of life as rated by care givers did not improve significantly. However, care givers felt that the tube had a positive impact on their child's health, particularly with regards to feeding and administration of medications.

before and after image-guided enteral tube insertion in young children with severe neurological impairment. The hypothesis was that enteral tube insertion improves the QOL of children with severe neurological impairment.

METHODS

Study design

A prospective observational study of children with severe neurological impairment before and after image-guided gastrostomy (G) or gastrojejunostomy (GJ) tube insertion was conducted, with QOL as the primary outcome. Image-guided enterostomy tube insertion is a minimally invasive technique using a retrograde percutaneous approach guided by ultrasound and fluoroscopy.³ Children were followed for 1 year with data collection (demographic, clinical and outcome measurement) at three time points: baseline (before or at the time of G or GJ tube insertion); 6 months after tube insertion; and 12 months after tube insertion. The study protocol was approved by the Research Ethics Board at The Hospital for Sick Children, Toronto.

Study setting

Children referred to the Interventional Radiology service at the Hospital for Sick Children, Toronto for image guided G and GJ tube placement were eligible for recruitment after September 2002.

Study participants

Parents were approached if they were sufficiently fluent in English to be able to complete questionnaires; their child was referred for image-guided G or GJ tube placement, under the age of 18 years, developed neurological impairment or global developmental delay related to a known or suspected central neurological disorder, and had no previous history of G or GJ tube insertion.

Variables

Neurological impairment

The nature of the child's neurological process was classified as static (eg, cerebral palsy) or progressive (eg, neurodegenerative). The child's degree of neurological impairment was classified by the research nurse with clinical observation and report by parents using the Gross Motor Functional Classification System (GMFCS)^{9 10} at baseline, 6 months and 12 months. This system classifies motor functional abilities from level I (mild) to level V (severe), with level V representing very limited self-mobility. GMFCS classification has not been validated for children less than 1 year of age, so the first measurement performed at an age greater than 1 year was reported as the baseline measurement.

Parental expectation

At baseline, parental expectation of change in QOL following G or GJ tube insertion was measured using an eight-point Likert scale.

Primary outcome

The primary outcome of the study was QOL. As a proxy measure of global QOL, we used a 10 cm, double-anchored visual analogue scale (VAS) to be completed by the parent. One VAS asked parents to rate the global QOL and the second to rate global health-related quality of life (HR-QOL) (see fig 1). The VAS has been validated as a global measure of QOL in other paediatric clinical settings (ie, shown to have face validity, testretest reliability, construct validity and responsiveness).¹¹⁻¹⁵

Figure 1 Primary outcome measure: visual analogue scale.12

Some of the children who come to see us feel that their life is not that great, while others think that their life is OK. How about your child? (Put an 'X" on the lines.)

OVERALL, my child's life is.....

The WORST



Considering my child's HEALTH, my child's life is.....



Secondary outcomes

HR-QOL questionnaire

A questionnaire-based measure of HR-QOL was created for our population of interest. Items relevant to this population of severely neurologically impaired children and their families were selected based on a literature review, review by the authors and content experts. The previously validated CHQ-PF50 served as the foundation for this questionnaire.¹⁶ Questions not relevant to the population of children were removed, and six new questions were added for a total of 20 questions, each scored using a five-point Likert scale, covering 10 domains (see table 1).

A higher score represented a better state for all questions. In addition, one question asked parents to rate their child's global health. Another question asked if they felt that the G or GJ tube improved their child's health. The face and content validity of the questionnaire was assessed by a group of paediatricians, an enteral feeding nurse specialist, an epidemiologist and a representative group of parents. The purpose of the study was not to validate this secondary outcome measure, however the reliability was calculated with data from the baseline administration. The internal consistency of the scale was high (Cronbach alpha 0.85).

Nutrition

Anthropometric data including weight, length and tricep skinfold thickness was assessed at baseline, and at 6 and 12 months follow-up. Measurements were collected by the research nurse in a standardised fashion.

Complications from intervention

Complications related to the tube insertion were documented.

