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Outcomes following feeding gastrostomy (FG) insertion in patients with learning disability: a retrospective cohort study using the health improvement network (THIN) database

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ABSTRACT

Objectives To measure the rates of lower respiratory tract infection (LRTI) and mortality following feeding gastrostomy (FG) placement in patients with learning disability (LD). Following this to compare these rates between those having LRTI prior to FG placement and those with no recent LRTI.

Design Retrospective cohort study.

Setting and participants The study population included patients with LD undergoing FG placement in the 'The Health Improvement Network' database. Patients with LRTI in the year prior (LYP) to their FG placement were compared with patients without a history of LRTI in the year prior (non-LYP) to FG placement. FG placement and LD were identified using Read codes previously developed by an expert panel.

Main outcome measures Incidence rate ratio (IRR) of developing LRTI and mortality following FG, comparing patients with LRTI in the year prior to FG placement to patients without a history of LRTI.

Results 214 patients with LD had a FG inserted including 743.4 person years follow-up. 53.7% were males and the median age was 27.6 (IQR 19.6 to 38.6) years. 27.1% were in the LYP patients. 18.7% had a LRTI in the year following FG, with an estimated incidence rate of 254 per 1000-person years. Over the study period the incidence rate of LRTI in LYP patients was 369 per 1000-person years, in non-LYP patients this was 91 per 1000-person years (adjusted IRR 4.21 (95% CI 2.68 to 6.63) p<0.001). 27.1% of patients died during study follow-up. Incidence rate of death was 80 and 45 per 1000-person year for LYP and non-LYP patients, respectively (adjusted IRR 1.80 (1.00 to 3.23) p=0.05).

Conclusion In LD patients, no clinically meaningful reduction in LRTI incidence was observed following FG placement. Mortality and LRTI were higher in patients with at least one LRTI in the year preceding FG placement, compared with those without a preceding LRTI.

Strengths and limitations of the study

- This study utilised The Health Improvement Network (THIN). THIN is a primary care database including 6% of the UK population, which is representative of national demographics, therefore providing a large cohort for analysis.
- Patients with learning disability were identified using Read codes developed by an expert panel for use in research, providing a robust mechanism to identify such patients.
- Feeding gastrostomy (FG) is incompletely coded in THIN, therefore new tube feed prescription is used as a surrogate of FG placement, however some cases will not be identified.
- Respiratory tract infection and death are largely accurately coded therefore the described rates of these outcomes are robust.

INTRODUCTION

Patients with learning disability (LD) are known to have high incidence of aspiration on video fluoroscopy.[1] For this reason the National Patient Safety Agency review in 2004 considered swallowing difficulties to be a key cause for concern in this group.[2] Aspiration is associated with recurrent episodes of pneumonia, often including hospitalisation. This contributes to the high incidence of chronic lung disease[3] and disproportionately high mortality from respiratory conditions in this patient cohort.[4] Patients with LD may undergo feeding gastrostomy (FG) insertion in an effort to reduce aspiration, usually as part of a multifactorial indication including the need for nutritional support.

Patients who receive nutrition through a FG are still at risk of aspiration. A Japanese study looking at elderly patients demonstrated that in those with prior aspiration pneumonia mortality following FG insertion was high and the the most common cause of mortality was pneumonia.[5] FG placement also

did not improve quality of life in a longitudinal study of 40 patients with LD.[6]

There is no current evidence describing the outcomes from FG insertion in patients with LD with respect to respiratory tract infections. Patients with LD are often excluded from clinical studies, despite the recognition that this group has greater healthcare needs, and poorer engagement with healthcare services. For this reason they have been described as a 'Cinderella population'.[7]

Admission to hospital for patients with LD is often challenging for both the patients and staff. Best interest decisions and delegated consent for FG placement are often required. Often the procedure is traumatic for the patient and carers. It is therefore important to ensure that FG placement is in the LD patient's best interests. Equally important is that the information given to family members and carers, who participate in the decision-making process, is evidence based.

The aim of this study was to examine the impact of FG placement on the risk of respiratory tract infections and mortality within the LD cohort using The Health Improvement Network (THIN) primary care database.

