Tubefeeding and Mortality in Children With Severe Disabilities and Mental Retardation

David Strauss, PhD*; Theodore Kastner, MD‡; Stephen Ashwal, MD§; and James White, MS‖

ABSTRACT. *Objective.* **To study the contribution of tubefeeding to mortality for children with severe disabilities and mental retardation. Previous research has suggested an association between tubefeeding and mortality. However, risk has never been determined using population-based data or defined in regard to patient variables.**

Methods. **Retrospective analysis of a comprehensive statewide data set comprised of 4921 children with severe disabilities and mental retardation living in community and congregate care settings. The outcome measure was mortality; primary study variables included the presence of a feeding tube, measures of functional independence, type of residence, and medical comorbidity.**

Results. **There were four findings. First, the use of a feeding tube was associated with virtually every disability. Second, when no study variables were controlled, statistically significant differences in mortality rates were noted between children who were tubefed and those who were not. The relative risk of mortality associated with use of a feeding tube was 2.1. Third, the use of a feeding tube was associated with a reduction in relative risk of mortality in children with tracheostomy (relative risk of mortality: .55). However, this association did not achieve statistical significance. Fourth, when study variables were controlled in a multivariate analysis, feeding tube use was associated with no identifiable increase in mortality among children with very severe disabilities, but was associated with an approximated doubled mortality rate among those with less severe disabilities.**

Conclusions. **We hypothesize that the increased mortality associated with tubefeeding may be attributable to a differential increase in pulmonary disease secondary to overly vigorous nutritional maintenance and subsequent aspiration after tube placement. For children with tracheostomy this risk may be reduced. If tracheostomy proves to be associated with a relatively more favorable outcome for tubefeeding, we hypothesize that it would reflect the benefits of tracheostomy in allowing access to the airway for suctioning and ventilation. Given the observed higher mortality rates among the less severely disabled children who are tubefed and the substantial costs associated with tubefeeding, a prospective, controlled study may be clinically indicated, ethically justifiable, and economically warranted.** *Pediatrics* **1997;99:358–362;** ***developmental disability, aspiration, mortality, tubefeeding, gastrostomy, logistic regression.***

ABBREVIATIONS. DDS, Department of Developmental Services (of California); CDER, Client Development Evaluation Report.

Surgical treatment of children with symptomatic gastroesophageal reflux has become one of three operative procedures most often performed on children in the United States. Despite this, there is only a partial understanding of the risks and benefits of treatment. This is attributable to incomplete knowledge of patient selection, pretreatment evaluation, surgical versus nonsurgical intervention, and outcome measurement variables. The deficit arises from a nearly complete absence of controlled research into the appropriate use of feeding tubes in children with disabilities. For example, recently published research by Fonkalsrud et al[1] and Heine et al[2] contained sufficient methodological weaknesses as to lead to conflicting recommendations.[3] The results were particularly troubling in light of the fact that although none of the children in the Heine study were preoperatively felt to have significant pulmonary disease, 6 of 30 children who underwent a percutaneous endoscopic gastrostomy tube placement died of chronic suppurative lung disease within 26 months of treatment.[2]

Children with mental retardation and other developmental disabilities have higher rates of feeding disorders and are therefore more likely to receive treatment than other pediatric subgroups. For this population, the concerns over the risks of a surgical procedure may be heightened. Several studies of children and adults with mental retardation have explored the role of tubefeeding as a predictor variable for mortality.[4–6] Recently, Kastner et al[7] reanalyzed data from Eyman et al[6] concerning the survival rates of three groups of children with severe mental retardation in California. They showed that mortality rates for children who were tubefed were substantially higher than for those who were not, by amounts ranging from 31% to 108% in the three groups.[7]

Although tubefeeding is widely used to improve the nutritional status of children with severe disabilities, it is known that nasogastric and gastrostomy feeding can actually worsen feeding outcomes.[8] Smith and associates[9] studied 39 developmentally delayed patients who had gastrostomy and fundoplication procedures. Of these, 40% had recurrent pneumonia, 31% had recurrent vomiting, and 23% had recurrent choking-gagging episodes. Eighteen

From the *Department of Statistics, University of California, Riverside, Riverside, California; ‡Morristown Memorial Hospital, Morristown, New Jersey; the §Department of Pediatrics, Loma Linda University School of Medicine, Loma Linda, California; and the ‖Department of Developmental Services, Sacramento, California.

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Reprint requests to (D.S.) Department of Statistics, University of California, Riverside, CA 92521.

