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Research Paper

Higher volume providers are associated with improved outcomes following ERCP for the palliation of malignant biliary obstruction

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ABSTRACT

Background: Relieving malignant biliary obstruction improves quality of life and permits chemotherapy. Outcomes of endoscopic retrograde cholangio-pancratography(ERCP) in inoperable malignant biliary obstruction have been examined in a national cohort to establish factors associated with poor outcomes.
Methods: Hospital Episode Statistics include diagnostic and procedural data for all NHS hospital attendances in England. Patients from 2006 to 2017 with a Hepaticopancreaticobiliary (HPB) malignancy who had undergone ERCP were studied. Patients undergoing a potentially curative operation were excluded. Associations between demographics, co-morbidities, unit ERCP volume and mortality were examined by logistic regression.
Findings: 39,702 patients were included; 49.4% were male; median age was 75 (IQR 66−88)years. Pancreatic cancer was the most common tumour (63.9%). Mortality was 4.1%, 9.7% and 19.1% for 7-day, in hospital and 30-day respectively. On multivariable analysis: men (OR 1.20(95%CI 1.14−1.26), $p < 0.001$); increasing age quintile 78−83(1.73(1.59−1.89), $p < 0.001$), >83(2.70(2.48−2.94),$p < 0.001$); most deprived quintile (1.21 (1.11−1.32), $p < 0.001$); increasing co-morbidity score >20(3.36(2.94−3.84),$p < 0.001$); small bowel malignancy (1.45(1.22−1.72), $p < 0.001$), intrahepatic biliary malignancy(1.10(1.03−1.17), $p = 0.005$) and year of ERCP 2006/07 (1.37(1.22−1.55), $p < 0.001$) were associated with increased 30-day mortality. Extrahepatic biliary tree cancers (0.67(0.61−0.73), $p<0.001$), high volume providers of ERCP (>318 annually, 0.91 (0.84−0.98), $p = 0.01$) and high volume of ERCP for malignant obstruction (>40 annually (0.91(0.85−0.98), $p = 0.014$) were negatively associated with 30-day mortality. Patients were less likely to require a second ERCP in high volume providers (>318, 8.0%) compared to low volume ((<204, 13.4%), $p<0.001$).
Interpretation: Short term mortality in patients with malignant biliary obstruction following ERCP was high. 30-day mortality was positively associated with increasing age and co-morbidity, men, deprivation, and earlier year of ERCP and negatively with extrahepatic biliary tree cancer and high volume ERCP providers.
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1. Introduction

Chemotherapy in hepatobiliary and pancreatic cancer has the potential to extend and improve quality of life, however it is contraindicated in jaundiced patients [1,2]. Although the use of chemotherapy in hepatobiliary and pancreatic cancer is increasing, many patients with biliary obstruction will be unfit to receive it despite biliary decompression.

A recent analysis of palliative patients undergoing percutaneous transhepatic cholangiography (PTC) for malignant biliary obstruction confirmed high mortality at 7 days (5.2%), in hospital (15.3%) and 30 days (23.1%) [3]. Increasing age and co-morbidity score, pre-existing renal dysfunction and cancer other than-pancreatic were all associated with worse 30 day mortality. A clear association between increasing provider annual PTC volume and reduced 30 day mortality was described. The existence of a volume effect in ERCP is controversial, with studies suggesting both an association and no association [4−7].

Abbreviations: ERCP, Endoscopic retrograde cholangiopancreatogram; HES, Hospital Episode Statistics; IMD, Index of Multiple Deprivations 2010; ICD10, International Classification of Diseases version 10; IQR, Interquartile range, OR, Odds ratio; ONS, Office of National Statistics; OPCS4, Office of Population Census and Surveys Classification of Interventions and Procedures, version 4; PTC, percutaneous transhepatic cholangiography; SMR, Standardised mortality rate; 95% CI, 95% confidence interval

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Research in context

Evidence before this study

ERCP in patients with malignant biliary obstruction is technically challenging. Procedures undertaken by higher volume providers appear more likely to be successful when examining ERCP for all indications. Palliative chemotherapy can improve the quality of life for patients with hepaticobilary cancer, but is contraindicated in jaundiced patients. Studies of outcomes for this specific cohort undergoing ERCP in a palliative setting are limited.