METHODS

The present study is a retrospective, population-based cohort study of all patients with LD, whom underwent FG placement. Patients were segregated by those with coded lower respiratory tract infection (LRTI) including specific aspiration pneumonia codes within 1 year prior (LYP) to FG placement and those without (non-LYP). LYP patients were considered to be those at high risk for aspiration.

Data source

THIN represents a group of general practices (primary care) covering 6% of the UK population, which is representative of the UK population structure.[8] Individual practices were eligible for inclusion in the study from the later of the following two dates to ensure that the practice was making full use of the electronic medical record (EMR): 1 year after the date their EMR was installed; and after the practice's acceptable mortality recording date. To ensure there was sufficient time to record baseline comorbidities data, individual patients were eligible for inclusion from the date their practice became eligible for inclusion in the study or 1 year after registration with their practice if this date was later. Available information includes demographical, procedural and mortality data. Diagnosis and clinical presentations are recorded in the Read code hierarchical coding system.[9]

THIN data access was provided by IQVIA to the University of Birmingham under the NHS South-East multicentre research ethics committee approval in 2003, prior to independent scientific review. This study was granted study specific approval (SRC18THIN008) from the IMS Health Scientific review committee.

Study population

Patients with LD were identified by Read codes developed by NHS Digital for a previous study (online supplementary data 1). A panel of four experts reviewed each potential Read code. A code was included If there was agreement by three or more experts.[10]

FG placement was identified by one of two methods; Read code for FG placement, or first prescription of non-oral, enteric, tube feed from the British National Formulary. Although these may also be used with a nasogastric tube, it is highly unlikely that this would be performed outside of a hospital setting.

Patients aged 16 to 46 with an LD code from any time point and incident FG placement between May 1995 and May 2017 were included.

Co-variates and outcome measures

Further variables sought included age, gender, smoking status, body mass index (BMI), Townsend deprivation index, epilepsy and Charlson comorbidity score.

Episodes of LRTI were identified by Read code following the FG placement. Mortality was also sought in the THIN database. The full list of Read codes for covariates can be found in online supplementary data 1.

Statistical analysis

Demographic characteristics were described for the LYP, non-LYP and total cohorts. Age is converted to quintiles because any relationship was considered unlikely to be linear. Baseline variables were compared between LYP and non-LYP cohorts.

The incidence rate (IR) of LRTI and mortality within 1 year of FG placement are reported for LYP and non-LYP cohorts. The rate of LRTI in the year prior to FG placement was also reported.

IRs were calculated for LRTI and mortality at any time point following FG placement, in the LYP and non-LYP cohorts. Incidence rate ratios (IRR) and 95% CIs are reported. Median time to event and IQR are reported for LRTI and mortality. Cumulative incidence charts were plotted for mortality and LRTI by LYP group and compared with competing risk regression to allow for competing risks and time to event data.

A multivariable Poisson regression model was constructed for factors associated with LRTI up to 1 year after FG placement. Covariates included age, gender, deprivation, Charlson score category (0 or 1+) epilepsy and LYP history.

All statistical analysis was undertaken in Stata V.15.[11] The threshold for statistical significance was set at $p<0.05$.

Patient and public involvement

Neither patients nor the public were involved in the development of the research question or design of the study. Patients or the public were not involved in the data collection or analysis stages of the paper. As the study utilises anonymised data, it is not possible to disseminate the study findings to the specific patients included. The study is published open access and therefore clinicians who look after patients relevant to this study will be able to view the findings to inform their practice.

Table 1 Patient demographics

		Non-LYP (n=156)	LYP* (n=58)	Total (n=214)	P value
Gender	Male	83 (53.2)	32 (55.2)	115 (53.7)	p= 0.8
	Female	73 (46.8)	26 (44.8)	99 (46.3)	
Median age in years (IQR)		27.0 (19.9-36.7)	30.8 (19.4-39.1)	27.6 (19.6-8.6)	p=0.6
Townsend	1	31 (19.9)	9 (15.5)	40 (18.7)	p=0.3
	2	30 (19.2)	16 (27.6)	46 (21.5)	
	3	38 (24.4)	14 (24.1)	52 (24.3)	
	4	21 (13.5)	12 (20.7)	33 (15.4)	
	5	25 (16.0)	4 (6.9)	29 (13.6)	
	Missing	11 (7.1)	3 (5.2)	14 (6.5)	
Epilepsy	Yes	103 (66.0)	46 (79.3)	149 (69.6)	p=0.06
	No	53 (34.0)	12 (20.7)	65 (30.4)	
Charlson comorbidity score	0	115 (73.7)	40 (69.0)	155 (72.4)	p=0.53
	1	27 (17.3)	12 (20.7)	39 (18.2)	
	2	5 (3.2)	4 (6.9)	9 (4.2)	
	3+	9 (5.8)	2 (3.5)	11 (5.1)	

