Effects of Gastrostomy Feeding in Children with Cerebral Palsy: An AACPDM Evidence Report

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Objective

The objective of the American Academy for Cerebral Palsy and Developmental Medicine (AACPDM) evidence reports is to provide the biomedical research and clinical practice communities with the current state of evidence about various interventions for the management of developmental disabilities. The AACPDM evidence reports aggregate all that has been published about outcomes of an intervention for a medical condition, gauge the credibility (i.e., strength of the internal validity) of that evidence, and identify gaps in our scientific knowledge. The original version of these reports is published in The AACPDM Database of Evidence Reports on the Internet at www.aacpdm.org where evidence reports will be updated at regular intervals to include new research.

The AACPDM reviews are not evidence-based "practice guidelines". As yet, the bodies of evidence in developmental disabilities are neither robust nor comprehensive enough to allow confident generalization to groups of people-at-large, a prerequisite for evidence-based practice guidelines. Absence of evidence of effectiveness in an evidence report should not be construed as proof that a treatment is not effective; rather, it may reflect areas in which more meaningful research is needed. In the meanwhile, clinicians

must be circumspect about their treatment recommendations, relying on current "best evidence" to inform individual choice.[a]

Disclosure

Every effort has been made to assure that AACPDM Evidence Reports are free from any real or perceived bias. The Academy's editorial review panel is a multidisciplinary group comprised of the current members of the AACPDM Treatment Outcomes Committee who serve three-year rotating terms. This Committee may invite up to two additional reviewers to encourage substantive input by knowledgeable proponents of all points of view. Potential conflicts of interest by authors and reviewers have been disclosed and are documented in The AACPDM Database of Evidence Reports. The Treatment Outcomes Committee is charged and overseen by the AACPDM Board of Directors with the task of developing evidence reports and operates under an approved methodology of systematic review of the scientific literature and under approved procedures .[1,2] Final sanction for each report is granted by the Board.

Consensus Process

The review authors organize intervention outcomes in a predefined manner and answer predefined questions to describe the scientific evidence. Members of the editorial review panel give their input and resolve any differing opinions to reach agreement about statements made therein on behalf of the Academy.

Nevertheless, the data in an AACPDM Evidence Report can be interpreted differently, depending on people's perspectives. Please consider the statements presented carefully.

Gastrostomy

Malnutrition and growth failure were long regarded as inevitable and irremediable consequences of severe CP. In recent years, however, technical advances in tube feeding and ready availability of commercially prepared formulas such as Jevity®, Pediasure®, and Ensure® have caused clinicians to re-examine that expectation.

Gastrostomy, in which a tube is surgically inserted directly into the stomach through an opening in the abdominal wall, has been used since the late 1800's to bypass gastrointestinal dysfunction. Subsequently, it has also been used to bypass oral motor dysfunction when conventional treatment (i.e., positioning, therapeutic techniques to facilitate lip closure and swallowing, thickened food and liquid, and extended feeding time) has failed to resolve severe, chronic oral feeding problems.

Feeding tube placement has the potential to impact multiple health-related quality of life dimensions. Its primary goal, as reported in the literature, is to improve physical well-being by reversing or preventing malnutrition. Other goals are said to be greater satisfaction of the feeding process for the child and caregiver dyad; time re-distribution for less stressful activities involving the child, siblings, and caregivers; a procedure for

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[a] "Best evidence" is represented by the study (or studies) in the evidence report that most closely approximates the patient characteristics of interest to the clinician, that used a therapeutic regime most like the one the clinician can provide, that investigated outcomes of greatest concern to this patient, and that provides the most credible or internally valid results.

giving medications with improved compliance and effectiveness; and increased patient vigor and responsiveness. Nevertheless, some reports have suggested that tube feeding may have high risks and unmet goals.

Impaired oral-motor function is a common feature of cerebral palsy (CP) including incoordination of tongue and swallowing muscles, temporomandibular joint contractures, hypoxemia, and discomfort, vomiting and aspiration pneumonia associated with gastroesophaggeal reflux (GER).[3,4] Such difficulties can be associated with lengthy meal times, fatigue during eating, food refusal, and malnutrition. Indeed, the North American Growth in Cerebral Palsy Project found that 27% of children with moderate to severe CP were malnourished, as measured by triceps skinfold thickness less than the 10th percentile.[5]

The consequences of malnutrition are far-reaching and clinically significant.[6] Although research that documents the effects of malnutrition specific to CP has been limited, linear growth failure, higher surgical morbidity, delay in decubitus ulcer healing and death have been reported.[7-13] Research in other pediatric groups has documented negative impacts in many organ systems (e.g., respiratory[14, 15] cardiac[16, 17], immune[18]) and impaired motor, cognitive, and social behavior and development[6, 19-22].

Nasogastric tube feeding, in which a tube is inserted into the stomach through the nasal passage, is most often used for short term enteral tube feeding. Several limitations for its long term use have been reported including nasal discomfort, irritation or penetration of the larynx, recurrent pulmonary aspiration, blockage or displacement of the tube, and decreased survival rates.[23]

When children have such a marked degree of oral-motor dysfunction that they 1) require nasogastric feedings beyond the short-term, acute care period, 2) take a long time to feed, 3) have inadequate weight gain, and/or 4) have an unsafe swallow (i.e., significant risk of aspiration of food) demonstrated on a contrast videofluoroscopy, clinicians and families may consider gastrostomy as an alternative to exclusive oral feeding. It has been recommended that children who have moderate to severe GER, children with ascites, and children who have had previous abdominal surgery require cautious presurgical evaluation and diagnostic measures to ensure a safe and successful outcome.[23]

Today, gastrostomy can be done surgically, laparoscopically or endoscopically (i.e., percutaneous endoscopic gastrostomy or PEG).[23,24] The PEG has been used increasingly in children with chronic disabilities.[23] It can be performed as a day case, preferably under general anesthesia, although children are often hospitalized for a period of time post-operatively for monitoring and initiation of feeds. An antireflux procedure to decrease risk of aspiration due to gastric reflux (i.e., fundoplication) may be done simultaneously with surgical gastrostomy.

Some literature suggests that tube feeding may fall short of its promise in individuals with neurologic impairments. For example, studies that contained a mix of neurological impairments [25] and/or developmental delay[26] and that contained both nasogastric and gastrostomy feeding reported recurrent morbidity (pneumonia, vomiting, choking-gagging) and /or late mortality. A retrospective analysis of 4,921tube fed children with severe disabilities and mental retardation found an approximately doubled

mortality rate among those with less severe disabilities than among those with very severe disabilities.[27] The authors hypothesized that the increased mortality rate may be attributable to a differential increase in pulmonary disease secondary to overly vigorous nutritional maintenance and subsequent aspiration after tube placement.

