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Citation: Sutcliffe, Lou, Flynn, Darren and Price, Christopher I. (2020) Percutaneous Endoscopic Gastrostomy and Mortality After Stroke in England From 2007 to 2018. *Stroke*, 51 (12). pp. 3658-3663. ISSN 0039-2499

Published by: Lippincott Williams & Wilkins

URL: <https://doi.org/10.1161/STROKEAHA.120.030502>
<<https://doi.org/10.1161/STROKEAHA.120.030502>>

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**Percutaneous endoscopic gastrostomy and mortality post-stroke in England
from 2007 to 2018: a retrospective cohort study**

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Cover Title: Post-stroke PEG in England from 2007 to 2018

Tables: 1

Figures: 2

Keywords: stroke; mortality; dysphagia; enteral nutrition; health services research

Subject Terms: Cerebrovascular Disease/Stroke; Mortality/Survival; Nursing

Word Count: 3791

ABSTRACT

Background and Purpose: Swallowing difficulties are common post-stroke.

National clinical guidelines recommend feeding by percutaneous endoscopic gastrostomy (PEG) when oral nutrition cannot be maintained although survival benefit might be short-term. It is unknown whether a decade of general care improvements have impacted upon PEG provision and outcomes. This retrospective cohort study examined PEG placement and mortality post-stroke in England.

Methods: National Health Service Hospital Episode Statistics and Office for National Statistics mortality data between April 2007 and March 2018 were linked to identify all admissions in England with stroke-related ICD10 codes (I61, I63 and I64) +/- PEG insertion and deaths at 3, 6 and 12 months. Linear and logistic regression examined trends over time and mortality.

Results: 923,236 stroke patients underwent 17,532 PEG procedures (mean rate 1.9%), with an average reduction of -27 procedures/year (95%CI -56 to 1.4; $p=0.06$) despite an average increase of 1804 stroke admissions/year. Mortality decreased amongst cases without a PEG procedure: -190 deaths/year (95%CI -276 to -104; $p<0.001$) at 3 months, -167 deaths/year (95%CI -235 to -98; $p<0.001$) at 6 months and -103 deaths/year (95%CI -157 to -50; $p<0.01$) at 12 months; and also reduced following PEG insertion: -28 deaths/year (95%CI -35 to -20; $p<0.001$) at 3 months, -33 deaths/year (95%CI -46 to -20; $p<0.01$) at 6 months and -30 deaths/year (95%CI -48 to -13; $p<0.01$) at 12 months. With all years combined, PEG insertion was weakly associated with reduced mortality at 3 months (OR 0.94; 95%CI 0.90 to 0.97), but significantly higher mortality at 6 months (OR 1.69; 95%CI 1.64 to 1.75) and 12 months (OR 2.14; 95%CI 2.08 to 2.20).

Conclusion: PEG procedures and subsequent deaths have decreased in the context of general mortality reductions following hospitalisation for stroke, but survival at 6 and 12 months remains significantly worse for patients with PEG placement.

Non-standard Abbreviations and Acronyms

PEG Percutaneous Endoscopic Gastrostomy

INTRODUCTION

Dysphagia affects approximately half of all acute stroke admissions and is associated with a poorer outcome [1,2]. Both UK and US clinical guidelines recommend that feeding by percutaneous endoscopic gastrostomy (PEG) should be considered if oral nutrition cannot be maintained by 3 to 4 weeks [3,4]. Although trial evidence has shown that PEG feeding is associated with fewer feeding failures and pressure sores, there is no statistically significant change in dependency or long-term mortality [5].

Stroke mortality rates have fallen significantly in the past decade [2,6], reflecting improved delivery of evidence-based care which includes pro-active identification and treatment of dysphagia [2,3,7]. It is feasible that more patients are surviving the acute phase of stroke with long-term swallowing difficulties, thereby increasing the demand for non-oral feeding. As no new trial evidence has been reported since 2006 [1,4,5], it is also unknown whether overall improvements in prognosis following stroke have led to a better outlook for patients following PEG insertion.