Values are n(%) unless otherwise specified.
LYP, LRTI in the year prior to feeding gastrostomy placement.

RESULTS

Patient demographics

There were 38 521 patients with an LD code in THIN, of whom 214 patients met the inclusion criteria for FG placement between age 16 to 46. The median age of the total cohort was 27.6 (IQR 19.6 to 38.6) years and 53.7% were male. Charlson comorbidity scores were 0, 1, 2 and 3 or more in 155 (72.4%), 39 (18.2%), 9 (4.2%) and 11 (5.1%), respectively and 69.6% had a coded diagnosis of epilepsy. BMI was available in only 82 (38.3%) patients, median 20 kg/m^2 (IQR 16.5 to 24.2 kg/m^2).

There were 58 LYP patients, 55.2% of whom were male, median age 30.8 (IQR 19.4 to 39.1) years, and there were 97.6 person-years follow-up. One hundred and fifty-six non-LYP patients were included, 53.2% of whom were male, median age 27.0 (IQR 19.9 to 36.7) years. The non-LYP patients had 645.8 person-years follow-up. Full cohort demographics for the whole study population and split by exposure are shown in table 1.

Lower respiratory tract infection in the year after feeding gastrostomy placement

Forty patients developed LRTI within 1 year of FG placement, which was more common in the LYP patients compared with the non-LYP group; IR 606 per 1000-person years and 149 per 1000-person years, respectively. Unadjusted IRR 4.07 (95% CI 2.09 to 8.06), (p<0.001) and adjusted IRR 4.05 (2.08 to 7.87), (p<0.001).

Lower respiratory tract infections in the whole follow-up period

Over the study period IR for LRTI in the LYP group was 369 per 1000-person years. In the non-LYP group this was 91 per 1000-person years, unadjusted IRR 4.04 (95% CI 2.59 to 6.21, p<0.001). (table 2 and figure 1). The time from FG placement to LRTI in the whole study population was 1.33 (IQR 0.4 to 3.72) years. In LYP patients this was 0.64 (0.27 to 1.84) years and in the non-LYP patients 2.37 (0.71 to 4.90) years.

In a multivariable Poisson regression model male gender (IRR 2.10 (95% CI 1.03 to 4.29), p=0.042), age 33 to 40 years (3.36 (1.11 to 10.16), p=0.031), age >40 years (5.22 (1.73 to 15.75), p=0.003) and LYP (4.05 (2.09 to 7.87), p<0.001) were significantly associated with developing LRTI in the year following FG placement (table 3).

Lower respiratory tract infection before and after feeding gastrostomy

The proportion with LYP was 27.1% and 18.7% developed LRTI in the year following FG placement, although with less than 1 year of follow-up in some patients. The LRTI incidence ratio for the complete cohort in the year prior to FG placement was 317 per 1000-person years compared with 254 per 1000-person years in the year after FG placement.

Mortality

Over the study period 58 patients died and median age at death was 38.2 (27.8 to 42.0) years. The IR in LYP patients was 80 per 1000-person years and 45 per 1000 person years in the non-LYP patients (unadjusted IRR 1.76 (95% CI 1.00 to 3.11), p=0.047) (table 2 and figure 2).