In contrast, some literature suggests that outcomes may be more favorable for individuals fed via gastrostomy tube, for individuals with CP, or both. Survival rates among 447 children with severe neurologic disabilities fed by gastrostomy tube were found to have had a significantly better survival rate than those fed by nasogastric tube.[28] This was so even when the data were further analyzed by the presence or absence of other significant diseases. When the rates were analyzed by medical condition, the children with CP were found to have had a better survival rate compared to the children with chromosomal abnormalities, head injury, progressive neurological diseases, or perinatal infections. In a different study[24], children diagnosed with CP also had the best recovery from failure to thrive compared to children who had chromosome abnormalities or who had experienced sudden trauma or perinatal infections.

Method of review

INCLUSION CRITERIA

This review was undertaken to examine the outcomes of gastrostomy tube feeding in individuals with CP. Studies with data about gastrostomy feeding, however, have not been homogeneous with respect to the either tube-feeding intervention or the participants' medical condition. The intervention in most studies included a variety of enteral feeding methods including nasogastrostomy and some participants also underwent fundoplication. Most studies also included participants with a wide variety of medical conditions under the umbrella of neurological impairment (NI), severe developmental disability (DD), or failure to thrive (FTT) as their population sample. The definition for CP differed among the studies, was not explicit, or included children with diagnosed genetic syndromes or progressive disorders as well as traumatic brain injury in later childhood.

This review is limited to studies in which the intervention was gastrostomy feeding or a variant, i.e., a form of tube feeding specified either as: 1) gastrostomy, 2) PEG, 3) jejunostomy, 4) gastrojejunostomy, or 6) some combination of these. Hereafter, this intervention will be referred to as gastrostomy. These interventions may have been combined with fundoplication. Studies of nasogastric tube feeding have been excluded.

This review is limited to studies in which the participants were children (under age 18 at time of gastrostomy placement) with CP defined as a non-progressive disorder of motion and posture due to brain dysfunction occurring before 12 months of age with commonly associated sensory and cognitive impairments.

Given the paucity of studies with this specificity of intervention and population sample, studies have also been included if:

1) There was a subgroup of any size with CP and gastrostomy placement for which specific outcomes were reported,
2) At least 90% of the whole sample had CP and gastrostomy feeding, even though specific outcomes for the subgroup with CP and gastrostomy were not reported.

3) The amount of variability in outcome by specific types of participants and type of intervention was reported and was minimal.

In the latter two circumstances, even though the data is not explicit for CP and gastrostomy feeding, it may be assumed to reasonably reflect the outcomes for individuals with CP and gastrostomy feeding.

LITERATURE SEARCH

The literature search included MEDLINE (1956 through March, 2002), HealthSTAR (1975-2000), ClinPSYC (1989-2000), CINAHL (1982-March, 2002), Best Evidence (1991-2001), and Cochrane Database of Systematic Reviews (4th quarter 2000) for studies published in English. The electronic search terms were (gastrostomy OR enteral feeding) AND (cerebral palsy OR brain injury OR developmental delay)". Reference lists in studies and review articles and researchers knowledgeable about this intervention were also consulted to identify potentially relevant studies. Sixty-five abstracts were initially examined. Thirty-four were excluded because the publication was not a clinical study. The full text of 31 studies was reviewed. Twenty-one of these studies did not investigate, or contain specific data about, effects of gastrostomy feeding compared to exclusively oral feeding of children with cerebral palsy as defined above and were, therefore, excluded. It was unclear from the published report whether the sample population of three of the remaining 10 studies met the operational definition for inclusion in this review, so the authors personally contacted the investigators for additional information. These three studies were subsequently confirmed and included.[29,30,31] Ten studies met the criteria for inclusion.

CLASSIFICATION OF THE RESULTS

All reported results of gastrostomy were classified on the basis of 1) dimensions of disablement (i.e., what kind of evidence there is) and 2) levels of evidence (i.e., how strong the evidence is).[b]

Dimensions of disablement (Table I) is a concept and a classification system that facilitates the measurement, management, and research of rehabilitation outcomes and minimizes the barriers between medical and social models of rehabilitation. It describes the effects of disablement (and interventions) in five dimensions: cellular and molecular physiology, body parts and systems, human activities, fulfillment of gender and societal roles, and in the dimension outside the affected individual including the family circumstances, prevalent societal attitudes, social policies, architectural barriers.

[b] The rationale and specific guidelines followed for classifying the treatment outcomes are available on the Academy's Internet web site at www.aacpdm.org. in the document titled "AACPDM Methodology for Developing Evidence Tables and Reviewing Treatment Outcomes Research". This classification was based on a beta version of a World Health Organization classification that has been several years in development. The final version of the WHO classification, recently completed, will soon be incorporated into the classification used by AADPDM.

Table I: Dimensions of disablement.[1]

Dimension	Description
Pathophysiology	Interruption or interference of normal physiology and developmental processes or structures
Impairment	Loss or abnormality of body structure or function
Functional Limitation / Activity	Restriction of ability to perform activities
Disability / Participation	Restricted participation in typical societal roles
Societal Limitation / Context Factors	Barriers to full participation imposed by societal attitudes, architectural barriers and social policies and other external factors, i.e., family circumstances

Levels of evidence classifications and other quality-rating schemes are based on 1) a hierarchy of research designs that range from the greatest to least according to ability to reduce bias and/or 2) a means of assessing the scientific rigor of the conduct of the particular research study.[c] Generally speaking, Level I research designs contain the most scientifically rigorous methods, can produce the strongest evidence, and, thus, can yield the most definitive results.[32] Level II designs are less scientifically rigorous so can produce, at best, less convincing evidence; thus, their results must be regarded as only tentative. Levels III and IV can produce still less persuasive evidence with results that can merely suggest causation. No conclusions regarding treatment effectiveness can be drawn from Level V evidence as it contains no before and after documentation or control of other variables that may account for the outcomes observed. However, even though a study may employ a Level I design, the actual conduct of the study may not implement all the controls for threats to validity possible under the design. Thus, evaluation of the conduct of the actual study is important.

The AACPDM levels of evidence classification (Table II), rates each study on the basis of its research design (Part A) plus a study quality indicator that reflects how well threats to validity appeared to be controlled within the parameters of the research design used (Part B). Unlike some other classifications, the AACPDM levels of evidence evaluation is limited to gauging only the internal validity of a study, i.e., its ability to attribute the observed outcomes to the intervention in that study External validity, or the confidence with which a finding might be expected to be true for others outside the study, is not reflected in this classification. Instead, whether a finding can be expected to generalize is believed to be more appropriately determined by individual users of the evidence reports who will focus on only the specific aspects of similarity between a patient of interest and the people who have been studied (e.g., their age, type and severity of cerebral palsy, conditions of treatment).