Added value of this study

Short term mortality was found to be higher than expected, 19.1% at 30 days. Receipt of chemotherapy appears lower in older patients and those with greater co-morbidity, even though such patients represent a significant proportion of those undergoing ERCP for this indication. High volume providers had lower associated 30 day mortality as well as lower rates of repeat procedures.

Implications of all the available evidence

Patients can be more accurately consented for ERCP for malignant biliary obstruction, including discussion regarding the association to short term mortality. Furthermore patients can be carefully selected for ERCP for malignant biliary obstruction to include those that are most likely to benefit. Providers may wish to consider whether centralising ERCP for malignant biliary obstruction into fewer, higher volume providers, to potentially reduce the number of deaths following shortly after ERCP. In contrast, studies reporting outcomes of ERCP for any indication have generally not shown a 30 day mortality benefit although improved procedure success rates have similarly been observed in higher volume providers.

A recent meta-analysis of ERCP for any indication, benign or malignant, included 59,437 patients in 13 studies [5]. The authors concluded that high volume endoscopists and high volume centres had better procedure success rates, defined as either successful cannulation of the intended duct or success of all attempted therapies, depending upon the available reported data. No variation was found in mortality, pancreatitis or a composite outcome measure of any adverse event. However, ERCP for malignant biliary obstruction can be technically more challenging than ERCP for benign indications such as choledocholithiasis. The patient population undergoing ERCP for malignant obstruction is also more likely to be older with increased co-morbidity. It is therefore important to address the impact of provider volume in this population.

A recent North American study demonstrated a link between higher volume ERCP providers and reduced complications including unplanned hospital attendance [8].

The aims of this study were to examine the mortality and risk factors associated with ERCP in patients with palliative cancer, and subsequent rates of chemotherapy.

2. Methods

2.1. Hospital Episode Statistics

Hospital Episode Statistics (HES) is an administrative database including all episodes of secondary care treatment within England under the National Health Service [9]. Information is recorded longitudinally to allow individual episodes to be linked. Data items include; diagnostic(International Classification of Diseases 10 (ICD10) codes), procedures (Office of Population Census and Surveys Classification of Interventions and Procedures, version 4 (OPCS4) codes), demographic and administrative variables. Records are linked to the Office of National Statistics (ONS) to provide mortality data. The data has been analysed in concordance with the data sharing agreement with NHS Digital for HES data. As per national guidelines any data item of 5 or less patients is suppressed from publication.

2.2. Patient cohort

All patients with an OPCS4 code for ERCP (Appendix 1) from April 2006 to March 2017 and an ICD10 code for a primary hepatobiliary, pancreatic or small bowel malignancy (Appendix 2) in the preceding 2 years or the following 6 months were included to allow for delays in coding of a cancer diagnosis, and to ensure diagnoses were chronologically appropriate. Patients under 18 years of age, or with missing or invalid age or sex data were excluded, as these variables along with NHS number are used to generate the unique patient identifiers in HES. Patients not resident within England or of unknown region of residence were also excluded as their follow-up may occur outside of England and thus not be captured in HES. Any patients that following ERCP underwent a potentially curative operation (Appendix 3) were excluded to ensure only palliative patients were included.

Cancer aetiology was considered to be the most frequently recurring cancer diagnosis code in HES in the preceding 2 years or 6 months following ERCP. Any patient in whom this did not match their initial diagnosis code were excluded, as patients were included based on their initial diagnosis meeting the criteria for inclusion.