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patients (51%) died during the 11-year study period, four of them shortly after surgery. Other studies report comparable recurrent morbidity and/or late mortality.[10–13] In reviewing the work of Eyman et al,[6] Sulkes[14] noted that the data "Could be telling us that tubefeeding itself is dangerous and should be avoided." He added that "If this possibility is even partly true, then physicians caring for disabled persons have even more reason than before to rule out dysphagia and gastroesophageal reflux and to try and maintain oral feeding."

The question of causality is crucial.[15] The extent to which observed excesses in mortality are the consequence of tubefeeding, rather than being merely a reflection of the medical problems associated with the need for tubefeeding, is unknown. Undoubtedly, the association of tubefeeding and mortality is at least partly spurious, as both variables are positively associated with factors such as severity of retardation and/or disability, lack of mobility, malnutrition, and other medical problems. On the other hand, the gastrostomy procedure, with or without fundoplication, carries a definite mortality risk.[16,17] This risk appears not to have been previously assessed relative to a comparison group, or defined in regard to patient variables.

The most reliable way to assess the relative risks and benefits of medical management versus nasogastric tubes, gastrostomy with or without fundoplication, gastric emptying procedures, and other interventions would be through a randomized controlled study. As suggested by Kastner et al,[7] however, a multivariate analysis may be used to achieve a statistical adjustment for other predictor variables. We report such a study here, measuring the relationship of tubefeeding and mortality for children with severe disabilities and mental retardation. An epidemiologic study of this kind is not a substitute for a controlled study because of the possibility of bias: even after mobility and medical conditions are statistically controlled, there may be differences between tubefed subjects and those not tubefed that affect risk. Such studies, however, represent an important preliminary step for two reasons. First, they may indicate risk factors that need to be taken into account in any subsequent epidemiologic studies or clinical trials. Second, they may strengthen the case for controlled experimentation (if the statistical adjustment still indicates that tubefeeding is associated with higher mortality) or effectively rule out such experiments (if the opposite result is obtained).

METHODS AND MATERIALS

Data Source

The subjects were children with severe developmental disabilities who received services from the California Department of Developmental Services (DDS) between January 1, 1987 and December 31, 1992. All were referred to one of the 21 regional centers contracted by the state to provide services to clients in their geographic area. The regional centers, which are privately owned corporations, coordinate all services including the choice of residential placement.

The data source was the *Client Development Evaluation Report* (CDER).[18] A CDER is completed once per year, and additionally on moving to a new placement, for anyone receiving services from DDS. The CDER consists of a 100-item Diagnostic Element and a 66-item adaptive behavior Evaluation Element, providing demographic, health, and behavioral data. Information is collected by case workers or psychiatric technicians trained to use the instrument. Evaluations are based on personal observations, supplemented where appropriate with interviews with parents. Mortality information was obtained from DDS sources, supplemented by annual computer tapes issued by the California Bureau of Vital Statistics.

Sample

We focused on the medically fragile younger clients with severe developmental disabilities. Mortality for this group is much higher than for the more ambulatory robust children, and the patterns of causes of death are very different. Furthermore, tube feeding is common in this group, some 26% of the children receiving such treatment at a given time. Finally, because of the high cost of care in this target group it is likely that the great majority receive at least some services from the state, and are thus included in our sample. This would imply that selection bias is minimal.

For this study an operational definition of severely handicapped and fragile was based on four variables reported in the CDER: (1) *Crawling or standing*: cannot pull to a standing position; (2) *Ambulation*: does not walk; (3) *Eating*: does not feed self, must be fed completely; and (4) *Toileting*: not toilet-trained or habit-trained. We shall refer to these collectively as Condition A. Of the more 100 000 clients known to DDS and represented by at least one CDER, some 7000 were children with one or more CDERs satisfied Condition A.

A distinctive feature of the study was that the unit of analysis was not an individual person, but instead a person-year. A year was taken to be the interval between two birthdays. To avoid bias, a given person-year was included in the sample only if it was eligible: roughly speaking, the conditions were that (1) it met condition A, (2) the age was between 2 and 14 inclusive, and (3) there was evidence that the child was in the system from the beginning of the year, and either died or was still in the system at the end. The procedure yielded a set of 12 683 person-years, arising from 4921 children; not every child with one or more CDERs meeting condition A contributed an eligible person-year. The first contributed person-year was at age 2 for about half the children. The majority of children contributed 3 or fewer person-years, though a maximum of 7 was possible. There were in all 612 deaths in the 12 683 person-years, for an overall annual mortality rate of 4.8%.

Description of Variables

Twelve CDER-based variables were included in the statistical analysis.