[c] The concept of a "quality determination" for articles used in systematic reviews is a matter of some debate. The science of critical appraisal of research, initially developed in internal medicine, is an on-going process. It is additionally difficult to apply this concept to research about disabling conditions in developing children. Despite the considerable challenge, there is agreement that teams developing systematic reviews can take certain steps to ensure that their approaches to grading the quality of research results meet current scientific standards.

Table II: AACPDM Levels of evidence. [1] This designation is in two parts, indicating the highest level of evidence the research design could have provided (i.e., Level I-V) plus an assessment of the conduct of the actual study (i.e., Strong, Moderate, Weak control to threats to internal validity).

Part A. Type of Research Design

Level	Non-empirical	Group Research	Outcomes Research	Single Subject Research
I		Randomized controlled trial All or none case series		N-of-1 randomized controlled trial
II		Nonrandomized controlled trial Prospective cohort study with con-current control group	Analytic survey	ABABA design Alternating treatments Multiple baseline across subjects
III		Case-control study Cohort study with historical control group		ABA design
IV		Before and after case series without control group		AB design
V	Descriptive case series or case reports Anecdote Expert opinion Theory based on physiology, bench, or animal research Common sense/ first principles			

Part B. Conduct of Study Assessment

Conduct of the study is judged as Strong ("yes" score of 7 or 6), Moderate (score 5), or Weak (≤4).

1. Were inclusion and exclusion criteria of the study population well described and followed?
2. Was the intervention well described and was there adherence to the intervention assignment? (For 2-group designs, was the control exposure also well described?
3. Were the measures used clearly described, valid and reliable for measuring the outcomes of interest?
4. Was the outcome assessor unaware of the intervention status of the participants (i.e., was there blind assessment)?
5. Did the authors conduct and report appropriate statistical evaluation including power calculations?
6. Were dropout/loss to follow-up reported and less than 20%? For 2-group designs, was dropout balanced?
7. Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?

Summary tables

TABLE III: INTERVENTIONS AND PARTICIPANTS
Table III summarizes the interventions and participants in the ten studies.

Table III. Summary of studies-interventions and participants

Study	Rx	Population	Total #	# with CP	Age at Gastrostomy
1988 Rempel[33]	Gastrostomy 25 Gastrostomy + fundoplication 32 (After 1981: 47)	CP with profound motor and mental impairment: spastic quadriplegia 55, diplegia 1; hypotonia 1; totally dependent 54; GER and/or aspiration with respiratory infection, vomiting, choking 41	57	57	47% before age 4 (majority before age 1)
1990 Sanders[30]	Gastrostomy 47 Nasogastric tube 4; Fundoplication 48	CP and Failure to Thrive: Severe Early group ❶ Middle group ❶ Late group ❶	51 14 27 10	51 ❷ 14 27 10	~ 3 mo.-3 yr. 1.5 - 7.3 yr. 8.5 - 15.75 yr.
1992 McGrath[34]	Gastrostomy 8 Gastrostomy + fundoplication 53	CP: spastic quadriplegia 55, spastic diplegia 3 , athetoid 2, atonic 1.	61	61	?-191 mo. (mean 37 mo.)
1994 Amundson[10]	Gastrostomy + fundoplication	CP	1	1	16 yr.
1994 Lewis[29]	PEG + nutritional management + GER medication	Spastic quadripledgia ❷ ; profound developmental delay; non-verbal; triceps skinfold <5^{tho}%ile	10	10	4-13 yr. ❸
1996 Corwin[24]	Gastrostomy	CP 37; chromosome abnormality 21; sudden trauma 7; perinatal infection 6; other 4	75	37	2 wk.-6.5 yr.
1998 Thorne[35]	Gastrostomy	Severe spastic quadriplegia CP: 75% primary; 25% acquired	62	47	7 mo. - 18.5 yr.
1999 Smith[36]	Tube feeding: (29 Gastrostomy 27+ fundoplication); 5 Jejunostomy; 6 Gastrojejunostomy	CP: spastic 35; athetoid 3;, mixed 2; non-verbal 93%; seizures 67%; cognitive delay 100%;	45	45	2 mo.-18 yr.
1999 Duncan[31]	Gastrostomy feeding + commercial formula ❹	CP 18; 1 near-drowning: non-ambulatory 19 ; anticonvulsant medications 9; at or above 5^{tho}%ile on wt. for ht. with gastrostomy feeding 16	19	18 ❷	28 mo.-18 yr. ❸
1999 Brandt[37]	PEG + nutritional management	CP 16, myopathy 2, TBI 2; oropharyngeal dysphasia or recurrent tracheal aspiration; severe brain impairment; tetraparesis; convulsions 10, ventriculoperitoneal shunt 2	20	16	8 mo.-15 yr.

Legend, Table III

❶	Early=started on enteral feedings within one yr. of CNS insult; middle=started within 8 yr; late=started after 8 yr.
❷	Personal communication with investigator confirmed this number met the definition of CP for this review
❸	Age at study entrance
❹	e.g., Jevity®, Pediasure®, Ensure®

TABLE IV RESEARCH METHODS
Table IV summarizes the research methods used in the ten studies. Levels of evidence were determined by the type of research design (Level I-V) plus a judgment about the degree to which the particular study controlled threats to internal validity within its

design parameters (S for Strong, M for Moderate, W for Weak).[d] Level V studies are not subjected to judgment about how well it controlled for threats to validity because there are no controls.

No studies about gastrostomy feeding in individuals with CP have yet included a control group. The only comparisons have been in a group of individuals before and after gastrostomy in which exclusive oral feeding outcomes were documented and compared with outcomes of gastrostomy feeding.

Table IV: Summary of studies-research methods

Study	Research Design	Level of Evidence	# CP Rx	Duration of Rx	Age at Follow Up
1988 Rempel[33]	Before and after case series	IV+W	57 (but before-after data only for 35)	3 mo. - 18.3 yr.	9 mo. -23.3 yr.
1990 Sanders[30]	Before and after case series Early group Middle group Late group	IV+W	~ 14 27 10	6 mo. - 5.5 yr.	
1992 McGrath[34]	Descriptive case series	V	61	1-78 mo.	
1994 Amundson[10]	Case report	V	1		
1994 Lewis[29]	Before and after case series	IV+W	10	2-10 mo.	
1996 Corwin[24]	Before and after case series	IV+W	37	18 mo.	
1998 Thorne[35]	Descriptive case series	V	47	6 mo.-9 yr.	19 mo. - 19.5 yr.
1999 Smith[36]	Descriptive case series	V	45		1-20 yr.
1999 Duncan[31]	Descriptive case series	V	18		28 mo.-18 yr.
1999 Brandt [37]	Before and after case series	IV+W	16	2-10 mo.	