In this context, we performed a retrospective analysis of routinely collected healthcare data across English stroke services to examine:

1. population level trends over time in PEG procedures after stroke
2. key demographic associations with PEG insertion
3. mortality after PEG insertion.

METHODS

Finished stroke admission episodes in England (International Classification of Diseases (ICD) 10 codes: I61 (haemorrhagic), I63 (ischaemic) and I64 (cause not specified)) with and without subsequent PEG insertion (Office of Population Censuses and Surveys v4 code: G445) were identified from National Health Service Hospital Episode Statistics for financial years between April 2007 and March 2018 [8]. Demographic data items were limited to gender (female/male), age (<60 years; 60-79 years; 80+ years) and ethnicity. Cases were linked to Office for National Statistics mortality records at 3, 6 and 12 months after admission [9]. All data reported were re-used with permission from the national healthcare data controller NHS Digital. Ethical review was not required due to regulator permitted use of population level routine data sources lacking personal identifying or sensitive information. Under conditions imposed by NHS Digital, it is not permitted for the authors to share data with other researchers and enquiries should be made through <https://digital.nhs.uk/services/data-access-request-service-dars>.

Linear regression was used to describe time trends in PEG procedures and mortality. Cases with missing demographic data were still included in the analysis. Logistic regression calculated odds ratios (OR) to examine associations between demographic characteristics (age, gender, ethnicity and ICD10 code) and PEG insertion. A standard alpha of 0.05 was chosen to indicate statistical significance. Regression models were evaluated using standard approaches and assumptions for linear regression (multicollinearity, normality of residuals, homoscedasticity, Durbin-Watson value) and logistic regression (linearity of logit, multicollinearity, independence of residuals). Analysis was conducted using SPSS Version 24.

RESULTS

Over eleven years, there were 923,838 stroke admissions in England with a mean increase of 1804 admissions per year (95% CI: 1257 to 2129, $p < 0.0001$). Stroke aetiology was coded as ischaemic (I63), haemorrhagic (I61) and unspecified (I64) for 669,088 (72.4%), 133,405 (14.4%) and 121,345 (13.1%) of cases respectively. The majority of patients were aged over 60 years (< 60 years: 136,721 (14.8%); 60-79 years: 393,125 (42.6%); 80+ years: 391,612 (42.4%); age missing 2380 (0.3%)) and Caucasian (774,992 (83.9%); non-Caucasian 63,505 (6.9%); ethnicity missing 85,431 (9.2%)). Gender distribution was equal (female 465,462 (50.4%); male 458,315 (49.6%); gender missing 61 (0.1%)). Due to insufficient identification information it was not possible to confirm whether a PEG procedure had been performed for 602 admissions, which were subsequently excluded from further analysis. Yearly counts that did ($n=17,532$) and did not ($n=905,704$) undergo PEG insertion and corresponding mortality rates are shown in Table 1 and Figure 1.

PEG procedures

Over 11 years there were 17,532 PEG procedures recorded, a mean of 1594 (SD 147) annually and an overall rate of 1.9%. The procedure rate fell from 2.3% in 2007/08 to 1.4% in 2017/18, although it is possible that this final year was affected by a lag in service activity reporting. An average absolute reduction of -27 procedures/year (95%CI -56 to 1.4; $p=0.06$) was observed despite annual increases in stroke admission volume. If PEG rates had remained static from 2007/08 (i.e. 2.3%) then an average of 42 additional procedures/year would have been expected.

Characteristics associated with PEG procedures

Annual admission numbers in key demographic subgroups are shown in Supplemental Tables I and II according to PEG insertion status. Logistic regression analysis showed that relative to age <60 years, PEG insertion had a positive association with patient age 60-79 years (OR 1.97; 95%CI 1.86 to 2.09) and 80+ years (OR 2.73; 95%CI 2.58 to 2.90). There was also a positive association with female relative to male gender (OR 1.10; 95%CI 1.08 to 1.14), whereas PEG insertion was less likely for patients of Caucasian ethnicity (OR 0.88; 95%CI 0.83 to 0.93) and for haemorrhagic compared to ischaemic stroke (OR 0.94; 95%CI 0.90 to 0.98).

