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# Does looped nasogastric tube feeding improve nutritional delivery for patients with dysphagia after acute stroke? A randomised controlled trial

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## Abstract

**Background:** nasogastric tube (NGT) feeding is commonly used after stroke, but its effectiveness is limited by frequent dislodgement.
**Objective:** the objective of the study was to evaluate looped NGT feeding in acute stroke patients with dysphagia.
**Methods:** this was a randomised controlled trial of 104 patients with acute stroke fed by NGT in three UK stroke units. NGT was secured using either a nasal loop ($n = 51$) or a conventional adhesive dressing ($n = 53$). The main outcome measure was the proportion of prescribed feed and fluids delivered via NGT in 2 weeks post-randomisation. Secondary outcomes were frequency of NGT insertions, treatment failure, tolerability, adverse events and costs at 2 weeks; mortality; length of hospital stay; residential status; and Barthel Index at 3 months.
**Results**: participants assigned to looped NGT feeding received a mean 17% (95% confidence interval 5–28%) more volume of feed and fluids, required fewer NGTs (median 1 vs 4), and had fewer electrolyte abnormalities than controls. There was more minor nasal trauma in the loop group. There were no differences in outcomes at 3 months. Looped NGT feeding cost £88 more per patient over 2 weeks than controls.
**Conclusion**: looped NGT feeding improves delivery of feed and fluids and reduces NGT reinsertion with little additional cost.

**Keywords:** *dysphagia, elderly, enteral feeding, nasogastric tube feeding, stroke*

## Introduction

Half of patients admitted to the hospital with acute stroke have dysphagia [1–5]. Approximately a third of these will require enteral tube feeding in the acute phase, and some (6–8%) will remain tube-dependent at 6 months [6]. Dysphagia is associated with severe disability, poor recovery, institutionalisation and death [2, 7, 8]. Dysphagia is associated with poor nutrition, which is present in a quarter of patients with stroke on admission to the hospital and worsens during hospital stay [3, 9, 10]. Interventions to improve nutritional state in stroke may improve outcomes [11, 12].

Nasogastric tube (NGT) feeding is the method of choice for early enteral feeding in stroke where there is significant dysphagia. In practice, it only delivers 44–70% of intended feed [13–16], usually because of tube dislodgment [4]. A

nasal loop (sling or bridle) is a possible means to reduce dislodgment. This approach secures a NGT by attaching it to a ribbon or tube, which is looped around the nasal septum [17]. In one small uncontrolled study of stroke patients fed using this technique, a high proportion of intended feed was delivered, indicating that this technique could have advantages over conventional practice [18]. A recently developed method using a magnetic insertion system (Appendix 1, supplementary data are available in *Age and Ageing* online) has made it simpler to insert a nasal loop [19]. We investigated the effect of this technique on feed and fluid delivery for dysphagic stroke patients in the first 2 weeks after acute stroke, using a randomised controlled trial.

## Methods

### Participants

Patients were eligible for this study if they were admitted with acute stroke to one of four non-selective stroke units (Nottingham City Hospital, Queens Medical Centre Nottingham, Derbyshire Royal Infirmary and Yeovil District General Hospital), and the clinicians responsible for their care decided that NGT feeding was required because of dysphagia identified by a standardised water swallow test [20]. Patients were excluded if there were contraindications to NGT feeding or if it had been established for more than 7 days elsewhere. Informed consent was requested from those with mental capacity and those without were included following consultation with relatives.

### Interventions

Both groups had standard NGT insertion by stroke unit nurses, with position confirmed by aspiration of gastric fluid with pH <5.5 or chest X-ray. The NGT was secured by an adhesive nasal sticker in the conventional group, and by a nasal loop in the intervention group (AMT Bridle© supplied by Pro-Care Ltd, UK CE mark 93/42/EEC). The nasal loop was inserted as described in the supplementary data once the position of the NGT was confirmed.

If the loop or NGT was inadvertently removed and if continued feeding was still indicated, then it was replaced. Two further loop insertions were permitted; after which, NGTs were secured as in the control group.

Dieticians, otherwise uninvolved in the study and initially unaware of allocation status, prescribed feed and fluid regimes on an individual patient basis.

### Objectives

The primary objectives of the study were to compare the proportion of prescribed feed and fluids delivered via NGTs secured either using a nasal loop or conventionally, and to estimate the cost-effectiveness and tolerability of the use of the nasal loop.