Sample size and statistical analysis

A 2 cm difference on a 10 cm VAS scale was chosen as a "clinically important difference" based on clinical consensus and the published literature.¹⁴ Based on an alpha error of 0.05, a beta error of 0.10 (ie, 90% power), a "clinically important difference" of

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Domain	ltems	Domain maximum score	Question
Global health	1	5	In general, would you say your child's health is?
Activities	1	5	In an average week, your child's activities are limited due to problems with his/her physical health?
Pain	2	10	In an average week, how much bodily pain or discomfort has your child had? In an average week, how often has your child had bodily pain or discomfort?
Mental health	2	10	In an average week, how much of the time do you think your child acted upset? In an average week, how much of the time do you think your child acted cheerful?
Health perceptions	3	15	My child seems to be less healthy than other children I know; when there is something going around, my child usually catches it; I worry more about my child's health than other people worry about their children's health
Parental impact: emotional	2	10	On an average day, how much emotional worry or concern did your child's physical health cause you? On an average day, how much emotional worry or concern did your child's emotional well-being or behaviour cause you?
Parental impact: time	2	10	In an average week, were you limited in the amount of time you had for your own needs because of your child's health? In an average week, were you limited in the amount of time you had for your own needs because of your child's emotional well-being or behaviour?
Family activities	2	10	In an average week, how often has your child's health limited the types of activities you could do as a family? In an average week, how often has your child's health caused tension or conflict in your home?
Feeding	3	15	Feeding my child takes a lot of time; feeding my child is stressful; feeding my child takes away time to do other activities with my child
Respite	2	10	It is difficult to get a baby sitter to look after my child; It is difficult to get respite care
Medications	1	5	It is difficult to give medications to my child

Table 1 Questionnaire domains, domain maximum score and questions

2 cm on the 10 cm VAS scale and a standard deviation of 2.5, a total of 20 subjects would be required for the study.

Scores for each domain on the questionnaire were summed. Weight and height measurements were transformed to *z* scores for age using the NutStat module of Epi Info with the 2000 CDC growth reference charts. Triceps skinfold measurements were dichotomised into two percentile categories, <5th centile for age and \geq 5th centile for age, using data from Frisancho.¹⁷ The proportion of children who had a change in triceps skinfold percentile category was calculated.

A repeated-measures regression model was used to analyse outcomes during the study period with the time variable in the model. Analysis was performed using SAS version 9.10 proc mixed. Covariates were tested by adding them one at a time: nature of neurological impairment (static vs progressive), parental expectation of impact of tube, type of tube (G vs GJ) and weight over time. Where appropriate, pairwise comparisons were performed using the Tukey–Kramer adjustment. All tests were performed with a two-sided alpha of 0.05. A p value of <0.05 was considered statistically significant.

RESULTS

During the study period, 76 patients were identified for enrolment. Sixty-three patients were eligible for enrolment, and 50 agreed to participate (79.%) (fig 2). A comparison of baseline characteristics of enrolled children and children whose parents declined is summarised in table 2. The baseline characteristics of the enrolled patients are given in tables 3, 4.

Enterostomy tube insertion was successful in 50/50 (100%) of patients. In total 1/50 (2%) patients developed a major complication. This patient developed peritonitis and was managed without surgical intervention. No patient died due to a procedural complication. During the study period, four children (8%) had procedures performed as a result of gastro-oesophageal reflux disease: three had their G tube advanced to a GJ tube, and one child had a fundoplication.

Three children died during the study period. Their mean age was 505 days. All died with a palliative care plan in place. The deaths were not directly attributable to tube insertion and were related to their underlying condition. Four patients had their tube removed during the study. Their mean age at time of tube insertion was 413 days; two had an underlying genetic disorder, and two had perinatal asphyxia.

Parental expectation

Parental expectation of the benefits of the intervention on their child's quality of life was rated as very high. Forty-nine out of 50 (98%) thought that after the intervention, their child's quality of life would be better.

Primary outcome

The mean QOL and HR-QOL VAS scores on a scale from 0 to 10 are shown in table 5. There was no significant change in scores over time. There was no significant difference in scores between any two time points (p>0.05). The only covariate that was significantly associated with QOL was the nature of neurological impairment. A progressive neurological disorder was associated with a lower QOL versus a static neurological disorder (4.3 vs 6.2, p = 0.04) over time.

Questionnaire

At baseline, 22% of parents rated their child's health as poor, 60% as fair or good, 18% rated as good and none as excellent. There was a significant improvement in the global health rating from baseline to 6 months (2.5 vs 3.0, p<0.01). However, this improvement was not sustained over time to 12 months (p>0.05).



Figure 2 Patients included in the study.

For the domain related to impact on activities, there was a significant improvement from baseline to 6 months (2.2 vs 2.8, p = 0.02). However, this improvement was not sustained over time to 12 months (p>0.05).

For the domains related to impact on parental time, there was a significant improvement over time (p = 0.02), and this was from 6 months to 12 months (5.5 vs 6.0, p = 0.05).

For the domains related to impact on feeding, there was a significant improvement in scores from baseline to 6 months (8.6 vs 10.5, p<0.01) and a trend to improvement from baseline to 12 months (8.6 vs 10.0, p = 0.08).

For the domain related to medications, there was an improvement in scores from baseline to 6 months and baseline to 12 months (p<0.001).

