Protein–energy supplementation of normal hospital diet did not improve outcomes after recent stroke

The FOOD Trial Collaboration. **Routine oral nutritional supplementation for stroke patients in hospital (FOOD): a multicentre randomised controlled trial.** Lancet. 2005;365:755-63.

Clinical impact ratings: GIM/FP/GP ★★★★★☆☆ Hospitalists ★★★★★☆☆ Neurology ★★★★★★☆ Phys Med & Rehab ★★★★☆☆☆

QUESTION

Does routine oral protein–energy supplementation of normal hospital diet improve outcomes in patients who have been admitted with a recent stroke and can swallow?

METHODS

Design: Randomized controlled trial (Feed Or Ordinary Diet [FOOD] trials).
Allocation: Concealed.*
Blinding: Blinded (outcome assessors).*
Follow-up period: Median 6.7 months.
Setting: 125 hospitals in 15 countries.
Patients: 4023 patients (mean age 71 y, 53% men, 8% undernourished) who were admitted with a recent stroke (first or recurrent stroke ≤ 7 d before admission) and whose clinicians were uncertain about whether to use oral nutritional supplements after they had passed the swallow screen. Patients with subarachnoid hemorrhage were excluded. Patients could be enrolled within the first 30 days of admission, or within 30 days of stroke occurring in hospital.
Intervention: Normal hospital diet plus oral protein–energy supplements (equivalent to 360 mL at 6.27 kJ/mL and 62.5 g/L in protein every d) (n = 2016) or normal hospital diet alone (n = 2007) until discharge.
Outcomes: A composite endpoint of all-cause mortality or poor outcome (defined as modified Rankin scale [MRS] scores 3 to 5, with the MRS scores ranging from 0 [no symptoms] to 5 [requiring constant attention day and night]), and all-cause mortality.
Patient follow-up: 99.7% (intention-to-treat analysis).

MAIN RESULTS

The groups did not differ for rates of the composite endpoint or all-cause mortality (Table).

CONCLUSION

Routine oral protein energy supplementation of normal hospital diet did not improve outcomes in patients who had been admitted with a recent stroke.

Sources of funding: National Health Service Research and Development in UK; Stroke Association; Chief Scientist Office of the Scottish Executive; Chest, Heart and Stroke Scotland; Royal Australian College of Physicians.

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*See Glossary.

Normal hospital diet plus oral protein energy supplements vs normal hospital diet after recent stroke at median 6.7 months†

Outcomes	Supplements	No supplements	RRI (95% CI)	NNH
Composite endpoint	59%	58%	1.5% (–3.6 to 6.9)	Not significant
			RRR (CI)	NNT
All-cause mortality	12%	13%	5.2% (–11.8 to 19.6)	Not significant

†Composite endpoint = all-cause mortality or poor outcome defined as modified Rankin scale scores 3 to 5 (range 0 to 5). Abbreviations defined in Glossary; RRI, RRR, NNH, NNT, and CI calculated from data in article.

COMMENTARY

The 3 FOOD trials by The Food Trial Collaboration add to the evidence base of how best to feed patients with stroke. The protein supplementation study is relatively straightforward. In patients with stroke who are able to take oral nutrition (undernourished or not), additional nutritional supplements beyond a normal hospital diet are probably not necessary. However, the other 2 trials require more thought.

The early ETF vs no ETF trial reassures me that no compelling urgency exists to start artificial nutrition in patients with dysphagic stroke. If I need a few additional days to discuss with patients or families the risks and benefits of artificial versus natural nutrition, I have them, keeping in mind that some form of nutrition should be started within the first week. Although I am reassured that NG feedings were not associated with a higher rate of aspiration pneumonia, I am constantly reminded of them being a nuisance every time I use them. In addition, the higher occurrence of gastrointestinal hemorrhages associated with their use (22 in the early ETF vs 11 in the no ETF group, P = 0.04), as found in the study, gives me further pause in ordering them.

The NG vs PEG trial shows that PEG tubes should not be used immediately, but only after an initial 2- to 3-week time-limited trial of NG feeding, allowing the necessary time for patients to resume natural nutrition. Indeed, of the 159 patients originally randomized to NG feeding, only 44 (28%) later received a PEG tube. If artificial nutrition is required beyond 2 to 3 weeks, then PEG feeding is the preferred approach. Previous clinical trials have shown that for patients with persistent dysphagia lasting ≥ 2 weeks, PEG tubes were not only safer (1, 2) but potentially associated with better survival at 6 weeks compared with NG feeding (88% in the PEG group vs 43% in the NG group) (2). Although the previous trials have methodologic shortcomings typical of unblinded trials with small sample sizes, they complement the data from the FOOD trials given that they ask different questions about the timing of PEG tube placement.