1. *Tubefeeding*: Use of a feeding tube was recorded as present or absent. Although the CDER does not currently distinguish between nasogastric, gastrostomy, or other feeding tubes, it appears that more than 90% of instances of tubefeeding involve a gastrostomy tube. In addition, the use of nonsurgical treatment, antireflux procedures, or gastric emptying procedures were not addressed.
2. *Rolling and Sitting*: A 9-point scale, ranging from "Does not lift head when lying on stomach" to "Assumes and maintains sitting position independently." Coders reported the highest level of skill attained. The importance of mobility as a predictor of mortality has been documented.[4,6,19] On the basis of the mortality rates for the rolling-and-sitting variable, we collapsed it to a new variable with four levels: (1) first level of rolling and sitting (cannot lift head); (2) second level (lifts head when lying on stomach); (3) levels 3 to 5 (lifts head and chest when lying on stomach, rolls from side to side, or rolls from front to back); and (4) levels 6 to 9 (rolls both back to front and front to back, or sits with at most minimal support for at least 5 minutes).
3. *Hand Use*. We used a simple dichotomy of "No functional use of hand" versus "Uses fingers independently."
4. *Crawling and Standing*. According to Condition A, only two groups were included in this study. These are "Does not creep, crawl, or scoot" and "Creeps, crawls, or scoots without the ability to stand." The crawling variable is thus dichotomous.
5. *Residential Placement*. Placements were grouped into four categories: own home, community care, health facilities, and insti-

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tutions. Parent/relative homes were counted as own home. Community care included small homes such as foster care as well as larger board-and-care facilities that serve seven or more people. Health facilities provide intermediate health care. Institutions, now called developmental centers in California, are operated by the state. Residence type was included in this study because it has been shown[20] that placements with higher levels of care (health facilities and institutions) are associated with lower mortality rates when other factors are taken into account. In institutions the majority (87%) of subjects were tubefed, compared with only 19% in own home and community care.

6. *Interaction With Peers*. This 4-point scale was dichotomized according to whether or not the child entered into social interactions. The unadjusted mortality rate for the latter group was approximately double that of the former.
7. *Auditory Perception*. A 7-point scale that we ultimately dichotomized according to whether the child appeared to distinguish voices from other sounds. The relative mortality at the lower level was more than double that at the higher level.
8. *Expressive Language*. A 7-point scale, dichotomized according to whether the child expresses words. The relative risk for this variable also exceeded 2.
9–12. *Medical Comorbidity*: CDER data during the 1987 to 1992 study period were used to identify the presence and severity of major medical conditions for each individual each year. After preliminary statistical analyses, the four following binary variables (presence/absence) were retained: severe general respiratory infections, severe pneumonia, esophageal and/or swallowing problems, and tracheostomy. Not surprisingly, the latter was strongly associated with the placement of a feeding tube.

Two other variables (severity of mental retardation, age) were eventually excluded from the multivariate modelling because they proved to contribute rather little when the other variables were taken into account.

Statistical Analysis

We modelled the hazard rate[21] directly in terms of the predictor variables, using logistic regression.[22] The units of the analysis were the 12 683 person-years. This procedure is not new; it is, for example, regularly used in the Framingham heart study, where it is known as "pooled repeated observations."[23]

Model building and diagnostic analyses were carried out using standard procedures,[22(pp82–175)] including stepwise logistic regression and likelihood ratio testing for groups of two-way and higher interactions. A full description of the model, which is not displayed here, may be obtained from the first author. The fit appeared adequate, according to the Hosmer-Lemeshow procedure (χ^2 =7.6 on 8 degrees of freedom; P = .47).[22(pp 140–145)] The model had substantial explanatory power (Goodman and Kruskal's Gamma= .39).[24]

To compare mortality rates for the different placements within strata that are homogeneous with respect to risk, we used the "multivariate confounder score" procedure of Miettinen.[25] Groups were constructed as follows. The logistic regression equation defined by our final model, but with the tubefeeding variable set to 0, was used to generate a predicted probability of death for each person-year. These probabilities were estimates of risk, adjusted for the effect of tubefeeding. They were then used to rank order all the 12 683 person-years from highest to lowest risk. Next, the person-years were partitioned into eight homogeneous "risk octiles." For example, the highest risk octile consisted of person-years where the subjects had the poorest functioning, often together with major medical conditions. Subjects in a persistent vegetative state[19] contributed to this group. The boundaries were chosen so as to give equal expected numbers of deaths in each. This choice resulted in approximately equal variances for the octile-specific mortality rates. Finally, within each octile the mortality rates for person-years with and without tubefeeding were calculated as the number of deaths divided by the number of person-years; the ratio of these rates was the relative risk associated with tubefeeding for that octile.