### Outcomes

The primary outcome was proportion of prescribed feed and fluids delivered via NGT over 2 weeks after randomisation. This was recorded daily by a ward nursing staff and verified by a researcher on daily visits, having been previously piloted to ensure accuracy. Secondary outcome measures at 2 weeks were: mean volume of feed and fluids delivered; proportion of participants not receiving any NGT feed; supplementary parenteral fluids; number of NGT insertions; number of chest X-rays to check NGT position; change in weight; treatment failure (early percutaneous endoscopic gastrostomy (PEG) insertion within 2 weeks or abandonment of NG feeding); and adverse events which were nasal trauma (nose bleeds, pressure sores, or nasal discharge reported by patients or by staff on daily inspection and review), chest infection (diagnosed and treated by clinical team), diarrhoea, vomiting, gastrointestinal bleeding, electrolyte abnormalities of sodium, potassium, magnesium and phosphate (outside of local laboratory ranges found on routine ward collection), and tolerability. Refeeding syndrome was defined as reduction in magnesium, phosphate and potassium levels associated with a clinical deterioration.

To assess tolerability, five statements on understanding the procedure, discomfort on insertion, day-to-day discomfort, ease of dislodgment, and whether NGT feeding was felt to be worthwhile were assessed using a Likert scale. The questionnaires were administered to participants who were able to respond. Family members and nurses who cared for the participants were used as proxy informants for those unable to respond. Pilot testing suggested that many participants would be unable to complete the questionnaires due to severe communication difficulties, and the validity of the proxy responses was uncertain. We therefore undertook a focus group study of nurses on the main recruiting centre (Nottingham City Hospital) to enquire about their perceptions of NGT and loop tolerability.

Secondary outcome measures at 3 months were mortality, length of hospital stay, PEG use, residential status and Barthel Index.

### Costs

We estimated the cost-effectiveness over the 2-week period from the limited perspective of costs associated with feeding only (technical efficiency rather than the cost utility of the intervention).

Six variables (Appendix 2 in supplementary data are available in *Age and Ageing* online) were measured to estimate the costs used in the cost-effectiveness calculation: the number of NGT insertions, the number of loop insertions, the number of days of NGT feeding, the number of feed bags delivered, the number of days of supplementary fluid and the number of chest X-rays to check NGT position over 2 weeks.

### Sample size calculation

To demonstrate an increase of feed and fluid delivery from a mean 43.5% (SD 25%) to 60%, based on prior local audit data, 50 patients were required in each arm for 90% power with a significance level of 0.05. Allowing for a 10% dropout rate, we aimed to recruit 110 participants.

### Randomisation

Randomisation was performed by the University of Nottingham Clinical Trials Support Unit using a web-based system. Randomisation was based on a computer-generated pseudorandom list using random permutated blocks of randomly varying size and stratified by site and stroke severity (total anterior circulation stroke (TACS) or other [21]). Recruits were consecutively randomised, and the allocation sequence was concealed from researchers and participants until the end of the trial once all analyses were complete.

### Blinding

Outcome measurements and the intervention were not blinded to group allocation, due to the nature of the intervention and concurrent data collection. Data were analysed independently by the study statistician, who was blinded to group allocation.

### Analyses

Data were analysed by intention to treat. The primary analysis was analysed using a multiple linear regression to take into account stratifying factors. Logistic regression was used to examine interactions and the effect of baseline differences. STATA version 8 SE was used for the statistical calculations. Nursing time costs were drawn from standard costs from the Personal Social Services Research Unit (PSSRU 2007) [22]. All other costs were the local purchase costs, with the exception of the cost of the nasal loop set, for which the base case used the cost for a single loop set (£76) and a secondary analysis used the bulk cost (£40). The incremental cost-effectiveness ratio was estimated as cost per change in percentage nutritional prescription received, and only related to the 2 weeks when the intervention was examined.

### Ethics and funding

The study received multi-centre ethical committee approval (Nottingham Research Ethics Committee). Funding for the study was received via a fellowship from the Royal College of Physicians and the Dunhill Medical Trust. Procare Ltd supplied the loops at a bulk price but had no role in the design, analysis or interpretation of the findings.

The protocol has been published previously [23].