2.3. Data extraction

The demographic data extraction included gender, ethnicity, Index of Multiple Deprivations 2010 (IMD) quintile (described in detail in Appendix 9) and primary malignancy. Age was extracted and analysed as quintiles as it was hypothesised that age would not have a linear association with 30 day mortality. Charlson co-morbidity score was constructed using ICD10 codes as a surrogate of overall co-morbidity, a technique that has been validated in HES analyses previously (construction of Charlson score can be found in Appendix 8) [10–12]. Cancer was excluded from the Charlson score, as it was universal in this patient cohort. Coded complications were extracted (Appendix 4) as were PTC (Appendix 5) or repeat ERCP within 30 days, mortality at 7 days, in hospital and 30 days, and emergency readmissions within 30 days. Post-ERCP receipt of palliative chemotherapy (Appendix 6) was also collected.

2.4. Data validation

Patients undergoing ERCP for palliation of malignant biliary obstruction were sought at Sandwell and West Birmingham NHS Trust by searching the endoscopy reporting system on which all procedures are documented. Once identified, electronic records for potential cases were reviewed to confirm the cancer diagnosis and that study inclusion criteria were met. The number of patients was then compared to the number of patients meeting the study criteria found in the HES database.

2.5. Analysis

Rates of procedural failure as defined by the surrogate measure of undergoing PTC or further ERCP within 30 days of index ERCP were given for the whole cohort, by provider volume tertile, and based upon cancer aetiology. This allowed comparison of procedural success between intrahepatic or hilar lesions and more distal biliary obstruction. Chi square tests were performed to determine statistical significance between further intervention and provider volume.

Multivariable logistic regression models utilising 30 day mortality as the dependent variable included: gender, age quintile, deprivation

quintile, ethnicity, Charlson co-morbidity score, primary cancer aetiology, year of ERCP and NHS hospital provider ERCP volume per annum (April to April) by tertile for both all ERCPS and ERCPs performed only for unresectable pancreaticobiliary cancer. Variables were selected based upon clinical relevance.

A standardised mortality funnel plot was constructed using the regression model for all ERCPs to generate expected numbers of deaths per unit. Control limits were set at 2 and 3 standard deviations using a random effects adjustment for over-dispersion [13].

Data were analysed using Stata® version 15 (StataCorp. 2017. Stata Statistical Software: Release 15. College Station, TX: StataCorp LP), p-values < 0.05 were considered statistically significant.

Funnel plots showing standardised 30 day mortality rate per provider following ERCP were constructed using Spotfire® version 6.5.

Due to the administrative nature of HES, missing data items are uncommon. Instances when this occurs (ethnicity and deprivation) will be disclosed in demographic tables and included as "unknown" in multivariable models. Missing data leading to incomplete case identification will be sought in the data validation.

HES data are available under a licence for service evaluation and as such, ethical approval is not necessary. The study was registered at University Hospital Birmingham. This manuscript is written in accordance with the STROBE guidelines.

3. Results

3.1. Validation

Between April 2013 and March 2015, 465 patients had an ERCP recorded at Sandwell and West Birmingham NHS trust compared to 462 (99.4%) found within HES. 38 patients underwent their first malignant ERCP but did not progress to curative surgery. When sought in HES by the same criteria 41 (92.7%) patients were found. This suggests a high degree of accuracy in the HES data.

3.2. Demographics

515,532 patients underwent their first ERCP between April 2006 and March 2017. Of those 49,487 patients had a cancer diagnosis within 2 years before or 6 months after index ERCP. 8930 were excluded having undergone a potentially curative operation following ERCP. 39,702 patients were included in the final analysis following all exclusions, as described in Fig. 1.

The median age of included patients was 75 (IQR 66–88) years. Males constituted 49.4% and the majority ethnicity was "White", including 84.5% of patients. The majority of patients did not have any co-morbidities recorded (59.0%). The commonest primary cancer was pancreatic, seen in 63.9% of patients. Full demographic details are reported in Table 1. Provider volume tertile boundaries were found to be <204 in the lower tertile, 204–318 in the middle tertile and >318 in the upper tertile. Detailed demographics of each provider volume tertile can be found in Appendix 10.

3.3. Complications

Following ERCP, the 30 day emergency re-admission rate was 24.9%. Renal failure within 30 days was coded in 3.3%, cholangitis in 3.7% and pancreatitis in 0.6%. Full details of complications are described in Appendix 7. Coded complication and emergency readmission rate did not vary by ERCP volume tertile (data not shown).