TABLE V (PARTS A AND B): OUTCOMES, MEASURES, AND RESULTS

Table V, in two parts, summarizes 45 results from the ten studies and shows the coding of each for the dimension of disability and level of evidence it represented. Some studies reported their results as group data, i.e., results that reflect the average effect of gastrostomy feeding in a group when its pre-and post-gastrostomy status was compared. Other studies have reported results according to the uniformity of effect within the group, i.e., how many individuals improved, got worse, or were unchanged after gastrostomy placement. Sometimes studies reported both types of results. Part A of the table includes 32 results that reflect comparisons of group averages; Part B, 13 results that reflect uniformity within a group data.

[d] The AACPDM methodology is based on current scientific standards for analyzing and weighting studies for bias and error and for judging study methods. Nevertheless, this type of critical appraisal is a new endeavor in medicine, in general, and within the Academy, in particular. The AACDPM methodology will continue to evolve both with experience and as the science of critical appraisal improves. Therefore, the assigned level of evidence should be regarded as an estimate, and relative to other studies, rather than an absolute.

Table V: Summary of studies-outcomes, measures, and results.

Part A. Average-of-group comparison results. These 32 results reflect comparisons of the average pre-gastrostomy status of a group with its average post-gastrostomy status.

Study	Outcome of Interest	Dim. of Disability	Measure	Result	Clin. Imp.	Statistics	Level of Evidence
1988 Rempel[33]	Weight %ile	I	NCHS Growth Charts	+	yes		IV+W
	Height %ile	I	NCHS Growth Charts	+	yes		IV+W
	Weight for Height %ile	I	NCHS Growth Charts	+	yes		IV+W
	Nutritional status	I	Anecdote	+	yes		V
	Feeling: disposition	FL/A	Anecdote	+	yes		V
	Ease of feeding	SL/C	Anecdote	+	yes		V
	Caregiver satisfaction	SL/C	Anecdote	+	yes		V
1990 Sanders[30]	Early group	~	~	~	~		~
	% ideal weight	I	IUN	+	yes		IV+W
	% ideal height	I	IUN	+	small		IV+W
	% ideal weight for height	I	IUN	+	small		IV+W
	Developmental progress	I	Anecdote	+	yes		V
	Middle group	~	~	~	~		~
	% ideal weight	I	IUN	+	yes		IV+W
	% ideal height	I	IUN	+	yes		IV+W
	% ideal weight for height	I	IUN	+	yes		IV+W
	Feeling: alert/irritable	FL/A	Anecdote	+	yes		V
	Late group	~	~	~	~		~
	% ideal weight	I	IUN	+	small		IV+W
	% ideal height	I	IUN	+	yes		IV+W
	% ideal weight for height	I	IUN	U	no		IV+W
1992 McGrath[34]	Ease of feeding	SL/C	Phone interview: recall time estimate	+	yes		V
1994 Amundson[10]	Social interaction	FL/A	Anecdote	+	yes		V
	Subcutaneous fat stores	I	Clinical observation	+	yes		V
	Pubertal development	I	Clinical observation	+	yes		V
	Weight	I	NCHS Growth Charts	+	yes		V
	Weight for length ratio	I	NCHS Growth Charts	+	yes		V
1994 Lewis[29]	Nutrition	I	Triceps skinfold	+	yes		IV+W
1996 Corwin[24]	Weight z	I	NCHS Growth Charts	+	yes	p=.0001	IV+W
	Height z	I	NCHS Growth Charts	+	yes	p=.007	IV+W
	Height for weight z	I	NCHS Growth Charts	+	yes	p=.01	IV+W
1998 Thorne[35]	Caloric adequacy	I	Food intake records ❶	+	yes		V
	Caregiver satisfaction	SL/C	Questionnaire ❷	+	yes		V
	Caregiver coping ❸	SL/C	Anecdote	-	yes		V
1999 Brandt[37]	Weight z	I	Brazil standards❹	+		p<.01	IV-W

Legend, Table V, Part A:

I; FL/A; SL/C	Impairment; Functional Limitation/Activity; Societal Limitation/Context Factors
LOE	Level of Evidence
+	Improved result after gastrostomy
-	Better result before gastrostomy
U	Unchanged result
IUN	Indices of Undernutrition
NCHS	U.S. National Center for Health Statistics
❶	Recommended Nutrient Intakes analyzed with Quilchena Nutrient Computer Software
❷	Quantified with Vertical Visual Analog Scale
❸	Managing feeding schedules, health routines and normal family life
❹	Medicion Del Cambio Del Estado Nutricional, Organization Mundial De La Salud

Table V: Part B. Uniformity of effect within a treatment group results. These 13 results reflect how many of a group were improved with gastrostomy feeding, how many were better before gastrostomy feeding, and how many were unchanged.

Study	Dim.	Outcome	Measure	Improved Result	Result Better Pre-Gastrostomy	Unchanged Result	LOE
1992 McGrath[34] N=61	FL/A SL/C	Comfort / abilities Caregiver satisfaction	Phone interview: recall Phone interview: recall	55/61 53/57			V V
1994 Lewis[29]	I	GER resolution	24 hr. pH probe	7/10 ❶	1/10	2/10	IV+W
1999 Smith[36]	SL/C SL/C I SL/C SL/C SL/C I	Caregiver satisfaction Family stress/function Failure to thrive Difficult to feed Time to feed Stress of feeding Aspiration	Phone interview: recall Phone interview: recall Phone interview: recall Phone interview: recall Phone interview: recall Phone interview: recall Phone interview: recall	32/37 ~ 33/37 34/37 33/37 34/37 8/22	~ 11/39 ~ ~ ~ ~ ~		V V V V V V V
1999 Duncan[31]	I I ~ I	Caloric adequacy Bone nutrient adequacy ~ Osteopenia	100% RDA calories ❷ 100% RDA calcium, phosphorous, Vit. D Radiologic diagnosis and/or records review for fractures	~ ~		19/19 ≤15/19 V ❸ 15/19 ❹	V V ~ V

Legend, Table V, Part B:

LOE	Level of Evidence
❶	Statistically significant p<.05
❷	Caregiver records of total dietary intake including quantity of commercial formula and any supplemental nutrients
❸	2/19 adequate for phosphorous, 3/19 for Vitamin D, 4/19 for calcium
❹	Osteopenia diagnosed by radiograph in 10, by non-traumatic fractures in 5

Clinical importance or relevance (seldom explicit in studies) is reported when stated in the articles or when it was apparent to the reviewers. Statistical information is specified to the extent provided. Each result is assigned the level of evidence of the study which produced it (see Table IV) with the exception that all anecdotal evidence is coded Level V. When there is an absence of controlled observation, anecdotes are useful to document that an outcome has, at least, been observed to occur in association with the intervention. Anecdotal reports of outcomes may also be useful in the formation of hypotheses for subsequent study.

