The Adequacy of Informed Consent for Placement of Gastrostomy Tubes

Allan S. Brett, MD; Jason C. Rosenberg, MD

Background: Gastrostomy tubes are placed commonly in patients with limited life expectancy. However, it is unclear whether the process of informed consent is adequate in these patients. This study examined the quality of informed consent in hospitalized patients undergoing placement of gastrostomy tubes.

Methods: Retrospective review of the medical records of a cohort of 154 consecutive hospitalized adults undergoing placement of gastrostomy tubes in the context of chronic progressive illness, in the setting of a large community-teaching hospital.

Results: The medical record documented a procedure-specific discussion of benefits and burdens of and alternatives to tube feeding in only 1 of 154 patients. Only 12 of 33 definitely or probably competent patients signed the hospital consent form; in the remaining 21, a surrogate decision-maker signed the form. The cumulative 1-year mortality for this cohort was 50%.

Conclusions: The quality of informed consent for placement of gastrostomy tubes was inadequate in a large community-teaching hospital. Indirect evidence from the literature suggests that these results are not unique to this institution. Physicians should become more familiar with the medical and ethical issues relevant to medically administered nutrition near the end of life, and institutions should develop procedures to improve the quality of decision-making for patients considering this intervention.

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Gastrostomy tubes are used commonly to provide nutrition and hydration for patients unable or unwilling to maintain an adequate oral intake. Among hospitalized patients aged 65 years or older in the United States, the number undergoing placement of a gastrostomy tube increased from 61 000 in 1988 to 121 000 in 1995.1 In 1990 and 1991, roughly 1 in every 100 hospitalized patients aged 85 years or older received a gastrostomy tube.1,2

The short-term mortality rates following gastrostomy placement are high.3,4 In a cohort of more than 7000 US veterans who underwent placement of percutaneous endoscopic gastrostomy (PEG) tubes between 1990 and 1992, median survival was 7.5 months and 1-year mortality was 59%.5 Among Medicare beneficiaries receiving gastrostomy tubes in 1991, 30-day and 1-year mortality was 24% and 63%, respectively.1 Because tube insertion itself is associated with fatal complications only rarely, the high short-term mortality clearly reflects a substantial underlying comorbidity in this population. Most patients receiving gastrostomy tubes have advanced dementia, other types of severe neurologic impairment, cancer, or advanced failure of other internal organs.1,2,3

The growing use of tube feeding in a population with limited life expectancy inevitably raises the following question: Do physicians discuss the benefits and burdens of tube feeding adequately with patients or surrogate decision-makers before gastrostomy tubes are inserted? Assessing benefits and burdens is an integral part of informed decision-making and should precede any elective life-sustaining intervention. However, anecdotal observations6,7 and a recent interview study8 raise serious questions about the quality of the informed consent process preceding the insertion of gastrostomy tubes. We therefore conducted a retrospective analysis of the medical records of consecutive patients receiving gastrostomy tubes, with particular attention to the quality of documented informed consent.
MATERIALS AND METHODS

The study was conducted at Palmetto Richland Memorial Hospital, Columbia, a 649-bed community-teaching hospital affiliated with the University of South Carolina School of Medicine. Patients are admitted to teaching services (covered by residents under attending physician supervision) and nonteaching services (covered only by private physicians). The hospital provides primary care for metropolitan Columbia and serves as a referral hospital for central South Carolina. In fiscal year 1998-1999, there were 22,275 discharges of adults aged 18 years and older; nonwhites (nearly all of whom were black) comprised 52% of discharges.

A computerized search of medical records identified all patients who had gastrostomy tubes placed surgically, endoscopically, or radiologically (International Classification of Diseases, Ninth Revision, Clinical Modification, codes 43.11 and 43.19) between July 1, 1997, and June 30, 1998. We reviewed the medical records of all adults aged 21 years and older. To limit the study to patients whose gastrostomy tubes were placed in the context of chronic progressive illness, we excluded patients in whom tube placement was intended to be temporary (eg, after trauma, following head and neck cancer surgery with curative intent).