## Results

Participants were recruited from September 2006 to December 2007. The Queens Medical Centre site ($n$ = 7) closed 6 weeks into the study period because its stroke unit merged with that in Nottingham City Hospital ($n$ = 5) to form a combined unit ($n$ = 87). Yeovil District General Hospital ($n$ = 5) recruited for the final 5 months. Recruitment at Derby Royal Infirmary was halted in May 2007 after only one participant was recruited due to local difficulties in supporting the study.

One thousand and two hundred fifty-nine patients (Figure 1) with acute stroke were identified; of whom, 489 had dysphagia, 206 required NGT feeding, 155 were eligible for the study and 105 were recruited. A decision was made, blinded to allocation, to exclude the single participant from the Derbyshire Royal Infirmary site when the study was halted there. Data from 104 participants were analysed—51 in the intervention group and 53 in the control group. Sixteen (15%) participants could give consent, and 88 (85%) required assent from relatives.

At baseline, groups were similar in age, stroke severity, prior level of functioning, and previous stroke history (Table 1). By chance, the proportions of patients currently treated for chest infection (43% vs 27%) and with dementia (34% vs 12%) were higher in the control group, and there was a higher proportion with a low admission serum albumin (a marker of poor outcome [24]) in the intervention group (63% vs 43%).

The intervention group received a higher proportion of prescribed feed and fluids (17%, 95% CI 5–28%, $P$ = 0.002) than the control group (Table 2). Post hoc analyses adjusting for the imbalance in chest infections gave a similar result (18%, 95% CI 6–29%, $P$ = 0.003) as did adjusting for the baseline imbalance in albumin levels (18%, 95% CI 6–30%, $P$ = 0.003) or dementia (14%, 95% CI 3–26%, $P$ = 0.016).

Secondary outcomes are shown in Table 2. Participants in the loop group received more volume of feed and fluids over the 2-week period via NGT (mean 17.0 L vs 11.4 L) and required fewer days of supplementary fluids (mean 3.8 vs 6.1). Fewer NGTs tubes (median 1 vs 4) and chest X-rays (median 0 vs 1) for position confirmation were required in the intervention group. Participants in both groups lost weight (mean 3 kg) as expected. Treatment failure was more common in the conventional than the looped NGT group (40% vs 25%). Outcomes at 3 months were similarly poor between conventional and loop groups (dead or BI <12, 89% vs 80%). Minor nasal problems such as nosebleeds were more common in the intervention group (37% vs 15%), but none required medical intervention. There were more electrolyte abnormalities in the control group (58% vs 31%). Overall, 19% developed hypokalaemia, 6% hypomagnesaemia, 18% sodium abnormalities and 14% hypophosphataemia. There were no significant differences in any of the five tolerability questions between the