For the domains related to bodily pain, mental health, health perceptions, parental impact on emotions and respite care, there was no significant change over time in domain scores (p>0.05).

Nutrition

Weight for age z scores improved significantly over time (p<0.01). There was no significant change in height for age z scores over time (p = 0.30) (see table 6). Of the fifty patients at baseline, 14 (28%) had a triceps skinfold measurement that was less than the 5th centile for age. For the 13 children in this group where follow-up data were available, 6/13 (46%) had an increase in percentile category to greater than the 5th centile for age. Thirty-six children at baseline had a baseline triceps skinfold

 Table 2
 Baseline characteristics: enrolled patients versus patients who declined

	Patients enrolled	Patients declined	
	N = 50	N = 13	
Age at tube insertion			
Median (range) days	591 (20, 5663)	729 (12, 6035)	
Nature of neurological disorder			
Static neurological disorder no (%)	42 (84%)	11 (85%)	
Type of tube: G tube no (%)	45 (90%)	13 (100%)	

greater than the 5th centile. For the 31 children in this group where follow-up data were available, 29/31 (97%) maintained their triceps skinfold measurement above the 5th percentile for age.

Satisfaction

At 6 months and 12 months after tube insertion, 43/47 (86%) and 36/43 (84%), respectively, felt that the G and GJ tube improved their child's health. There was no significant difference in the mean rating at 6 and 12 months (p = 0.24; n = 43).

DISCUSSION

Our results suggest that there was no significant increase in the QOL of children with severe neurological impairment in the first year after G or GJ tube insertion as reported by parents. This finding may be explained by the context of the severe underlying condition, wherein the benefits of this one intervention are not sufficient to improve overall QOL. Alternatively, parents may not conceptualise QOL as a comprehensive, multidimensional construct but as individual elements. Thus, we would not observe changes in overall QOL and only in particular dimensions. Our results do suggest several benefits associated with the intervention. Weight for age increased to a clinically significant degree over the study period. Parents felt that the intervention had a positive impact on their child's health and in particular on feeding and ease of administration of medications. There were transient improvements on the impact of child's health on activities and parental time. This suggests that tube feeding is positively associated with certain aspects of health and HR-QOL. Furthermore, the procedure was safe with few major complications.

Table 3 Baseline characteristics: neurological diagnosis of enrolled patients

	Patients enrolled $N = 50$	
	No (%)	
Nature of neurological disorder		
Static	42 (84)	
Progressive	8 (16)	
Diagnosis associated with neurological impairment		
No identified diagnosis	9 (18)	
Genetic or syndrome	8 (16)	
Preterm: intracerebral haemorrhage and/or periventricular leucomalacia	8 (16)	
Perinatal asphyxia (term)	7 (14)	
Metabolic disorder	6 (12)	
Cerebral malformation	6 (12)	
Postnatal insult	4 (8)	
Congenital infection	2 (4)	

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	Enrolled patients		
-	Static neurological disorder (N = 42)	Progressive neurological disorder ($N = 8$)	Total (N = 50)
Age at tube insertion median (range) days	591 (20, 5663)	630 (185, 2442)	591 (20, 5663)
Sex: female no (%)	23 (54)	3 (38)	26 (52)
Oral feeding no (%)	24 (55)	2 (25)	26 (52)
Nasogastric tube feeding no (%)	29 (69)	7 (88)	36 (72)
Duration of nasogastric tube feeding (median days)	28	14	27
Type of tube no (%)			
Gastrostomy	37 (88)	8 (100)	45 (90)
Gastrojejunostomy	5 (12)	0 (0)	5 (10)
Gross motor classification scale† no (%)			
Level V	29 (69)	5 (63)	34 (68)
Level IV	6 (14)	2 (25)	8 (16)
Level III	5 (11)	1 (13)	6 (12)
Reason for tube insertion no (%)			
Dysphagia	42 (100)	8 (100)	50 (100)
Failure to thrive	21 (50)	2 (25)	23 (46)
Aspiration on videofluoroscopic feeding study no (%)	18/27 (67)	4/6 (67)	22/33 (67)
Seizure history no (%)	21 (50)	4 (50)	25 (50)
Tracheostomy no (%)	3 (6)	0 (0)	3 (6)
Medications no (%) for gastro-oesophageal reflux disease	21 (50)	3 (38)	24 (48)
Antiepileptics	22 (52)	3 (38)	25 (50)

 Table 4
 Baseline characteristics of enrolled patients by nature of neurological disorder

†Two patients withdrew before 1 year of age (score not validated in infants under 1 year).