We reviewed each medical record in detail to obtain demographic and clinical information, and we read every physician’s progress note in the chart. We classified patients into 4 categories of primary diagnoses: acute stroke, chronic dementia, other neurologic conditions, and nonneurologic conditions with failure to thrive. The latter category included patients with terminal cancer or advanced failure of 1 or more organ systems. If the medical record directly alluded to the patient’s capacity for decision-making during the period before gastrostomy tube placement, the patient was categorized as clearly competent or incompetent. In cases with no direct statement, we inferred competence or incompetence through review of progress notes or other information suggesting the presence or absence of delirium or dementia. To assess informed consent, we searched for progress notes documenting discussions with patients or surrogate decision-makers. We considered any documented discussion of specific benefits and burdens of and alternatives to tube feeding, however brief, to constitute adequate informed consent. The hospital’s generic surgical consent form has a place to write in the name of the procedure but no space in which to record procedure-specific benefits, burdens, and alternatives.

To assess mortality following discharge from the hospital, workers at the South Carolina Department of Public Health and Information Services, Columbia, searched a microfilm database to determine the vital status of each discharged patient. The database was complete through September 1, 1999.

### RESULTS

Between July 1, 1997, and June 30, 1998, 272 gastrostomy tubes were placed in adults aged 21 years and older. We excluded 118 patients (48 with a primary diagnosis of trauma, 29 undergoing treatment for head and neck cancer, 27 with an unavailable complete medical record, and 14 for miscellaneous reasons), leaving 154 patients for inclusion in the study.

Demographic and clinical characteristics of patients are noted in Table 1. The mean age (± SD) was 71 years (± 13.9). The large proportion (69.5%) of nonwhite patients is higher than the hospital’s overall nonwhite proportion of 52%. More than two thirds of the patients had neurologic diagnoses; the nonneurologic group consisted primarily of patients with advanced cardiac, pulmonary, kidney, or liver disease, and patients with cancer. Competence or incompetence was clearly indicated in 67.5% of patients. In most cases, the procedure was authorized by a surrogate decision-maker (according to the signature on the official hospital consent form).

The progress notes documented a discussion with the patient or surrogate outlining procedure-specific benefits and burdens of and alternatives to tube feeding in only 1 of the 154 patients. According to the formal hos-

<table>
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<th>Table 1. Characteristics of Study Population*</th>
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<tbody>
<tr>
<td><strong>Ethnicity</strong></td>
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<tr>
<td><strong>Primary diagnosis</strong></td>
</tr>
<tr>
<td>Acute stroke</td>
</tr>
<tr>
<td>Chronic dementia</td>
</tr>
<tr>
<td>Other neurologic</td>
</tr>
<tr>
<td>Nonneurologic</td>
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<tr>
<td><strong>Competence</strong></td>
</tr>
<tr>
<td>Clearly competent</td>
</tr>
<tr>
<td>Competent (not clearly stated)</td>
</tr>
<tr>
<td>Incompetent (not clearly stated)</td>
</tr>
<tr>
<td>Clearly incompetent</td>
</tr>
<tr>
<td>Unknown</td>
</tr>
<tr>
<td><strong>Code status</strong></td>
</tr>
<tr>
<td>Full code</td>
</tr>
<tr>
<td>Do not resuscitate</td>
</tr>
<tr>
<td><strong>Who authorized gastrostomy</strong></td>
</tr>
<tr>
<td>Patient</td>
</tr>
<tr>
<td>Surrogate (in person)</td>
</tr>
<tr>
<td>Surrogate (over telephone)</td>
</tr>
<tr>
<td>Swallowing study obtained</td>
</tr>
<tr>
<td>Advance directive available</td>
</tr>
<tr>
<td><strong>Admitted from</strong></td>
</tr>
<tr>
<td>Home</td>
</tr>
<tr>
<td>Nursing home</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td><strong>Discharged to</strong></td>
</tr>
<tr>
<td>Nursing home</td>
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<tr>
<td>Rehabilitation facility</td>
</tr>
<tr>
<td>Home</td>
</tr>
<tr>
<td>Other</td>
</tr>
<tr>
<td>Death in hospital</td>
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*Data are given as number (percentage). Some percentages do not sum to 100 because of rounding.
hospital consent form, surrogate decision-makers (usually family members) authorized the procedure in 92.2% of cases (70.1% with an actual signature and 22.1% over the telephone). Although we judged 33 patients to be competent (18 clearly so and 15 by inference), only 12 signed the hospital consent form. Only 11 of the 18 clearly competent patients signed the form; in the remaining 7, a surrogate decision-maker signed the form.