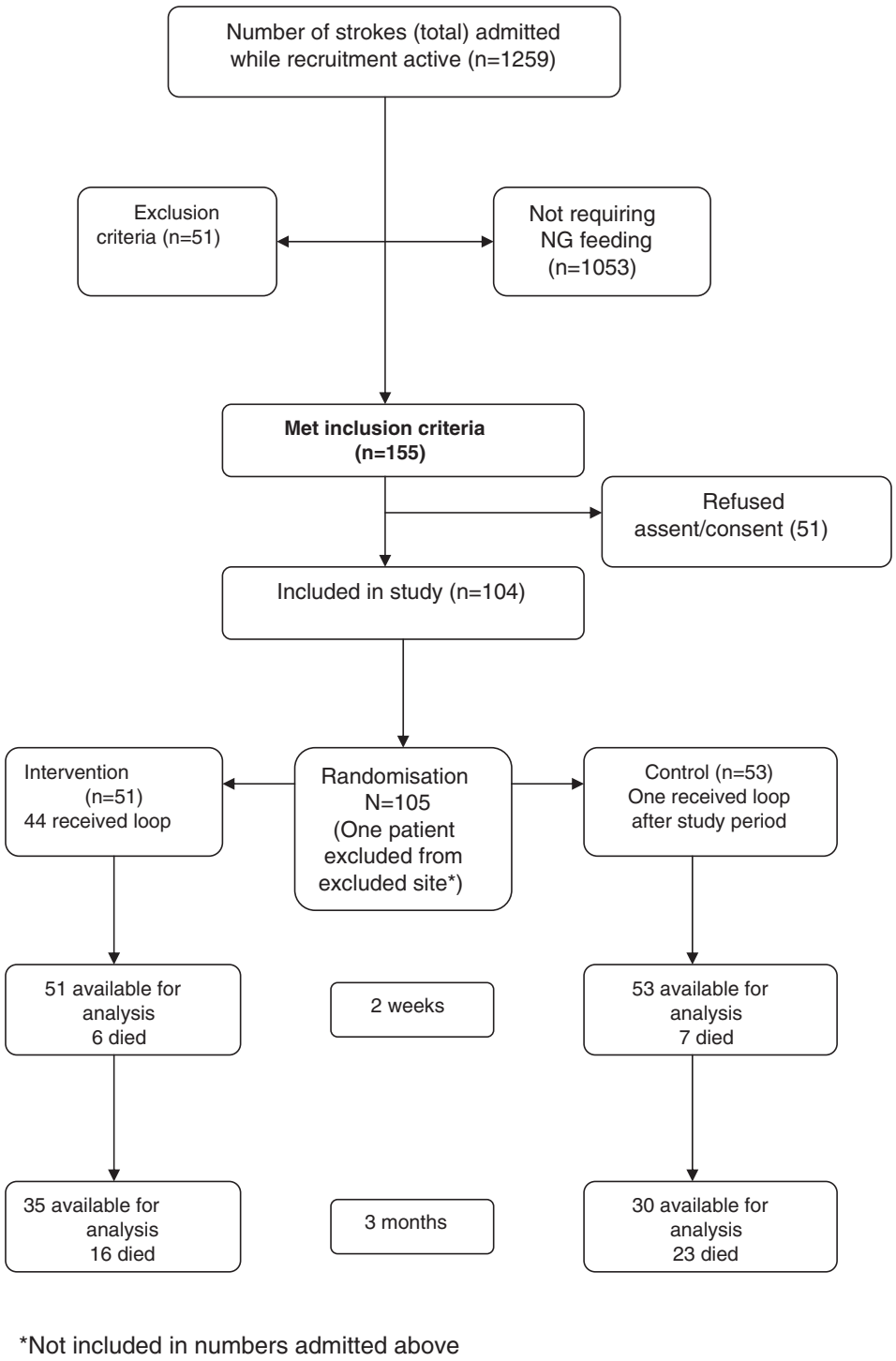


**Figure 1**. Participant flow.

groups ($n$ = 84: 48 participant responses and 36 proxy responses), although more control groups found the tube uncomfortable (41% vs 28%) and that the tube was more easily removed (27% vs 16%).

A key finding from the nurse focus groups was that they perceived the greatest patient distress associated with NGT feeding to be during the insertion or reinsertion of a NGT. This distress was perceived to be greatest in those patients lacking understanding of why the process was being done.

Mean costs were higher in the loop group (£426 vs £338 per patient over 2 weeks) in the base case model in which loops were priced at £76 each (Appendix 3 in supplementary data are available in *Age and Ageing* online). An incremental cost of £5.20 was estimated for each extra percent of prescribed feed delivered.

Table 1. Baseline characteristics

| Characteristic | Loop ($n$ = 51) | Control ($n$ = 53) |
|---|---|---|
| Nottingham | 50 | 49 |
| Yeovil | 1 | 4 |
| Sex | | |
| Male | 20 | 23 |
| Female | 31 | 30 |
| Mean age (SD) | 79 (10) | 81 (10) |
| Previous stroke or TIA | 17 (33%) | 15 (28%) |
| History of dementia | 6 (12%) | 18 (34%) |
| Median pre-admission Barthel Index (IQR) | 19 (14–20) | 18 (13–20) |
| Care home resident | 6 (12%) | 6 (11%) |
| Mean serum albumin, g/dL (SD) | 33.2 (5.8) | 35.6 (5.7) |
| Weight (kg) (SD) | 68.5 (16.3) | 72.4 (22.6) |
| Stroke subtype | | |
| TACS | 37 (73%) | 35 (66%) |
| PACS | 12 (24%) | 14 (26%) |
| LACS | 2 (4%) | 1 (2%) |
| POCS | 0 | 3 (6%) |
| Median NIHSS (IQR) | 18 (14–23) | 19 (16–23) |
| Median GCS (IQR) | 13 (10–14) | 13 (10–14) |
| Current LRTI | 14 (27%) | 23 (43%) |
| Stroke onset to decision to NG feed (days) median (IQR) | 3 (2–5) | 3 (2–5) |
| Stroke onset to randomisation (days) median (IQR) | 4 (3–6) | 4 (3–6) |

IQR, interquartile range; SD, standard deviation; TACS, total anterior circulation stroke; PACS, partial anterior circulation stroke; LACS, lacunar stroke; POCS, posterior circulation stroke; GCS, Glasgow Coma Score; LRTI, lower respiratory tract infection.