Evidence table

TABLE VI (PARTS A AND B) ORGANIZATION AND INTERPRETATION

The evidence table (Table VI) must also be displayed in two parts to accommodate these two different types of results. Interpretation can be made visually with this table or more in-depth interpretation is possible by referring back to the summary tables.

Part A of the evidence table aggregates the 32 group-average results produced by eight of the studies. Each outcome is indicated by a superscript that is the citation number of each study that produced this result associated with a level of evidence (coded I - V for type of research design + S, M, or W for strong, moderate or weak control to threats of validity in conducting the study). By rows, one can see which dimensions of disability have been targeted for investigation and which types and how often outcomes

have been measured. For example, weight has been investigated six times in four different studies[10,24,30,33,37] and each result showed that weight improved subsequent to gastrostomy placement. However, only two of these weight results were statistically evaluated; both were found to be statistically significant.[24] The confidence with which one can regard this evidence that weight gain can be attributed to gastrostomy tube feeding is low considering that six of these results were from weakly-controlled Level IV studies and one result is Level V.

Part B aggregates the 13 uniformity of effect results. Each outcome is indicated by the number of participants within a treated group (i.e., 7/10 or 7 out of 10) which is followed by a level of evidence and citation for the study that produced the result. For example, by rows, one can see that effect of gastrostomy on gastroesphogeal reflux has been investigated once.[29] GER improved in seven of the 10 children studied and was a statistically significant finding; one child's GER got worse; and GER was unchanged in two children.

Table VI: Evidence table-outcomes of gastrostomy feeding for CP.
Part A. Average-of-group comparison results. These results reflect 32 comparisons of the average pre-gastrostomy status of a group with its post-gastrostomy status from eight studies. Each outcome is indicated by a superscript that is the citation number of each study that produced this result associated with a level of evidence (coded I - V for type of research design + S, M, or W for strong, moderate or weak control to threats of validity in conducting the study). Each entry reflects whether the group-average outcome was better after gastrostomy compared to the pre-gastrostomy group average.

Outcomes by Dimensions of Disability	Improved Results after Gastrostomy (Statistically Significant)	Improved Results After Gastrostomy (But Not Statistically Evaluated)	Results Better Before Gastrostomy	Results Unchanged or Not Statistically Significant
Pathophysiology				
Impairment				
Weight	IV+W[24, 37]	IV+W[33, 30, 30, 30] V[10]		
Weight for height		IV+W[33, 30, 30] V[10]		IV+W[30]
Height for weight	IV+W[24]			
Height	IV+W[24]	IV+W[33, 30, 30, 30]		
Nutritional status		IV+W[29] V[33]		
Fat stores		V[10]		
Caloric adequacy		V[35]		
Development		V[10,30]		
Functional Limitation/Activity				
Feeling: disposition/mood		V[30,33]		
Social interaction		V[10]		
Disability/ Participation				
Societal Limitation / Context Factors				
Ease of feeding		V[33, 34]		
Caregiver coping			V[35]	
Caregiver satisfaction		V[33,35]		

Table VI: Part B. Uniformity of results within a treated group. The results of 13 measures from four studies show how many participants improved, how many fared better before the gastrostomy, and/or how many were unchanged. The number of participants within a treated group (i.e., 7/10 or 7 out of 10) is followed by a level of evidence and the citation for the study that produced the result. Statistically significant results indicated by *.

Outcomes by Dimensions of Disability	Improved Result	Result Better Before Gastrostomy	Unchanged Result
Pathophysiology			
Impairment			
Caloric adequacy			19/19 V [31]
Failure to thrive	33/37 V[36]		
Gastroesphogeal reflux	7/10 IV-W [29] *	1/10 IV-W[29]	2/10 IV-W[29]
Aspiration	8/22 V[36]		
Bone nutrient adequacy			≤15/19 V [31]
Osteopenia			15/19 V [31]
Functional Limitation/Ability			
Comfort / Ability	55/61 V[34]		
Societal Limitation/ Context			
Time to feed	33/37 V[36]		
Difficult to feed	34/37 V[36]		
Stress of feeding	34/37 V[36]		
Family stress/function		11/39 V[36]	
Caregiver satisfaction	53/57 V[34] 34/37 V[36]		

GREATER ELABORATION OF THE EVIDENCE

One can delve into any data in the table by using the superscript citations and refer back to the summary tables to elaborate the meaning of a data point. For example, in the row that showed the effects of gastrostomy feeding on weight gain in the impairment dimension of disability, one entry (i.e., IV+W[24]) represents the strongest evidence that gastrostomy improved weight gain. Referral to Table III shows that this evidence came from a study reported in 1996 that contained 75 children with neurological impairment, 37 of whom had CP. The intervention was gastrostomy placement, that is, there was no information about the nutritional management of the gastrostomy feeding or extent to which oral feeding was continued. Gastrostomies for the 75 children were placed between 2 weeks and 6.5 years of age. From Table IV, this evidence can be further elaborated as follows. It came from a before and after case series design; thus, the average score for the whole group measured once before and, once again, 18 months after the gastrostomy placement was compared. Lacking a control group, any rate of change could not be compared directly with the rates that occurred in people who did not receive the intervention but were otherwise comparable. Final elaboration of this evidence from the Summary of Results (Table V) reveals that the outcome of interest was measured as a weight z score using the U.S. National Center for Health Statistics[38]. Results were published for the CP subgroup separately and were clinically and statistically significant at $p<.0001$.

CAUTION INTERPRETING RESULTS

Caution is advised concerning the correct interpretation of results that are not statistically significant (*ns*). Results may be *ns* because of lack of adequate power in the study sample and design. The power of a study is the probability that the study, given its design and sample size, can detect a true difference of a pre-determined magnitude (effect size). In the absence of a reported power calculation, there is always the possibility that a true difference existed between the two treatments being compared, but that there was inadequate power to detect the difference. However, if a power calculation is reported and the sample size needed to produce the power is obtained, then an *ns* result statistically supports the conclusion that there is no difference between the two treatments compared. Unfortunately, no study in this review reported power calculations and sample sizes were generally small enough that adequate power is questionable.

Medical complications table

Table VII aggregates the reported medical complications and adverse effects

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Table VII. Medical Complications and Adverse Effects. Note that some children had multiple complications.