In a multivariable Poisson regression model, age 33 to 40 years (2.59 (1.03 to 6.52), p=0.043) and age >40 years (2.62 (1.01 to 6.77), p=0.047) were significantly

Table 2 Incidence rate ratio of lower respiratory tract infections and mortality following FG placement

	LRTI within 1 year		LRTI at any time		Mortality at any time	
	LYP	Non-LYP	LYP	Non- LYP	LYP	Non- LYP
Events	22	18	36	59	20	38
Person years	36	121	98	645	251	842
Incidence rate (per 1000)	606	149	369	91	80	45
Incidence rate ratio	4.07 (2.09–8.06)		4.04 (2.59–6.21)		1.76 (1.00–3.11)	
P value	<0.001		P=0.001		P=0.047	
Incidence rate ratio (adjusted)	4.05 (2.08–7.87)		4.21 (2.68–6.63)		1.80 (1.00–3.23)	
P value (adjusted)	<0.001		<0.001		P=0.05	

FG, feeding gastrostomy; LRTI, lower respiratory tract infection; LYP, LRTI in the year prior to feeding gastrostomy placement.

associated with mortality during study follow-up following FG placement in comparison to age group <19 years. LYP (1.80 (1.00 to 3.23), p=0.05) was of borderline significance in this adjusted model (table 4).

DISCUSSION

This is the first study to assess the outcomes of FG insertion in a cohort of patients with LD. No reduction in LRTI following FG placement was observed. Furthermore, patients having one or more LRTIs prior to their FG (LYP) were more likely to have LRTIs after FG placement, both in the first year after their FG and in long-term follow-up. Patients with one or more LRTIs prior to FG placement also had increase in mortality over the study period. Male gender was associated with increased LRTI within 1 year. Increasing age was associated with both increased mortality and LRTI within 1 year of FG placement.

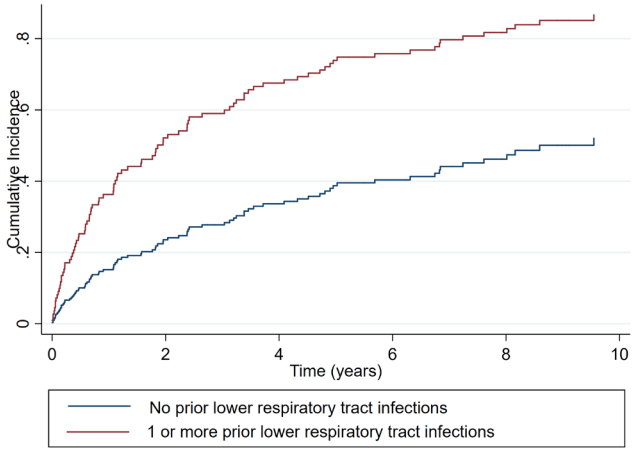

Figure 1 Cumulative incidence regression for lower respiratory tract infections following FG placement. FG, feeding gastrostomy.

There are no other studies looking at outcomes following FG placement specific to patients with LD. A prospective FG audit including 350 FG placements over 571 person years of data found a 1 year mortality of 35%, significantly higher than reported in the above study.[12] However, the median age was 62 years compared with 28 years in the present study and all indications were included. Thirty-one of 350 FG were placed in patients with LD in whom five (16.1%) died over median 20 months follow-up. In the present study 11 (5.1%) died within 12 months and over the study period 55 (25.7%) patients died, although with a median time to death of 3.5 years. Although the proportions observed are different, only small numbers of deaths are observed and therefore comparison may be misleading. There is also likely to be variation in practice between providers, with a national overview provided by the present study compared with a single provider in the study by Clarke, Pitts, Latchford & Lewis.[12]

Short-term mortality could not be addressed in this study as there were too few outcomes despite the sample size. There was also a wide variation in time to LRTI with large IQRs. Therefore, although there appears to be shorter time to LRTI following FG placement in patients in the LYP patient group compared with the non-LYP group, this result requires further evaluation before any implications for clinical practice can be considered.

LRTI are used as a surrogate of aspiration pneumonia in the present study. Although there are codes specifically for aspiration pneumonia, the study included all LRTI codes to provide good sensitivity. In patients who have a FG in situ or proceed to have a FG placed up to 1 year later, it was assumed that aspiration at least contributed to their LRTI.