## Discussion

Looped NGT feeding was more effective than conventional NGT feeding at providing feed and fluids in the short term to acute stroke patients with dysphagia. Fewer NGTs were required. There was more minor nasal trauma in the group using the loop, and more electrolyte disturbances were recorded in the conventional group. No difference in tolerability between the forms of NGT fixation as detected by questionnaires was noted. Nurses perceived NGT insertion to be the most distressing aspect of NGT feeding for patients, especially in those with poor comprehension. The costs of using the nasal loop were greater than the costs of conventional means of securing the tube (by £88).

Despite the random allocation of participants to treatment options, there were some potentially important baseline differences between the groups. However, adjustment for these factors showed that these were unlikely to have affected this result. Although this study was multicentred, most of the participants were recruited from one site. This limits the generalisability of our findings.

The primary outcome was not recorded blind to allocation, but attempts were made to ensure that this was recorded in a closely monitored and standardised manner to reduce the likelihood of bias.

Evaluation of tolerability was difficult because of the high prevalence of communication problems. Although the views expressed in the nurse focus groups might reflect nurses' distress as opposed to the participants' distress, it seems reasonable to assume that reducing the number of NGT insertions is a humane and clinically important thing to do. Given that 85% of participants did not have capacity to give consent to the study, it is likely that a high proportion of people with stroke who are fed by NGT may not understand why the procedure is being done, which makes the reduction in the need for NGT reinsertion achieved using the loop of particular clinical value.

Our limited cost model only included the costs associated with short-term feeding. It did not consider the impact upon longer-term feeding costs outside the study duration of 2 weeks or other elements of stroke care such as therapy interventions or medication delivery. It did not appear to affect the rate or timing of PEG insertion as others have suggested [25, 26], although our trial was not designed to examine these outcomes.

The use of a nasal loop to secure NGTs led to an increase from 57% to 75% of the proportion of prescribed NG feed and fluids given over 2 weeks, and this equated to about 5.5 L of additional feed and fluids over this period. The costs to achieve improved nutrition and hydration with reduced distress from repeated NGT insertions (£88/patient) are fairly trivial compared with the overall costs of stroke [27, 28].

A more difficult question is whether the delivery of the extra feed in this trial was itself worthwhile. The FOOD trials [11] of 859 patients suggested that early feeding (by NGT, compared with parenteral fluids alone) reduced deaths but increased the number of dependent survivors. Whether improved nutritional delivery reduces mortality and improves quality of life, except in those already malnourished, is uncertain. This trial was not designed to address that question; approximately 4,000 recruits would