Study	Type of effect	# of Cases
1988 Rempel[33] N=57	Deaths (after one year) Major complications: gastrointestinal bleeding and ulceration 5, wound dehiscence 1, peritonitis and bowel obstruction needing re-operation 3, tube migration 2 Postoperative GER requiring fundoplication Became overweight for height	8 13 ~ 4 12
1990 Sanders[30]	Deaths (early treated group 1/ 14; middle group 2/27; late treated group 4/10)	7
1992 McGrath[34] N=61	Deaths (after 2 years) Early complications: prolonged intubation 5, atelectasis 10, pneumonia 1, sepsis 1, fever 3, abdominal distention 1, emesis 1, gastroenteritis 3 Late complications: vomiting 4, retching 3, dumping syndrome 4, paresophageal hernia 7, unable to bolus feed 1, recurrent reflux/aspiration 1, small bowel obstruction 4, recurrent pneumonia/aspiration 1, apnea 2, wound infection 2	16 20 ~ 24 ~ ~
1994 Lewis[29] N=10	Progression of GER to erosive esophagitis	1
1998 Thorne[35] N=62	Disconnection Constipation Vomiting Leakage around device Retching Cramping Leakage through device Respiratory tract infection Diarrhea Granulation tissue Skin irritation Blockage Distention Dislodgment Site infection	52 49 45 46 45 44 40 38 35 31 30 24 22 20 17
1999 Smith[36] N=45	Deaths (after 18 years; N=61 for death rate only) Serious complications: volvulus, prolapse, bowel obstruction, ulceration, gastrointestinal bleeds, peritonitis Minor complications: diarrhea, constipation, tube obstruction, local infection, dislodgment, leakage, valve dysfunction	16 8 ~ 38 ~
1999 Brandt[37]	Mild complications: granulation tissue at osteotomy Small peritoneum (disappeared after 24 hours) Ostotomy infection (purulent secretion, local inflammation, pain with tube manipulation) easily treated	10 1 4

Analysis and discussion of the evidence

1. WHAT EVIDENCE IS THERE ABOUT THE EFFECTS OF GASTROSTOMY ON ASPECTS OF IMPAIRMENT?

Growth and nutrition

These were investigated in 25 measures in nine studies based on eight different outcome variables. Part A of the evidence table, Table VI, shows 23 of the outcomes of interest which include weight, height, weight for height, height for weight, fat stores, and failure to thrive. Part B of the evidence table shows three growth and nutrition outcomes which include caloric adequacy, bone nutrient adequacy, and failure to thrive.

All but three results favored gastrostomy. One unchanged result, shown in Part A of the evidence table, was from a group of children who received gastrostomy late, i.e., eight years or more after their CNS insult, and who had a significant number of chronic secondary conditions. Although the percent of weight and percent of height measures favored gastrostomy, there was no change in the percent of weight for height measure.[30] The other two results that were unchanged after gastrostomy were from a study shown in Part B of the evidence table that tracked the percent of the Recommended Daily Allowance (RDA) ingested in gastrostomy tube feedings using standard commercial formulas. It was found that none of the children received the RDA for calories in their standard tube feeds. In addition, four or fewer received the RDA for calcium, phosphorous and/or Vitamin D that are important for healthy bone.

Child Development

Two anecdotal reports, shown in Part A, suggested that development improved: early developmental progress[30] and pubertal development[10].

Gastrointestinal function

This was investigated in two studies (Part B of the evidence table). One result found that aspiration symptoms decreased in nine out of 23 children[36], and the other found that GER resolved with nutritional rehabilitation via gastrostomy and medication for reflux , in seven out of 10 people, was worse in one, and unchanged in two[29].

Osteopenia

One study [31] (Part B of the evidence table) probed the correlation between adequacy of bone nutrients via tube feeding with standard recommended quantities of commercial enteral formulas and osteopenia in a group of children who were tube fed. Only four children were getting enough calcium, three enough phosphorous, and two enough vitamin D whereas most were getting substantially below the RDA for micronutrients needed for healthy bone (i.e., calcium, phosphorous, and vitamin D). Fifteen of the 19 children were found to have osteopenia (10 by radiographic diagnosis and five by diagnosis of fracture unexplained by significant trauma). Two of these five children who had had multiple fractures in previous months or years were found to have been getting less than 75% of the RDA for calcium, phosphorous, and Vitamin D. Anecdotally, after supplementation of these micronutrients to the standard formula of these two children, no more fractures had occurred in 11 and 28 months, respectively.

2. WHAT EVIDENCE IS THERE ABOUT THE EFFECTS OF GASTROSTOMY IN DIMENSIONS OF DISABLEMENT OTHER THAN IMPAIRMENT?

Pathophysiology

There is no evidence regarding effects on cellular or molecular structure or function.

Functional Limitation/Activity

Four measures evaluated effects on functional limitation in a person's activities. Positive effects were found in social interacting[10], emotional disposition or feeling [30, 33] and a collection of activities designated as comfort/ability[34].

Disability/Participation

Effects of gastrostomy on participation in normal societal roles have not been investigated.

Societal Limitation/Context Factors

Three aspects of effects on the context of the child's life were investigated: ease of feeding the child, caregiver satisfaction, family stress and function. Ease of feeding was probed five times in three studies. As shown in Part A, ease of feeding[33, 34] improved on average for each of two groups studied. As shown in Part B, the task of feeding was found to be easier for most caregivers but not all: time spent in feeding was reduced in 33 out of 37 individuals [36], difficulty of feeding decreased in 34 of 37 individuals[36], and the stress of feeding improved in 33 of 37 people[36].

Caregiver satisfaction was evaluated four times in four studies with positive effects found for gastrostomy for most but not all[33-36]. Two of these results appear in Part A of the evidence table and two in Part B.

Effects on family stress and function were evaluated twice through inquires about caregiver coping[35] and family stress[36]. The first result (shown in Part A of the evidence table) showed caregiver satisfaction overall but reported a subset of that cohort (number not reported) stated their family coping was stressed more. The other result (shown in Part B) showed that 11 of 39 families said that they felt more stressed because access to respite care had become more limited, the mobility of their child had become more restricted, and/or there had been a change in their relationship with their child.

3. WHAT LINKAGES EXIST FOR TREATMENT EFFECTS WITHIN AND ACROSS THESE DIMENSIONS OF DISABLEMENT AND IN WHICH DIRECTIONS?

The limited evidence in this report suggests that there may be a linkage between micronutrient deficiency, in addition to immobility and anticonvulsant medications, and osteopenia which is commonly observed in individuals with C.P There are also hints of linkages between improved nutrition/growth and improved emotional disposition of the child as well as improved nutrition and decreased GER.