Eighty-two patients (53%) died during a follow-up period ranging from 14 to 26 months. In-hospital mortality was 17%, and an additional 15% died within 1 month of hospital discharge (usually in a chronic care facility). The cumulative mortality 1 year after discharge, including deaths during the index admission, was 50% (Table 2).

**COMMENT**

Our study strongly suggests that the quality of informed consent for gastrostomy tube placement was inadequate in a large community-teaching hospital. Several observations support this conclusion. First and most important, only 1 of 154 medical records contained a progress note documenting a discussion with the patient or surrogate decision-maker regarding specific benefits and burdens of and alternatives to permanent gastrostomy tube feedings. The standard hospital informed consent form was signed in all cases, but this document was a generic surgical consent form, with no specific entries about permanent medically administered nutrition. Second, although 33 patients appeared to be competent to make medical decisions, only 12 of them signed the consent form; a surrogate for the patient authorized the procedure in the other 21 cases. Third, 34 of the 142 surrogate decision-makers did not sign the consent form but instead authorized the procedure over the telephone, with a nurse signing on behalf of the surrogate in all these cases. Gastrostomy tube placement was always elective, and surrogate decision-makers were nearly always family members living within a reasonable distance from the hospital. Thus, there should have been adequate opportunity for surrogates to have face-to-face discussions with members of the health care team and to sign the forms themselves.

A small body of literature suggests that fully informed patients or their surrogates might in fact decline permanent tube feeding at a higher-than-expected rate. For example, in the study by Callahan et al,8 nearly half of patients undergoing gastrostomy placement (or their surrogates) reported that no alternatives had been discussed before insertion of the tube. O’Brien and colleagues9 asked 379 mentally competent nursing home residents if they would want a gastrostomy tube if they became unable to eat because of permanent brain damage; only 33% expressed a preference for tube feedings in this circumstance. In an interview study10 of 121 competent patients with amyotrophic lateral sclerosis, only 28% favored feeding by gastrostomy.

The most important potential limitation of our study is that the written medical record may not capture adequately the quality of informed consent. Although high-quality but undocumented discussions might have occurred in some cases, we believe that to be the exception and not the rule. Our close reading of all medical chart notes suggested an inevitability about gastrostomy placement, with no consideration of alternatives. Typically, at some point during the hospitalization, a progress note would document dysphagia, aspiration, or inadequate energy intake in a patient unable or unwilling to swallow and would conclude with a comment that the patient may need a gastrostomy tube. Next, in many patients a swallowing assessment would be obtained from a consultant in the physical and occupational therapy department, who invariably would confirm the clinical impression of dysphagia or aspiration. Finally, a consultant (usually a gastroenterologist) would examine the patient, agree with the necessity for tube feeding, and schedule the procedure. Occasionally, percutaneous tubes were placed fluoroscopically by a radiologist, without additional consultation. This general sequence was recently suggested by Callahan et al8 in their interview study of patients (or their surrogates) who had received percutaneous endoscopic gastrostomy tubes during the previous few months. According to the authors, respondents generally perceived “the decision for PEG as a forgone conclusion” and that the process was “an irreversible cascade” once the idea was first raised.

Second, our patients may not be representative of patients receiving gastrostomy tubes generally in the United States. However, our mix of underlying diagnoses and our in-hospital and 1-year mortality rates were similar to those previously reported1-3 for patients receiving gastrostomy tubes. The proportion (68.2%) of black patients in our cohort was higher than the proportion (about 50%) of black admissions to our hospital and much higher than the proportion of black persons in the US population. Other studies1-2 from large databases have noted that black patients undergo gastrostomy tube placement at a rate roughly twice that of white patients. It is unclear whether this reflects differences in underlying disease prevalence or racial differences in attitudes about tube feedings.