A key strength of this analysis compared with others examining the impact of FG placement is the use of primary care data. The THIN database is an important tool to examine the LD population. The database is recognised to have a high accuracy and is therefore used

Table 3 Poisson regression model for lower respiratory tract infection within 1 year of FG placement

		Incidence rate ratio	95% CI	P value
Age quintile	<19	1	–	–
	19 to 24	1.38	0.43 to 4.43	0.586
	24 to 33	1.28	0.36 to 4.63	0.699
	33 to 40	3.36	1.11 to 10.16	0.031
	>40	5.22	1.72 to 15.75	0.003
Gender (male)		2.10	1.03 to 4.29	0.042
Epilepsy		1.73	0.78 to 3.81	0.177
Charlson score 1 or above		1.73	0.86 to 3.47	0.125
Townsend deprivation score *(5 is the most deprived)*	1	1	-	-
	2	0.68	0.25 to 1.83	0.441
	3	1.11	0.43 to 2.86	0.822
	4	0.67	0.21 to 2.19	0.513
	5	0.68	0.17 to 2.70	0.580
	Missing	0.54	0.10 to 2.80	0.462
LRTI in the year prior to PEG placement *(LYP)*		4.05	2.08 to 7.87	<0.001

FG, feeding gastrostomy; LRTI, lower respiratory tract infection; LYP, LRTI in the year prior to feeding gastrostomy placement; PEG, percutaneous endoscopic gastrostomy.

for analysis for a wide range of conditions and outcomes. Specific benefits of the present study include a relatively large number of patients with LD with robust diagnostic and demographical data. Respiratory infections in this cohort are often managed in primary care and as such, only a small minority of cases present to secondary care. Therefore, presentation to primary care is a more sensitive measure of such infections.

Patients with LD are often challenging to identify from medical records. The Read codes used in the current cohort were developed by an expert group, in which codes were only included in the final set if three out of four panel members agreed that the code was representing a group of patients with LD. This set of Read codes has been utilised a number of studies previously.[13] This provides reassurance that the cohort in the present study accurately represents patients with LD. Although over 200 were included, and most clinically significant associations are likely to have been identified, a larger cohort would have allowed detection of more subtle factors, including an accurate estimate of their effects.

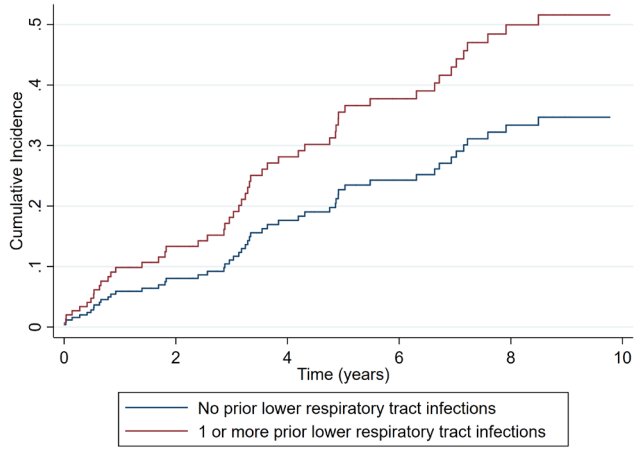

Figure 2 Cumulative incidence regression for mortality following FG placement. FG, feeding gastrostomy.

Identification of patients undergoing FG placement in the THIN database was also difficult. As a procedure performed in secondary care, the FG placement was not always coded in primary care data. Therefore, first feed prescription was used as a surrogate marker to identify when a FG had been placed. Despite these methods, it is likely that not all FG placements are captured within the data; however, we can be confident that those included represent a cohort of patients with LD undergoing FG placement. Unfortunately Read codes describing treatment decisions around FG placement also prevented identification of a cohort in whom FG placement was recommended but rejected. Therefore, comparison of a cohort with FG in situ to a control group without FG was not feasible.

The indication for FG placement, for example, dysphagia, recurrent aspiration or insufficient calorific intake, could not be identified in this study, which is a significant limitation. It is accepted that FG placement will be for inadequate oral nutrition which may have multifactorial causes. By seeking respiratory tract infections within 1 year prior to FG placement, patients in whom this is a component of the indication for FG placement are identified and compared with those with other indications.