3.4. Repeat biliary drainage procedures

Within 30 days of first ERCP, 9.3% of patients underwent a repeat ERCP and 5.6% had a PTC. In those undergoing ERCP in an upper tertile volume provider (total ERCPs >318), repeat ERCP at 30 days was 8.0% compared to 13.4% in the lower tertile volume providers (total ERCPs < 204, $p < 0.001$). Similarly PTC within 30 days of index ERCP was 4.5% and 8.7% in the upper and lower tertile ERCP volume providers respectively ($p<0.001$) (Table 2).

Within 30 days of first ERCP, repeat ERCP was most commonly undertaken in cancers of the intrahepatic biliary tree and liver (11.3%), followed by cancers of the extrahepatic biliary tree (10.7%). PTC post ERCP in the same time period was most common in small intestine malignancy (9.4%).

3.5. Chemotherapy

Patients with gall bladder cancer were the most likely to receive chemotherapy following ERCP (28.5%) followed by pancreatic cancer (28.2%). The rate of chemotherapy reduced with increasing age quintile; 2.1% of patients over 83 years compared to 46.8% of those younger than 64 years. Patients with higher Charlson co-morbidity scores were less likely to receive chemotherapy; 0, 29.4%; >20, 4.5%. Chemotherapy became more common over the study period from 20.8% in 2006/07 to 28.9% in 2016/17. Full results are presented in Table 3.

3.6. Mortality

Mortality at 7 days, in hospital and 30 days was 4.1%, 9.7% and 19.1% respectively. The median survival from the first ERCP was 4 (IQR 1–10) months.

The mortality rates for tertiles of total ERCP volume per provider were; <204 ERCPs 19.9%, 204–318 ERCPs 19.9%, and >318 ERCPs 18.3%. Mortality by tertile of unresectable cancer ERCP volume per provider were <23 ERCP 20.5%, 23–40 ERCP 19.5%, and >40 ERCP 18.4%.

Multivariable regression analysis demonstrated factors associated with increased 30 day mortality include: male gender OR 1.20 (95% CI 1.14–1.26), $p<0.001$; increasing age quintile >83 2.70 (2.48–2.94), $p<0.001$; increasing deprivation, quintile 1 1.21(1.11–1.32), $p<0.001$; increasing Charlson co-morbidity score, >20 3.36(2.94–3.84), $p<0.001$; earlier year of ERCP, 2006/2007 1.37 (1.22–1.55), $p<0.001$; cancer of liver and intrahepatic bile ducts 1.10 (1.03–1.17), $p = 0.005$; and small intestine cancer 1.45(1.22–1.72), $p<0.001$. Factors associated with reduced 30 day mortality included: extrahepatic biliary tract malignancy 0.67(0.61–0.73), $p<0.001$; upper tertile providers for total ERCP volume >318 0.91 (0.84–0.98), $p = 0.010$. Complete results are displayed in Table 4.

A further multivariable regression analysis was undertaken including volume of ERCP in unresectable cancer only. An increased volume of ERCPs in unresectable cancers (>40) was also associated with decreased mortality (0.91(0.85–0.98), $p = 0.014$). Full results of this model are also shown in Table 4.

3.7. Standardised mortality rates

98.7% of individual provider 30 day mortality rates were within 3 standard deviations of the mean within the study period (Fig. 2). Although higher volume tertile providers were seen to have a lower 30 day mortality, there was significant variation between providers of similar annual ERCP volume. The relationship between provider volume and 30 day mortality did not appear to be linear. When case mix was taken into account, only a single provider had a mortality higher than 3 standard deviations above the mean 30 day mortality.