4. ARE THERE SUBGROUPS FOR WHOM GASTROSTOMY MAY BE MORE OR LESS EFFECTIVE?

The group average results indicate that children have a rapid response to nutritional support regardless of age even though there is a more pronounced state of malnutrition as age increases. The uniformity of effect results demonstrate, however, that not all children improved nor did the contexts of their family life improve. Three of these studies investigated factors that may account for subgroups that do better than others. All three studies found that attainment of minimum growth standards occurred more frequently in children treated early before malnutrition and morbidity became established and this was related to age.[30,33,37] Sanders, et. al.[30] found that the death rate in their series was distinctly higher in the subgroup of children who had the most pronounced state of malnutrition and multiple secondary chronic conditions prior to gastrostomy. These conditions were most prevalent in their subgroup treated late, i.e., children who were treated eight years or more after their CNS insult. This finding is supported in a related study of children with severe neurological disabilities in which the presence of other significant diseases was the strongest predictor of death.[28]

Another study [31] suggests that children for whom the caloric and nutrient intake is carefully monitored and the nutrient intake supplemented will do better than children for whom enteral feeds are based only on an estimate of caloric need and the necessary amount of formula necessary to meet that estimated need is given. Standard formulas are based on expected caloric intake of the normally active child with the recommended daily allowance (RDA) being provided by that volume of formula. The sedentary child, however, has a lesser caloric need and this reduced volume of formula does not, therefore, provide the RDA. Calculating the caloric needs of the sedentary child will take into account this diminished activity, variations in basal metabolic rates, level of seizure activity, and the degree of spasticity or frequency of muscle contractions. In addition, the nutritional intake of the tube-fed, non-ambulatory child is not driven by the child's appetite drive, so volume of enteral feeding is also dependent on caregivers.

. The uniformity of effect results also demonstrate, that the contexts of the family life of some participants improved while others did not. There has not been discussion about what factors may account for this.

5. WHAT KINDS AND SEVERITY OF MEDICAL COMPLICATIONS HAVE BEEN DOCUMENTED?

Table VII lists medical complications. It is important to keep in mind that many of the children in these studies had significant morbidity prior to gastrostomy placement and for others, malnutrition was a serious and potentially life threatening problem. In addition, the study designs used lacked a comparison or control group. Consequently, with the exception of surgical complications, it is not known what the rates of complications or deaths would have been in similar groups of children who continued to be exclusive oral feeders. Moreover, it is difficult to make meaningful statements about risks and complication from the published data because types and rates of complications are not reported in a standard manner, and some of the children experienced multiple complications.

In four different studies, the death rates were reported as 14% (after one) [33], 14% (after 5.5 years)[30], 26% (after two years)[34] and 26% (after 18 years)[36]. Rempel, et.

al.[33] concluded that the death rate in their series was indicative of the severe morbidity in the group prior to gastrostomy. Sanders, et. al.[30] concluded the same based on a further analysis of their overall death rate: a 7% rate in their early and middle treated groups compared to a 40% in their late treated group. The late treated group had significant chronic secondary conditions including esophagitis and lung disease from repeated pneumonias. In contrast, McGrath, et al.[34] detected no significant differences between their survivors and non-survivors in either the average age at time of the gastrostomy or in the medical complications or procedures that they experienced.

The overall rates of major complications in three of the studies were reported to be 17% [36], 23% [33], and 39.3% [34]. These included bowel obstructions, gastrointestinal bleeds, ulceration and peritonitis. Osteotomy infection, generally regarded as a major complication was reported 20% of the participants in another case series[37], but the authors regarded this as a minor complication the infection was easily and successfully treated.

High rates of minor complications were reported in two studies.[35,36] Some of these were related to the devices themselves such as leaking through or around the tube, dislodgment, disconnection, or blockage.[e] Other complications such as site irritation, infection and granulation tissue were also related to the device. Still others were gastrointestinal complications such as constipation, diarrhea, cramping, vomiting, etc. One of the studies explored the complication rate between types of devices (i.e., a gastrostomy tube versus skin level devices such as the Bard button).[35] Contrary to what was expected, the group using the skin level devices had a higher incidence of minor complications but nutritional benefit and caregiver satisfaction did not vary among the groups.

There has been concern expressed in the literature that gastrostomy may exacerbate existing GER or even cause GER to occur. The data in this review restricted to individuals with CP may suggest otherwise. Three studies [33, 34, 37] reported low rates of post-gastrostomy GER (Table VII). Of greater interest, however, is the finding in one case series description of children [29], that only one child had progression of GER to erosive esophogitis whereas GER resolved with nutritional rehabilitation through gastrostomy (i.e., 7 out of 10; see Table V, Part B). These children were receiving medication for GER in their tube feeds so that attribution of improvement to nutritional rehabilitation through gastrostomy alone is erroneous. Nevertheless, this result is encouraging because the combination of improved nutrition through tube feeding coupled with anti-reflux medication may offer an alternative or addition to fundoplication, a surgical procedure commonly used with varying degrees of success in this population, to alleviate GER and its secondary morbid effects.

Excessive weight gain occurred in 21% of the children in one study.[33] Given the difficulty of physical management of severely involved children, this might be viewed as an iatrogenic adverse outcome. This underscores the need for close interdisciplinary working relationships among the family, physicians, dieticians, and nurses.

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[e] A limitation of this review is that it may not give a complete picture of the complications known to be associated with gastrostomy technology. The complete literature about gastrostomy use should be consulted for more extensive information about complications associated with the devices and their rates.

6. WHAT IS THE STRENGTH OF THE EVIDENCE?

How credible the evidence is depends on several factors: the strength of the internal validity of the results (i.e., its level of evidence), how extensively the population has been sampled (i.e., number of different studies and number of participants), and the consistency of results across the studies.

The levels of evidence indicate the extent to which the studies approached some "gold standard" and are, therefore, more likely to inform than to mislead us. This body of evidence is composed of very low levels of evidence. Five studies used Level IV designs and the conduct of each study was weak, i.e., failed to control for threats to validity possible within that research design. These studies produced 18 Level IV results which can be regarded only as suggestive of causation. Five other studies used Level V designs producing 27 Level V results from which no conclusions can be drawn because there were no controls with which to assess causation of observed outcomes. Common reasons for the judgment of weak internal validity in the Level IV studies were related to 1) the samples of children, 2) the intervention, 3) the measures, and 4) lack of statistical evaluation.