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Timing and route of enteral tube-feeding did not reduce death or poor outcome in stroke and dysphagia

The FOOD Trial Collaboration. **Effect of timing and method of enteral tube feeding for dysphagic stroke patients (FOOD): a multicentre randomised controlled trial.** Lancet. 2005;365:764-72.

Clinical impact ratings: GIM/FP/GP ★★★★★★☆ Hospitalists ★★★★★★☆ Neurology ★★★★★★☆ Phys Med & Rehab ★★★★★☆☆

QUESTIONS

In patients with recent stroke and dysphagia, does early initiation of enteral tube-feeding (ETF) (vs no tube-feeding for ≥ 7 d) improve outcomes (study 1)? Does ETF via percutaneous endoscopic gastrostomy (PEG) (vs nasogastric [NG] tube) improve outcomes (study 2)?

METHODS

Design: 2 randomized controlled trials with similar design (Feed Or Ordinary Diet [FOOD] trials).
Allocation: Concealed.*
Blinding: Unblinded.*
Follow-up period: 6 months.
Setting: 83 hospitals in 15 countries (study 1) and 47 hospitals in 11 countries (study 2).
Patients: Patients admitted to hospital with recent stroke (within 7 d before admission) who had dysphagia were enrolled in study 1 (n = 859, mean age 76 y, 46% men, 9% undernourished) if the clinician was uncertain when to start tube-feeding; or study 2 (n = 321, mean age 76 y, 45% men, 22% undernourished) if the clinician chose to start tube-feeding but was uncertain whether to use PEG or NG tube. Patients with subarachnoid hemorrhage were excluded.
Intervention: In study 1, ETF as soon as possible ("early initiation") via the clinician's preferred method (n = 429) or no tube-feeding (only parenteral fluids were given) for ≥ 7 days (n = 430). In study 2, ETF via PEG (n = 162) or NG tube (n = 159) within 3 days of enrollment.
Outcomes: Death and a composite endpoint of death or poor outcome. Poor outcome was defined as modified Rankin scale (MRS) scores 3 to 5, with the MRS scores ranging from 0 (no symptoms) to 5 (requiring constant attention day and night).
Patient follow-up: 100% (intention-to-treat analysis).

MAIN RESULTS

In study 1, early initiation of ETF did not reduce death or the composite endpoint of death or poor outcome more than no tube-feeding for ≥ 7 days (Table). In study 2, ETF via PEG did not reduce death or the composite endpoint of death or poor outcome more than ETF via NG tube (Table).

CONCLUSIONS

In patients with recent stroke and dysphagia, early initiation of enteral tube-feeding did not reduce death or poor outcome more than no tube-feeding for ≥ 7 days and enteral tube-feeding via percutaneous endoscopic gastrostomy did not reduce death or poor outcome more than nasogastric tube-feeding.

Sources of funding: National Health Service Research and Development in UK; Stroke Association; Chief Scientist Office of the Scottish Executive; Chest, Heart and Stroke Scotland; Royal Australian College of Physicians.

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*See Glossary.

Timing and method of enteral tube-feeding (ETF) in stroke and dysphagia†

Study	Comparisons	Outcomes at 6 mo	Event rates	RRR (95% CI)	NNT
1	Early initiation of ETF vs no ETF for ≥ 7 d	Death Death or poor outcome	42% vs 48% 79% vs 80%	12% (–2 to 24) 1% (–5 to 8)	Not significant Not significant
				RRI (CI)	**NNH**
2	ETF via PEG vs ETF via NG tube	Death Death or poor outcome	49% vs 48% 89% vs 81%	2% (–19 to 28) 10% (–0.06 to 21)	Not significant Not significant

†PEG = percutaneous endoscopic gastrostomy; NG = nasogastric; poor outcome = modified Rankin scale scores 3 to 5 (range 0 to 5). Other abbreviations defined in Glossary; RRR, RRI, NNT, NNH, and CI calculated from data in article.

COMMENTARY *(continued from page 36)*

The FOOD trials do not, however, address the most challenging aspect of artificial nutrition in patients with stroke: not what or when—but if—artificial nutrition and PEG tubes should be used, because many patients have strong preferences regarding their use (3). The symbolic association of feeding tubes with disability and dependence is borne out by these studies, because 40% to 50% of patients did not survive to 6 months and of those who did, 65% had severe disability (MRS score 4 to 5), 20% had moderate disability (MRS score 3), and only 15% had no or slight disability (MRS score 0 to 2). Eliciting patient preferences regarding the use of feeding tubes and negotiating alternatives, such as hand-feeding (the true risks and benefits are unknown in this population), require intense discussions with concepts and words that most find uncomfortable but are critical for establishing the proper goals of care.

The FOOD trials provide us with a solid foundation of evidence. The marker of good care, however, will be that the treatment patients with dysphagic stroke receive is consistent with the underlying values of what makes their lives worth living.

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