An overall significance test for relative mortality rates for subjects with versus without feeding tubes, without control for other study variables, was carried out with a straightforward 2×2 χ^2 procedure. However, the situation was more complex when other variables were taken into account since, as shown by the logistic regression analysis, the relative risk depended strongly on the values of the other study variables. Furthermore, the application of standard test procedures such as the Mantel-Haenszel test[26] across the risk octiles is known to be invalid.[27] A simple overall test of the controlled relative risk may nevertheless be based on the sign test[28] of the eight octile-specific relative risks (Figure), the null hypothesis being that the median of the distribution from which they are drawn is 1 . . . A test for *trend* of the eight relative risks was based on their Spearman rank correlation with their sequence numbers 1, 2, . . . , 8.[28(p338)]

RESULTS

Four findings were identified. First, the use of a feeding tube was strongly associated with virtually every disability. Table 1 shows some typical examples; the first two variables, arm use and auditory perception, were chosen for illustration purposes because they have no obvious causal link with the use of a feeding tube.

Second, when no study variables were controlled a statistically significant difference in mortality rates was noted between tubefed children and those not tubefed (Table 2). The overall relative risk was 2.10, which was even larger than that noted by Kastner et al[7] (χ^2 test for 2×2 table; $P < .01$). The discrepancy arises because Eyman et al[6] focused on the most severely debilitated subgroups. Among groups with additional disabilities, the feeding tube-mortality association was weaker and no longer significant (χ^2 tests; $P > .05$).

Third, feeding tube use among those with tracheostomy was associated with a reduction in relative risk of mortality. The estimated relative risk was .55 (Table 2). The size of the sample was small, however, and this reduction did not achieve statistical significance.

Perhaps of most interest was the fourth finding, obtained when the study variables (measures of functional independence, type of residence, and medical comorbidity) were controlled in a multivariate statistical analysis. Overall, tubefeeding was still associated with a higher risk ($P < .01$). In addition, however, the relative risk associated with tubefeeding (ie, the ratio of probability of death in a given person-year among those with versus those without a feeding tube) decreased steadily as risk level increased. Specifically, the relative risk declined from more than 2.0 in the first "risk octile"—the first of the eight risk-homogeneous groups of person-years,

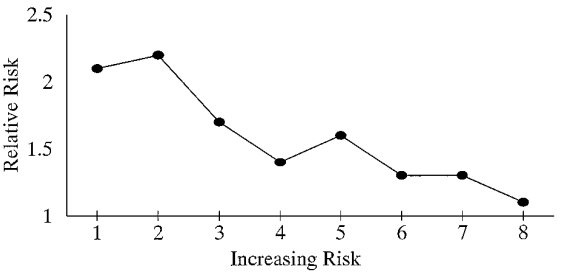

Figure. Relative risk for children with and without feedtubes, within eight homogeneous risk groups. Note that the relative risk tends to be smaller for the higher-risk subjects. The values 1.0 would correspond to equal risk for the children with and without a feedtube.

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TABLE 1. Association of Use of Feedtube With Several Variables From the *Client Development Evaluation Report**

	Hand Use		Auditory Perception		Lifts Head When Lying on Abdomen	
	Some	None	Some	None	Yes	No
Sample size	7374	5309	7920	4763	9507	317
Proportion with feedtube	17%	40%	17%	42%	19%	51%

* Based on entire sample of 12 683 person-years.

TABLE 2. Prevalence of Tubefeeding, and Mortality Rates of Children With and Without a Feedtube, Among Various Subgroups

	Fraction Tubefed (%)	Mortality (%)		Relative Risk
		Tubefed	Not Tubefed	
Whole sample (N = 12 683 person-years)	27	7.8	3.7	2.1*
Cannot lift head (N = 3176)	51	9.7	7.3	1.3†
Esophageal problems (N = 140)	68	11.6	8.9	1.3†
Tracheostomy (N = 400)	93	7.8	14.3	.55†

* Significantly different from 1 ($P < .01$).
† Not significantly different from 1 ($P > .05$).

consisting of those with the lowest risk—down almost to 1.0 in the group at highest risk. This trend was also statistically significant ($P < .01$). Thus, although feeding tube use was not associated with any identifiable increase in mortality among children with very severe disabilities, it *was* statistically associated with higher mortality in children with less severe disabilities.