A progressive neurological disorder was significantly associated with a reduction in QOL over time. This finding is not unexpected, as one would expect the QOL of children with a progressive neurological disorder to decrease over time. By improving nutritional status, one may postulate that tube feeding would improve QOL. Our findings do not support this hypothesis of an association between weight and QOL. Parental expectations and type of tube (G vs GJ) were also not associated with QOL over time.

The strengths of this study include prospective data collection, the first measurement of QOL in this context, large sample size (ie, sufficient statistical power to detect "clinically important differences"), long-term follow-up (12 months) and data collection pre- and postintervention (ie, subjects act as their own controls). The primary outcome used a 10 cm VAS, a tool that has been validated in the literature. We also administered a multidimensional questionnaire which allowed for exploratory analysis to help interpret changes on QOL based on the VAS scores. Several limitations merit mention. The QOL and HR-QOL represent the perceptions of care givers and parents. Given that this group of children are unable to rate their own QOL, there are no better alternatives. A cohort study or randomised controlled trial comparing tube versus oral feeding would be more optimal designs to measure the impact of the intervention. The current standard of care for these

 Table 5
 Quality-of-life and health-related quality-of-life scores

	Mean visual analogue scale score (95% Cl)		
	Baseline	6 months	12 months
	n = 50	n = 47	n = 43
Quality of life	5.5 (4.6 to 6.4)	5.8 (4.9 to 6.7)	6.4 (5.5 to 7.1)
Health-related quality of life	5.6 (4.6 to 6.4)	6.0 (5.1 to 6.9)	6.5 (5.6 to 7.4)

children, however, is tube feeding, the waiting list is short, and few parents decline the intervention when recommended. Therefore, these designs were considered neither feasible nor ethical.

No study has prospectively examined the impact of tube feeding in children with severe neurological impairment on QOL. Sullivan *et al* found that G tube feeding resulted in significant weight gain in children with cerebral palsy; they did not assess the impact on the QOL of the child.⁷ In another study, Sullivan *et al* found that G tube feeding resulted in an improvement in the QOL of care givers⁸ and that care givers reported reduced feeding times, increased ease in administration of medications, and reduced concerns about their child's nutritional status. Our study similarly demonstrated that one way by which G tube feeding impacts positively on the child and family is through facilitation of care (ie, impact on feeding and administrations).

CONCLUSION

We observed that image-guided G and GJ tube insertion in children with severe neurological impairment was not associated with a significant improvement in QOL as rated by their parents in the first year after tube placement. It was, however, associated with a positive impact on feeding, ease of administration of medications and weight for age. Parents generally felt that the intervention had a positive impact on their overall child's health. Counselling of families considering G tube

Table	6	Nutritional	outcomes
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	Weight for age <i>z</i> score (95% CI)	Height for age z score (95% CI)
Baseline (n = 50)	-2.8 (-3.4 to -2.1)	-2.1 (-2.8 to -1.4)
6 months (n = 47)	-2.0 (-2.7 to -1.4)	-1.8 (-2.5 to -1.1)
12 months (n = 43)	-1.8 (-2.5 to -1.2)	-2.0 (-2.8 to -1.3)

insertion should be based on a balanced understanding of potential benefits and complications of the intervention. As clinical decision-making for this group of severely disabled children is complex, it should be family-centred with explicit discussions about the goals of tube feeding and potential impact on health and QOL.

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Archivist

Cardiovascular risk factors in the children of mothers with gestational diabetes

The incidence of type 2 diabetes in childhood has increased worldwide. It represents up to 45% of all new cases of diabetes in the USA and in Japan type 2 diabetes is seven times as common as type 1. Maternal diabetes in pregnancy increases the risk of type 2 diabetes in the child. Now a study in Hong Kong (Wing Hung Tam and colleagues. *Pediatrics* 2008;**122**:1229–34) has shown that maternal gestational diabetes is associated with an increase in cardiovascular risk factors in children.

A previously reported study of gestational diabetes included 63 women with gestational diabetes mellitus (GDM) and 101 with normal glucose tolerance (NGT). Their children were assessed at 7–10 years (median 8 years) of age. Six children (3.7%) had impaired glucose regulation or diabetes at follow-up, four in the maternal GDM group and two in the maternal NGT group (difference not significant). Mean systolic and diastolic blood pressures were significantly higher in the maternal GDM group (94 vs 88 mm Hg and 62 vs 57 mm Hg). After adjustment for age and sex, serum high-density lipoprotein concentrations were significantly lower (1.58 vs 1.71 mmol/l) in the maternal GDM group. A raised concentration of insulin in cord blood was associated with increased risk of abnormal glucose tolerance in the children. Maternal gestational diabetes increases the prevalence of cardiovascular risk factors in 8-year-old children.

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