Mortality

Table 1 and Figure 2 show that mortality consistently decreased at all time points after stroke irrespective of PEG status. Amongst patients without a PEG procedure there were statistically significant reductions of -190 deaths/year (95%CI -276 to -104; $p < 0.001$; R squared 0.62) at 3 months, -167 deaths/year (95%CI -235 to -98; $p < 0.001$; R squared 0.69) at 6 months and -103 deaths/year (95%CI -157 to -50; $p < 0.01$; R squared 0.73) at 12 months. These reductions equated to mean annual decreases in the death rate at 3, 6 and 12 months of -1.7% (190/17,777), -0.8% (167/20,982) and -0.4% (103/24,889).

For patients with PEG placement, mortality fell by -28 deaths/year (95%CI -35 to -20; $p < 0.001$; R squared 0.57) at 3 months, -33 deaths/year (95%CI -46 to -20; $p < 0.01$; R squared 0.53) at 6 months and -30 deaths/year (95%CI -48 to -13; $p < 0.01$; R squared 0.46) at 12 months. These reductions equated to mean annual decreases in

the death rate at 3, 6 and 12 months of -9.4% (28/299), -5.7% (33/584) and -3.9% (30/766).

When all years were included, PEG insertion was weakly associated with a mortality reduction at 3 months (OR 0.94; 95%CI 0.90 to 0.97), but with significantly higher mortality at 6 months (OR 1.69; 95%CI 1.64 to 1.75) and 12 months (OR 2.14; 95%CI 2.08 to 2.20).

DISCUSSION

Between 2007 and 2018 there was a small but steady decline in PEG procedures across English stroke services in the context of significant post-stroke mortality reductions. The positive impact of general improvements in stroke care on patient outcomes during this period has already been documented [6,10], but a reduction in PEG insertions has not previously been reported. Explanations could include avoidance of severe neurological impairment for selected patients due to increasing use of emergency reperfusion therapies, greater availability of speech therapists and trained nursing staff to support modified oral feeding approaches amongst dysphagic patients who might have previously remained nil by mouth [11, 12], longer periods of nasogastric tube use before permanent enteral feeding is considered and / or a shift towards more in-depth discussion with dysphagic patients and families regarding the balance between a reduced risk of aspiration from non-oral feeding versus the poorer quality of life reported by some individuals reliant upon PEG nutrition. The growth in stroke admissions observed during the 11 year interval might also reflect a trend towards increased recognition and hospitalisation of milder stroke patients who were less likely to require non-oral feeding. However, this is unlikely to be the only

explanation because PEG procedures continued to decline even though the largest increase in admissions occurred during the first 6 years.

There are limited international data available for comparison of PEG use post-stroke. An evaluation of United States healthcare data between 2001 to 2011 revealed an average PEG rate of 3.6% amongst 967,119 patients within 30 days of ischaemic stroke [12]. Although higher than the English average rate of 1.9%, half of the US study pre-dated publication of key evidence informing clinical guidelines [5]. Data were not presented regarding US longitudinal trends for PEG insertion, but 53.5% took place within 7 days of admission without significant variation in this proportion over 10 years, suggesting a more pro-active approach than is proposed by current national guidelines. A similar procedure rate of 3.05% was reported amongst 3,504 Australian stroke admissions during an examination of PEG outcomes between January 2005 and December 2013 [13]. However, this cohort represented only two metropolitan hospitals, and no information was presented describing local criteria for PEG insertion. The lower rate observed in England may reflect international differences in clinical guidelines and audit processes to promote compliance, variations in cultural views about quality of life and the availability of carers with skills for supporting non-PEG feeding amongst dysphagic patients. Adherence to clinical guidelines and understanding variations between settings would be facilitated by agreement of an internationally standardised post-stroke nutrition dataset which links demographic and clinical information (e.g. stroke type and severity) with oral (e.g. normal / modified diet) and non-oral (e.g. nasogastric / PEG tube) feeding decisions.