Table 4 Poisson regression model for mortality following FG placement

		Incidence rate ratio	95% CI	P value
Age quintile	<19	1	–	–
	19 to 24	1.84	0.71 to 4.82	0.210
	24 to 33	1.65	0.62 to 4.39	0.315
	33 to 40	2.59	1.03 to 6.52	0.043
	>40	2.62	1.01 to 6.77	0.047
Gender (male)		0.93	0.54 to 1.61	0.792
Epilepsy		0.80	0.44 to 1.44	0.452
Charlson score 1 or above		1.21	0.68 to 2.18	0.508
Townsend deprivation score *(5 is the most deprived)*	1	1	–	–
	2	0.57	0.25 to 1.30	0.183
	3	0.63	0.29 to 1.38	0.250
	4	0.79	0.33 to 1.88	0.594
	5	0.42	0.15 to 1.17	0.098
	Missing	0.32	0.7 to 1.49	0.146
LRTI in the year prior to PEG placement *(LYP)*		1.80	1.00 to 3.23	0.050

FG, feeding gastrostomy; LRTI, lower respiratory tract infection; LYP, LRTI in the year prior to feeding gastrostomy placement; PEG, percutaneous endoscopic gastrostomy.

Unfortunately, data on BMI was missing in a very high proportion of patients. As such this could not be included in the analysis. It is hypothesised that patients requiring a FG are less mobile and therefore, in the absence of appropriate equipment, they do not routinely have their weight checked and recorded in primary care.

CONCLUSION

This novel population-based study demonstrates that FG placement does not appear to confer a reduction in LRTIs in the LD cohort. A small increase in mortality was also noted in patients with a recent history of respiratory tract infections prior to FG placement. Physicians making decisions regarding FG placement in patients with LD should incorporate this into their assessment of risk and benefit and ensure patients, carers and family members are aware of likely outcomes following FG placement. Further research is required in patients with LD to establish sub-groups that are most likely to benefit from FG placement.

Contributors PRH and NJT were responsible for the initial conception of the study. PRH, TT, JSC and KN then contributed to the data collection and analysis of the data. PRH, TT, JSC, NJT, NB and KN all contributed to the final version of the manuscript for submission.

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REFERENCES

1. Somerville H, Tzannes G, Wood J, *et al*. Gastrointestinal and nutritional problems in severe developmental disability. *Dev Med Child Neurol* 2008;50:712–6.
2. NPSA. *Understanding the patient safety issues for people with learning disabilities*. London: National Patient Safety Agency, 2004.
3. Strauss D, Cable W, Shavelle R. Causes of excess mortality in cerebral palsy. *Dev Med Child Neurol* 1999;41:580–5.
4. Hollins S, Attard MT, von Fraunhofer N, *et al*. Mortality in people with learning disability: risks, causes, and death certification findings in London. *Dev Med Child Neurol* 1998;40:50–6.
5. Tokunaga T, Kubo T, Ryan S, *et al*. Long-term outcome after placement of a percutaneous endoscopic gastrostomy tube. *Geriatr Gerontol Int* 2008;8:19–23.
6. Lee L, MacPherson M. Long-term percutaneous endoscopic gastrostomy feeding in young adults with multiple disabilities. *Intern Med J* 2010;40:411–8.
7. Leslie P, Crawford H, Wilkinson H. People with a learning disability and dysphagia: a cinderella population? *Dysphagia* 2009;24:103–4.
8. Bourke A, Dattani H, Robinson M. Feasibility study and methodology to create a quality-evaluated database of primary care data. *Inform Prim Care* 2004;12:171–7.
9. Booth N. What are the Read Codes? *Health Libr Rev* 1994;11:177–82.
10. The NHS Information Centre PSaPCS. *Access to Healthcare for People with Learning Disabilities*, 2010.
11. Statacorp. *Stata Statistical Software: release 14*. Texas: StataCorp LP, 2015.
12. Clarke E, Pitts N, Latchford A, *et al*. A large prospective audit of morbidity and mortality associated with feeding gastrostomies in the community. *Clin Nutr* 2017;36:485–90.
13. Buszewicz M, Welch C, Horsfall L, *et al*. Assessment of an incentivised scheme to provide annual health checks in primary care for adults with intellectual disability: a longitudinal cohort study. *Lancet Psychiatry* 2014;1:522–30.