4. Discussion

In the present study, considerable short term mortality following an ERCP for malignant biliary obstruction was observed. Mortality increased with advancing age and greater co-morbidity. Low volume providers had lower 30 day survival, when considering total ERCP volume, but also restricting analysis to ERCP for unresectable cancer

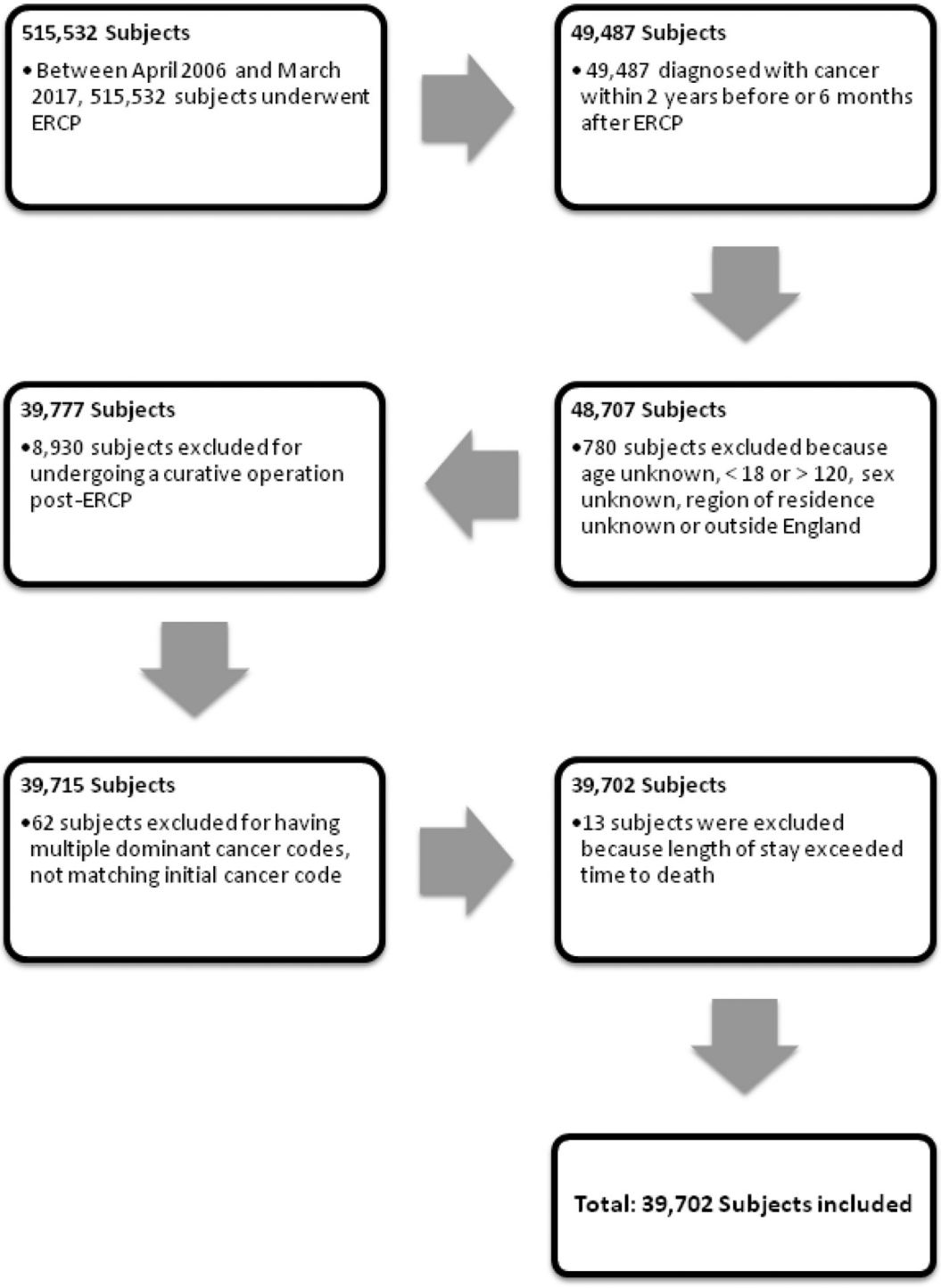

Fig. 1. Study flow chart.

only. Low volume providers also required more ERCPs to be repeated or PTCs to be undertaken within 30 days of first ERCP.