1) The samples of children said to have cerebral palsy sometimes included or appeared to include children with diagnosed genetic disorders, progressive neurological disease, and sudden trauma. Additionally, the timing of the intervention varied dramatically within the samples of populations studied.
2) Most studies provided no information regarding actual nutritional changes before and after gastrostomy feeding so that technically the intervention reviewed was presence of a gastrostomy rather than gastrostomy feeding or nutritional intake via gastrostomy tube versus oral feeding. Only three studies[30, 31, 35] documented caloric intake. One [30] found that calories required to achieve growth varied considerably in all groups and could not be predicted by activity level, muscle tone, status of seizure control, or presence of infections. Duncan, et al.[31] documented that many children's long term prescribed diets using standard enteral formulas were inadequate in providing adequate calories or micronutrients.
3) Limited applicability of routinely used nutritional assessment tools in children with CP has been discovered by these studies. Traditional anthropometric measures were found by these and other investigators to be less valid and reliable for this population; even reliable height or recumbent length and weight were difficult to obtain. Moreover, alterations in body composition were documented which raised concern about the use of most anthropometric indicators to determine nutritional status and growth. In addition, other outcomes were assessed using primarily unvalidated questionnaires.
4) Finally, statistical evaluation was available for only five of the 45 results; four were statistically significant group average results and one was a uniformity of results outcome.

This body of evidence is also extremely limited in the extent to which the population has been sampled. The results of the effects of gastrostomy for children with CP are known only from 281 individuals who have been investigated in ten studies.

The strongest factor lending credibility to this body of evidence is the consistency of results in favor of gastrostomy. There was only one exception in the group-average

results. However, the uniformity of results shows that there was a minority of individuals who did not improve.

Summary and directions for future research

The primary goal of gastrostomy feeding is to provide adequate nutrition in children who are failing to thrive and who may, therefore, be at risk for significant morbidity or even death. To what extent has the role of gastrostomy in 1) promoting the growth and development of children who have CP and inadequate dietary intake or malnutrition and 2) improving the quality of life of the children and families been substantiated by research?

There is a paucity of published evidence (i.e., only 45 measures or anecdotes), but it rather consistently supported gastrostomy as beneficial to most, though not all, of the children in these studies and their families. Nutritional status, growth and development improved in the children, and this improvement was clinically important. Caregivers reported that children felt better and were more sociable. A large majority of the caregivers and/or families judged feeding to be easier and family life to be improved; however, care was not uniformly facilitated. It has also been shown that the standard enteral commercial formulas may not provide either adequate calories or adequate minerals and vitamins for non-ambulatory tube-fed children. These standard formulas are designed to supply the Recommended Daily Allowance (RDA) which assumes the person ingests the expected number of calories to meet the caloric expenditure for an active growing child or active adult. Tube-fed individuals seldom ingest that quantity of formula; thus, their nutritional needs may still be unmet. Careful attention to caloric intake and nutritional supplementation may result in greater benefits of gastrostomy feeding. This micronutrient deficiency, in addition to immobility and anticonvulsant therapy, may be a contributing factor to the osteopenia and subsequent fractures commonly observed in non-ambulatory individuals with CP. This needs to be confirmed in future studies.

The published evidence is weak. The strongest evidence is only Level IV-W evidence from research designs and study methods with little control of threats to internal validity (18 results). The majority of evidence is merely Level V (27 results), i.e., too confounded by lack of before and after documentation and by other variables for any conclusions to be drawn. The overall number of children on which the body of evidence is based is small (i.e., 281 individuals in ten studies). Therefore, any conclusions about the effects of gastrostomy on nutritional status, growth, morbidity, developmental potential, activities, and family life must remain highly speculative given the current data available to us. Given the preliminary nature of the body of published evidence with its sparse but consistently positive outcomes and high rates of complications, more definitive research is definitely needed and warranted.

Issues of subject selection and measurement first need to be addressed to facilitate future research. The participant inclusion criteria with regard to CP was so diverse that it constituted a threat to the validity of research findings for children with CP. Development of a consensus about and use of a standardized operational definition of CP in research is sorely needed. Until this is accomplished, it will be impossible to compare outcomes across most studies, across types of interventions, or both. Given the low

frequency and variable severity of CP, multi-center study mechanisms may be necessary to recruit adequate homogeneous samples.

The studies were not explicit about the reason for tube placement in individual children (i.e., malnutrition, gastroesphogeal reflux disease, prolonged feeding) or about the criteria used to decide on tube placement (i.e., growth curves, clinical judgment). Measurement tools, generally a problem because of the lack of standardized, validated, and reliable measures (i.e., questionnaires, checklists) presented even greater methodological issues in this topic than did subject inclusion. This research has been valuable in identifying the need to resolve critical measurement issues before future studies can accurately gauge the effects on nutritional status, growth and development, activities, participation in normal society, and quality of life for family members. These, and other, studies identified that body composition of children with CP was different from able-bodied children and that many of the traditionally valid and reliable anthropometric measures were ineffective. Only weight, arm muscle and fat stores proved to be stable in one sample.[35] Growth and body composition norms as well as caloric needs for this population need to be defined. Appropriate measures need to be employed. For example, equations to estimate height from segmental measures in children with CP may allow for better assessment of linear growth changes.[39] The utilization of more direct measures of body composition (e.g., dual energy w-ray absorptometry) might be employed in subsequent research. There is a critical need for validated questionnaires or measures to assess impacts in dimensions of disablement other than impairment. Finally, causal association between gastrostomy and gastroesphogeal reflux as well as use of anti-reflux medications versus fundoplication to treat GER after gastrostomy needs to be specifically investigated.

Future studies need to incorporate research designs that can generate valid results for small heterogeneous populations such as this. Study participants and intervention must be sufficiently defined by standards accepted throughout the field. The reasons for gastrostomy placement need to be explicit and related to the outcomes reported. The gastrostomy intervention investigated must be expanded from merely being the placing of a gastrostomy tube to include monitoring and description of the feeding, i.e., adequacy of caloric and nutrient intake. Studies might investigate effective drug delivery post-gastrostomy and the effects of tube feeding on secondary and associated conditions of CP including co-mobidities into adulthood. Finally, future studies need to incorporate measures across dimensions of disability in order to elucidate whether reduced impairment (i.e., nutrition, growth, development, and morbidity) if found to be definitely associated with gastrostomy feeding, carries over to improved functional activities, to increased participation in social roles of daily life, and to a better quality of life for family members. Given that the greatest benefit of gastrostomy feeding may lie in the facilitation of care, future studies should systematically document the impact of gastrostomy on the intensity of caregiving that is required.

In conclusion, this body of published evidence should be regarded as a pilot phase. It's primary importance to date is in establishing preliminary evidence that gastrostomy may have beneficial effects in children with CP and in identifying critical methodological issues that must first be resolved before more definitive research can be accomplished.

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