Table 2. Outcomes

| Outcome | Loop ($n$ = 51) | Control ($n$ = 53) | Group comparison |
|---|---|---|---|
| Primary outcomes | | | |
| Proportion of feed and fluids delivered, mean (95% CI) | 0.75 (0.67–0.83) | 0.57 (0.49–0.65) | Mean difference (95% CI): 0.17% (0.05–0.28) $t$-test, $P$ = 0.002 |
| Secondary outcomes at 2 weeks | | | |
| Total volume (mL) delivered by NGT, mean (95% CI) | 16,994 (14,323–19,665) | 11,367 (8,935–13,799) | Mean difference (95% CI): 5,627 (1,976–9,278) $t$-test $P$ = 0.002 |
| No NGT feed or fluids ($n$) | 3 (6%) | 4 (8%) | OR 0.76 (0.16–3.6) chi-square $P$ = 0.43 |
| Median (IQR) NGTs | 1 (1–3) | 4 (2–6) | Mann–Whitney $P$ < 0.0001 |
| Median (IQR) CXRs to check NGT position | 0(0–1) | 1(0–2) | Mann–Whitney $P$ = 0.01 |
| Mean (SD) weight change (kg) | −3.3 (4.8) ($n$ = 44) | −2.9 (8.4) ($n$ = 29) | Mean difference (95% CI): −0.06 (−3.2–3.0) $P$ = 0.8 |
| Adverse events | | | |
| Nasal trauma | 19 (37%) | 8 (15%) | RR 2.47 (1.3–2.7) |
| Nose bleed | 11 | 3 | |
| Pressure areas | 5 | 5 | |
| Nasal discharge | 3 | 0 | |
| Diarrhoea | 2 (4%) | 4 (8%) | RR 0.52 (0.99–6.48) |
| Vomiting | 8 (16%) | 4 (8%) | RR 2.08 (0.67–6.48) |
| Chest infection | 20 (38%) | 23 (43%) | RR 0.90 (0.57–1.3) |
| Gastrointestinal bleeding | 6 (12%) | 4 (8%) | RR 1.56 (0.47–5.2) |
| Electrolyte abnormalities | 16 (31%) | 31 (58%) | RR 0.54 (0.34–0.85) |
| Refeeding syndrome | 2 (4%) | 5 (9%) | RR 0.94 (0.85–1.04) |
| Tolerability | | | |
| Tolerability: understood need for NGT | 22/43 (51%) | 21/41 (51%) | OR 1.0 (0.42–2.35) |
| Tolerability: found insertion of NGT distressing | 19/43 (44%) | 16/41 (39%) | OR 1.24 (0.52–2.95) |
| Tolerability: experienced day-to-day discomfort | 12/43 (28%) | 17/41 (41%) | OR 0.68 (0.27–1.70) |
| Tolerability: NGT was too easily removed | 7/43 (16%) | 11/41 (27%) | OR 0.56 (0.24–1.36) |
| Tolerability: glad to have been NG fed | 21/42 (50%) | 22/39 (56%) | OR 0.77 (0.32–1.85) |
| Secondary at 3 months | | | |
| Dead (%) | 16 (31%) | 23 (43%) | $P$ = 0.2 |
| Barthel Index, median (IQR) | 4 (0–10) | 4 (0–8.5) | $P$ = 0.6 |
| Dead or Barthel<12 (%) | 41 (80%) | 47 (89%) | $P$ = 0.7 |
| Mean length of stay, days (SD) | 64 (38) | 57 (42.5) | $P$ = 0.4 |
| PEG inserted (%) | 13 (25%) | 9 (17%) | $P$ = 0.2 |
| Care home (%) | 24 (47%) | 18 (34%) | $P$ = 0.4 |

OR, odds ratio; RR, risk ratio; SD, standard deviation; IQR, interquartile range.

have been required to show a change of 5% in mortality and 720 to show a difference of 9% in death or disability with 90% power. However, once a clinician, after due consultation, has decided that tube feeding is indicated, it makes sense to deliver this as effectively as possible.

Patients with stroke and severe dysphagia are frequently restless, and perhaps, for this reason, even the use of a nasal loop was not successful in every case (7/104 (7%) received no NG feeding), because an NGT either was impossible to site or did not remain in place long enough to deliver meaningful nutrition. The only other intervention proposed to increase feed delivery is restraint using mittens, which are both ethically questionable and unevaluated.

Long-term outcome in this patient group was poor. In this study, 88/104 (84%) were either dead or severely disabled at 3 months. This emphasises the need not only to reduce the number of people with severe stroke but to optimise the quality of life for survivors, including minimising any distress related to feeding. Clinicians, and the patients and families they counsel, may find the observations in this study of such poor prognosis helpful in discussion to establish whether NGT feeding is to be chosen or declined after a major stroke. The trial recruited the majority of those who were fed with a nasogastric tube after acute stroke, and the findings are likely to be applicable to other non-selective stroke units.

This study provides the evidence base for the UK Royal College of Physician's guidelines [29] for stroke which advocate the use of the nasal loop.

## Key points

- Looped nasogastric tube feeding improves nutritional delivery after stroke in patients with dysphagia.
- Looped nasogastric tube feeding reduces the need for repeated reinsertion of nasogastric tubes.
- Patients with stroke requiring nasogastric tube feeding have a poor prognosis.

## Conflicts of interest

None declared. The funders and the manufacturers of the nasal loop (bridle) had no part in the conduct and analysis of the research.

## Supplementary data

Supplementary data mentioned in the text is available to subscribers in *Age and Ageing* online.

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