Third, it is possible that physicians in our institution are less likely than other American physicians are to conduct and document discussions of the benefits and burdens of tube feeding. However, a systematic difference between our physicians and others seems unlikely for 2 reasons. First, physicians and ethicists from several clinical institutions have questioned the quality of decision-making for gastrostomy tube placement in re-

<table>
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<th>Interval</th>
<th>Mortality (%)</th>
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<tr>
<td>In-hospital</td>
<td>16.9</td>
</tr>
<tr>
<td>7 days†</td>
<td>20.1</td>
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<tr>
<td>30 days</td>
<td>31.8</td>
</tr>
<tr>
<td>60 days</td>
<td>37.7</td>
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<tr>
<td>90 days</td>
<td>40.9</td>
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<tr>
<td>120 days</td>
<td>42.9</td>
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<tr>
<td>180 days</td>
<td>46.8</td>
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<tr>
<td>1 year</td>
<td>50.0</td>
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*Data are given as percentages.
†Intervals start with the date of discharge from the hospital.
cent years. And second, although we did not formally assess informed consent for other procedures, the progress notes of some patients documented such discussions for other life-sustaining interventions, notably cardiopulmonary resuscitation and mechanical ventilation. Thus, our physicians were capable of documenting end-of-life discussions but seemed less inclined to do so for tube feeding than for certain other interventions. Interestingly, a recently published study from a hospital in New York found documented discussions about withholding or withdrawing care in only 10% of acutely ill patients with end-stage dementia.

A final limitation is that our methods did not allow us to identify medical records of patients who considered but declined placement of a gastrostomy tube. Conceivably, discussions of benefits, burdens, and alternatives were documented in the progress notes of those patients.

We believe that 4 steps can be taken to improve the quality of decision-making regarding permanent medically administered nutrition. First, professional organizations should mount educational campaigns to ensure that practicing physicians are familiar with the medical evidence on outcomes of permanent tube feeding. A good starting point is a recent literature review by Finucane and colleagues, which summarizes published data on mortality and complications associated with tube feeding. These authors show, for example, that contrary to popular belief, there is no clear evidence that tube feeding prevents aspiration pneumonia.

Second, similar educational campaigns should focus on the ethical and legal issues surrounding tube feeding in advanced dementia. A recent excellent and provocative essay by Gillick should be required reading not only for primary care physicians but also for consultants who insert gastrostomy tubes.

Third, the process of informed consent should be institutionalized in a way that maximizes the likelihood of meaningful discussions of benefits and burdens of and alternatives to tube feedings. In a recent analysis of consent forms from 616 US hospitals, spaces to document procedure-specific risks, benefits, and alternatives were present in only 30%, 6%, and 5% of the forms, respectively. Although the written consent form is no substitute for meaningful discussions between physicians and patients or surrogates, a form requiring procedure-specific details could at least trigger such discussions more consistently. In addition, institutions should consider developing preprinted materials that present a balanced overview of permanent tube feedings to patients and families. One group has proposed a specific clinical guideline for decision-making when a gastrostomy tube is considered.

Finally, several authors have implied that unreflective placement of gastrostomy tubes occurs frequently because of the pressure to move patients quickly from hospital to nursing home. The rationale is that, for patients with borderline swallowing function and diminished capacity for self-feeding, it is more efficient for nursing home staff to administer tube feedings than to take the time to feed patients orally. Although this tactic is understandable from the perspective of economic pressures facing hospitals and chronic care facilities, it is ethically unacceptable and deserves attention at the level of national policy-making.

In conclusion, our study provides evidence that informed consent for gastrostomy tube placement was inadequate in a large US hospital; the literature suggests that our findings are generalizable to other settings. We encourage researchers to conduct additional studies at other centers. In addition, we challenge educators to develop ways to enhance physicians’ understanding of medical and ethical issues relevant to medically administered nutrition near the end of life, and institutions to develop procedures to improve the quality of decision-making for patients considering this intervention.

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REFERENCES


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