30 day mortality in the present study is high. A significant component of this will be the natural history of a patient with advanced cancer. The regression models also demonstrate that there is variation in mortality between providers based on procedure volume. This suggests that a significant component to the observed mortality is related to the procedure, not merely the underlying cancer. A recent meta-analysis of ERCP for any indication did not demonstrate variation in mortality based upon provider volume [5]. However all indications were included, compared to the present study that only includes patients with palliative malignant biliary obstruction. ERCP in malignant biliary obstruction is often more technically challenging, therefore the impact of higher annual ERCP volume is potentially more important.

Repeat ERCP or PTC within 30 days of first ERCP was used as a surrogate for failed or inadequate biliary decompression. Lower rates of repeat procedures were observed in higher volume providers. This further supports the suggestion of a volume effect, whereby those providers doing more ERCPs for cancer have better outcomes. A recent meta-analysis of ERCP outcomes by annual provider volume included 3 studies reporting procedure success rates of ERCP for any indication defined as success at cannulation or intended therapies. A similar

Table 1
Study patient demographics.

	Variable	*n* (%)
Gender	**Male**	19,603 (49.4%)
	Female	20,099 (50.6%)
Age quintile	**< 64**	8041 (20.3%)
	64 to 71	8189 (20.6%)
	72 to 77	7709 (19.4%)
	78 to 83	8059 (20.3%)
	> 83	7704 (19.4%)
Deprivation quintile	**1**	7035 (17.7%)
	2	7664 (19.3%)
	3	8333 (21.0%)
	4	8592 (21.6%)
	5	8049 (20.3%)
	Unknown	29 (0.1%)
Ethnic Group	**White**	33,536 (84.5%)
	Asian or Asian British	843 (2.1%)
	Black or Black British	667 (1.7%)
	Mixed	116 (0.3%)
	Any other ethnic group	494 (1.2%)
	Unknown	4046 (8.5%)
Charlson co-morbidity score	**0**	23,443 (59.0%)
	1 to 5	8548 (21.5%)
	6 to 10	3421 (8.6%)
	11 to 15	2267 (5.7%)
	16 to 20	1033 (2.6%)
	> 20	990 (2.5%)
Type of Cancer	**Liver and Intrahepatic Bile Ducts**	7964 (20.1%)
	Gallbladder	1510 (3.8%)
	Extrahepatic and unspecified biliary tract	4115 (10.4%)
	Pancreas	25,359 (63.9%)
	Small Intestine	754 (1.9%)
	Previous PTC	1620 (4.1%)

effect was observed with high volume providers had better success rates (OR 2.0) [5]. However the definition of volume varied between studies, the largest effect (OR 5.65) defined high volume as >87 ERCPs per annum [14]. The remaining 2 studies considered high volume to be >200 ERCPs per annum, of which one reported improved success rates of ERCP in higher volume providers (OR 1.9), in keeping with the present study [15], however the other study did not [16].

A negative association with mortality for higher volume providers has also been reported in patients undergoing PTC [3]. Both studies use HES data linked to the ONS to provide accurate mortality statistics following a procedure. 30 day mortality was 23.1% after PTC compared to 19.1% after ERCP. In keeping with the present study; increasing age, co-morbidity, male gender and greater deprivation were found to be associated with 30 day mortality. No association was observed between volume and complication rates or unplanned hospital admissions. This is in contrast to a recent North American study of all ERCPs including benign and malignant indications. However, in the present study, provider volumes are much higher suggesting that this may only be a concern when provider volume is very low or be more important in ERCP for benign indications.

Table 2
Proportion of patients undergoing repeat biliary drainage procedures within 30 days of index ERCP.