Consistent with previous reports, we found that PEG insertion was commoner amongst older patients [1,5,12,13,14] and females [12,13]. Increasing age is linked to greater stroke severity but also reflects accumulation of non-stroke co-morbidities that increase the background risk of aspiration (e.g. Parkinsonism) and/or reduce adherence to a modified oral feeding regimen (e.g. cognitive impairment) [13,14]. The weaker positive association with female gender may reflect a previously reported observation that mean age is higher than men at the time of a first stroke [15], and consequently women may have a greater frequency of pre-existing swallowing difficulties due to the effect of aging and/or age-related comorbidities. Ethnic variations in stroke aetiology and subtype have already been recognised which might change the frequency of severe dysphagia and requirement for non-oral feeding [16], thereby providing a possible explanation for the positive association found with non-Caucasian race. However, it is less clear why haemorrhagic stroke is associated with fewer PEG procedures than ischaemic stroke when these vascular aetiologies can produce similar impairments. It may reflect a different early prognosis amongst individuals with haemorrhage or associated clinical characteristics that might influence the decision to initiate long term non-oral feeding, such as cognitive impairment due to amyloid angiopathy. Further research is required to understand these demographic and clinical associations, employing comprehensive data capture processes.

Improvements in survival following PEG placement are likely to reflect the same trend observed across the general stroke population due to measures such as better provision of secondary prevention, but another explanation could be a growing tendency to preferentially select dysphagic patients with a more promising outlook.

Descriptive US data over a decade shows a minor trend towards younger stroke patients being favoured for PEG placement with a mean (SD) age of 76.3 (11.7) years in 2001 falling to 74.1 (13.3) years in 2011, but there was a parallel increase in comorbidities in this group from a mean (SD) Charlson Comorbidity Index of 1.36 (1.36) to 2.05 (1.92) [12]. In our UK cohort, the proportion of patients aged 80+ years with a PEG fell from 54.3% to 45.7% between 2007 and 2018 in the context of a smaller reduction from 43.7% to 40.8% amongst admissions without a PEG (Supplemental Table I and II), but no additional clinical data were available. Understanding the underlying mechanisms for better survival post-PEG would require a mixed methods approach with relevant clinical data collection and qualitative examination of practitioner and public preferences over a range of non-oral feeding scenarios.

The overall pattern observed for short, medium and long-term survival following PEG placement was similar to findings from the 'Feed Or Ordinary Diet' (FOOD) trial [17]. Published in 2005, this influential trial showed no initial difference in mortality when 321 dysphagic patients were randomised to PEG or nasogastric tube, but by 6 months the PEG group had experienced 49% (79/162) mortality and a statistically significant increased risk of death or poor outcome. Similarly, in a retrospective community cohort study, 54% of 174 US stroke patients died within 6 months of PEG tube placement [18]. Our cohort has shown that this mortality trend continues at 12 months. The high rate of poor outcomes for stroke patients following PEG placement is likely to reflect an ongoing risk of aspiration and the general health of patients with persistent dysphagia, who remain susceptible to other complications associated with severe stroke such as pulmonary embolism. Australian stroke patients surviving

beyond 6 months with a PEG in situ were more likely to be younger, have better overall health (lower American Society of Anesthesia score) and have a higher serum albumin level pre-insertion [13]. It was an unexpected finding in our cohort that PEG placement was weakly associated with a survival advantage at 3 months after stroke, but it is important to recognise that this group comprised dysphagic survivors from the acute phase who were subsequently judged to have a prognosis justifying initiation of permanent non-oral feeding, whereas patients that died within the first few weeks of admission are unlikely to have undergone PEG placement. In addition, dysphagic patients surviving beyond the initial acute period who were judged unsuitable for PEG placement because of severe impairments and co-morbidities would have had a high short-term mortality from their poor health status combined with ongoing risks of aspiration and poor nutritional intake. This apparent positive association between PEG placement and initial survival after stroke has not been reported previously and might have been detected because of the large size of the national dataset. It is important that clinicians continue to carefully consider the prognosis for individual patients when recommending non-oral feeding and remain cautious about prognosis beyond the first few months during discussions with patients and families.