DISCUSSION

The finding that feeding tube use in children with developmental disability is associated with higher mortality has important clinical implications. We hypothesize that it may reflect a differential increase in pulmonary disease secondary to overly vigorous nutritional maintenance and subsequent aspiration. This hypothesis is consistent with the long term follow-up study of Smith and coinvestigators[9] who reported a reduced but still substantially high incidence of recurrent pneumonias (40%), recurrent vomiting episodes (31%), and recurrent choking-gagging episodes (23%) after fundoplication and gastrostomy. Similar long-term findings were reported in other studies.[10–13] For children with tracheostomies, this risk appears reduced and may reflect the benefits of tracheostomy in allowing access to the airway for suctioning, supplemental oxygen and nebulized medication administration, and assisted ventilation. We found that inspection of *International Classification of Diseases* (9th revision) cause of death data was not especially illuminating, as frequently only the underlying cause (eg, congenital abnormality) rather than the immediate cause was reported. A more in-depth analysis of causes of death would be valuable.

Gastroesophageal reflux is common in children with developmental disabilities and it is now appreciated that gastrostomy placement alone is associated with an increased risk of subsequent gastroesophageal reflux that approaches 25% to 44%.[2,29] Such children usually require surgical antireflux procedures and in neurologically impaired children the incidence of significant postoperative complications (eg, wound infection, pneumonia, and respiratory impairment) has been estimated to range from 12% to 20%.[30–32] In addition, the risk of later symptoms associated with recurrent reflux after fundoplication ranges from 12% to 25%. As recently reviewed by Bagwell, postoperative complications also occur in 26% to 45% of such children and long-term mortality ranges from 9% to 40%.[33] These concerns are heightened by the results of another recent study by Heine and colleagues.[2] They found that 7 of 30 severely impaired children (mean age 6 ± 5.7 years) died an average of 9.7 (± 8.8) months after percutaneous endoscopic gastrostomy placement. Six of the deaths were attributable to pneumonia. Interestingly, they did not find an increased incidence of aspiration attributable to gastroesophageal reflux in these six children but suspected that the higher mortality might have been related to a greater incidence of pharyngeal incoordination with aspiration of food and salivary secretions as important contributing factors to the observed lung disease.

Children with very severe disabilities (eg, an inability to lift their head when lying on the abdomen) evidence similar risk whether or not they are tubefed. If feeding tubes offer other benefits such as a reduction in care taker burden, they will continue to play an important role in the management of this group. For children with less severe disabilities, our multivariate analysis did not show that the higher risk of mortality could be explained entirely by other risk factors. It may, on the contrary, suggest that the use of feeding tubes in this group of patients could be improved. At present for this group, clinicians should exercise caution when recommending use of a feeding tube.

Our findings are limited by the retrospective nature of the analysis and limitations in the data collected by the instrument. In addition, further work would be desirable with variables currently unavailable to us, such as the nutritional and growth status of the patient; pretreatment evaluations (videofluoroscopy, esophageal pH monitoring); types of feeding tube placement (gastrostomy vs nasopharyngeal); use of fundoplication or procedures to eliminate gastric outlet obstruction; use of specific feeding practices (bolus vs continuous feeding); and position during or after feeding. The study, does, however, point toward the importance of a properly controlled experiment that can address the research concerns identified above. This would involve random assignment of children with mental retardation and severe disabilities to various treatment/nontreatment groups. Randomization is the most appropriate study design for eliminating the types of potential

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researcher/practitioner bias seen in much of the current literature. Such a study should involve only those patients for whom surgery is currently regarded as prophylactic. This would exclude those presenting with severe gastroesophageal reflux or vomiting, and also those with a history of aspiration pneumonia.

We also suggest that a prospective, controlled clinical study is ethically justified. We recognize that this issue is not without controversy. The role of placebo controls in research studies has been widely debated.[3,34,35] On one hand, the United States Food and Drug Administration, the World Health Organization, and other regulatory groups support the use of placebos in clinical trials. On the other hand, it has been argued that placebo-controlled trials for well-characterized disorders violate the Declaration of Helsinki on the use of human subjects, which states that all patients, including controls, should receive established treatment.

In a review of clinical trials in schizophrenia, Addington[36] notes two accepted contraindications to the use of placebo controls: when standard drugs are known to prevent death or irreversible decline, or when there is an accepted treatment available for a severe, irreversible disease. We feel that the available body of evidence suggests that the use of feeding tubes in most children with severe disabilities and mental retardation meets neither of these criteria.

There is increasing use of the randomized clinical trial to identify cost savings associated with ineffective medical therapies. Thus, for example, Ilstrup[37] highlights the results of three randomized clinical trials at the Mayo Clinic that tested the effectiveness of currently utilized treatments. Given the popularity of surgical feeding tube placement for children with severe developmental disabilities, we believe that conservative use of feeding tubes has the potential to produce overall health care savings from a reduction in unnecessary treatment. A controlled study that addresses the costs of care associated with feeding tube use would be valuable to health planners and payers.

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