The data reported here were obtained from national sources containing only anonymised cases and limited demographic information, and it was not possible to link individuals to other clinical information sources describing stroke characteristics, comorbidities and cause of death, or identify recurrent stroke admissions. However, as these are state-funded mandatory healthcare and mortality datasets which receive information regarding every admission and death across England, they

provide the most complete information available at a national level during an extended time period. It was impossible to determine the timing of PEG placement and how many patients later regained swallowing function. It is likely that patients only underwent a PEG procedure on one occasion, but any subsequent re-admission with a further stroke would have counted as a minor contribution towards the 'no PEG' group because information governance regulations prevented the authors from identifying and excluding them.

CONCLUSION

Over 11 years PEG insertion rates in English stroke services have fallen, whilst survival has improved for all admissions. This is likely to reflect improvements in many aspects of stroke care. However it is important to recognise that a large proportion of patients undergoing PEG placement still die within 6 and 12 months of admission, and a decision to offer permanent non-oral feeding requires careful consideration in partnership with patients and carers to agree that the resulting quality of life is acceptable.

Acknowledgments

We are grateful to Dominic Rowney (Principal Information Analyst, NHS North of England Commissioning Support Unit) for his valuable advice on healthcare data management.

Sources of Funding

No external funding

Disclosures

None.

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Tables

Table 1. Stroke admissions and mortality according to PEG status.

Year (April - March)	Total stroke admissions	Without PEG procedure				With PEG procedure			
		Number of cases (% total)	Mortality (% cases)			Number of cases (% total)	Mortality (% cases)		
			3 month	6 month	12 month		3 month	6 month	12 month
2007/08	71566	69909 (97.7)	19357 (27.7)	22285 (31.9)	25654 (36.7)	1657 (2.3)	461 (27.8)	720 (43.5)	908 (54.8)
2008/09	73924	72342 (97.9)	18675 (25.8)	21671 (29.9)	25148 (34.8)	1582 (2.1)	385 (24.3)	653 (41.3)	847 (53.5)
2009/10	78353	76708 (97.9)	18158 (23.7)	21304 (27.8)	25009 (32.6)	1645 (2.1)	397 (24.1)	673 (40.9)	787 (47.8)
2010/11	82863	81194 (97.9)	18055 (22.2)	21258 (26.2)	25044 (30.8)	1669 (2.0)	399 (23.9)	662 (39.7)	803 (48.1)
2011/12	85772	84133 (98.1)	17461 (20.8)	20758 (24.7)	24911 (29.6)	1639 (1.9)	362 (22.1)	621 (37.9)	799 (48.8)
2012/13	87593	85861 (98.0)	17843 (20.8)	21265 (24.8)	25360 (29.5)	1732 (1.9)	380 (21.9)	654 (37.7)	841 (48.6)
2013/14	86837	85006 (97.9)	16956 (19.9)	20254 (23.8)	24383 (28.7)	1831 (2.1)	338 (18.5)	664 (36.3)	905 (49.4)
2014/15	87444	85853 (98.2)	17207 (20.0)	20594 (23.9)	24754 (28.8)	1591 (1.8)	301 (18.9)	560 (35.2)	780 (49.0)
2015/16	89118	87654 (98.4)	17385 (19.8)	20612 (23.5)	24735 (28.2)	1464 (1.6)	222 (15.2)	465 (31.8)	641 (43.8)
2016/17	89389	87919 (98.4)	17151 (19.5)	20374 (23.2)	24526 (27.9)	1470 (1.6)	196 (13.3)	408 (27.8)	607 (41.3)
2017/18	90377	89125 (98.6)	17300 (19.4)	20432 (22.9)	24261 (27.2)	1252 (1.4)	153 (12.2)	346 (27.6)	513 (40.9)
Overall	923236	905704 (98.1)	195548 (21.6)	230807 (25.5)	273785 (30.2)	17532 (1.9)	3594 (20.5)	6426 (36.7)	8431 (48.1)

Figure Legends

Figure 1: Yearly mortality rates at each time point after stroke according to PEG status.

Figure 2. Mortality without (A) and with (B) a PEG procedure for all stroke admissions from April 2007 to March 2018.