	Repeat ERCP	PTC post ERCP
<204 ERCPs per annum, per provider	853 (13.4)	557 (8.7)
204–318 ERCPs per annum, per provider	1181 (9.4)	751 (6.0)
>318 ERCPs per annum, per provider	1666 (8.0)	930 (4.5)
Malignancy of Liver and Intrahepatic Bile Ducts	903 (11.3)	622 (7.8)
Gallbladder malignancy	141 (9.3)	73 (4.8)
Malignancy of extrahepatic and unspecified biliary tract	442 (10.7)	177 (4.3)
Pancreas malignancy	2174 (8.6)	1295 (5.1)
Small Intestine malignancy	40 (5.3)	71 (9.4)

Table 3
Rates of chemotherapy following ERCP by age, co-morbidity, cancer type and year of procedure.

	Variable	n (%)
Age quintile	<64	3766 (46.8)
	64–71	3131 (38.2)
	72–77	2031 (26.3)
	78–83	950 (11.8)
	>83	159 (2.1)
Charlson co-morbidity score	0	6893 (29.4)
	1–5	2141 (25.0)
	6–10	627 (18.3)
	11–15	232 (10.2)
	16–20	99 (9.6)
	>20	45 (4.5)
Malignancy of Liver and Intrahepatic Bile Ducts		1530 (19.2)
Gallbladder malignancy		430 (28.5)
Malignancy of extrahepatic and unspecified biliary tract		767 (18.6)
Pancreas malignancy		7152 (28.2)
Small Intestine malignancy		158 (21.0)
2006/2007		732 (20.8)
2007/2008		721 (20.6)
2008/2009		846 (22.8)
2009/2010		827 (23.6)
2010/2011		888 (24.5)
2011/2012		894 (25.1)
2012/2013		972 (27.1)
2013/2014		1029 (28.2)
2014/2015		1014 (27.1)
2015/2016		1054 (29.0)
2016/2017		1060 (28.9)

Death within 30 days of an ERCP in a patient for palliation needs to be interpreted with caution. ERCP is an invasive and uncomfortable procedure performed to permit chemotherapy, improve pruritus or, uncommonly, to treat cholangitis. In patients unlikely to survive 30 days or receive palliative chemotherapy and without severe pruritus symptoms, ERCP may not be in the patient's best interests.

Ascertainment bias is an important consideration for database studies. Data validation by comparison to local audit data, from sources independent of HES, supports the accuracy of the HES database coding. The number of index ERCPs identified in local audit matched the number found in HES. The number of patients meeting the inclusion criteria identified in local audit compared to HES was also very similar, providing reassurance that the inclusion and exclusion criteria for the study were accurately coded, therefore supporting the validity of the results presented.

Although OPCS codes were available for metal stent insertion, there is no code specific for plastic stent insertion. Therefore the present study unfortunately cannot analyse the impact of metal stents on ERCP outcomes in the management of malignant biliary obstruction. Mortality was noted to fall over the study period, which is likely to be a result of better peri-procedural medical care, but also may potentially be related to increasing use of metal stents.

The Charlson co-morbidity scores appeared lower than might be expected for a population with mean age of 75 years. However it is important to note that some common co-morbidities are not included in Charlson. Furthermore, co-morbidities documented in HES result from hospital episodes, and it is possible that co-morbidities managed solely in primary care may be incompletely recorded.

Patients will present for ERCP only when biliary obstruction has occurred. This cohort will therefore include variably advanced cancers. Considering this, the improved survival of the distal cholangiocarcinoma group is likely to be due to biliary obstruction at an earlier stage of cancer progression. It is a significant limitation of HES that cancer staging data is not available for analysis.

The coding structure of HES requires a primary diagnosis for each episode with up to 19 further diagnoses listed. Therefore if a complication occurs following discharge from hospital it would be more likely to be listed as the primary diagnosis in a new episode. However

Table 4
Multivariable logistic regression models of factors associated with 30 day mortality following ERCP for malignant biliary obstruction including provider volume of all ERCPs and provider volume of ERCP for malignant biliary obstruction only.

		All ERCP provider volume				Provider ERCP volume for palliation of malignant biliary obstruction only			
	Variable	Odds Ratio		95% CI	P value	Odds Ratio	95% CI		P value
Gender	Female	Reference category				Reference category			
	Male	1.20	1.14	1.26	<0.001	1.20	1.14	1.27	<0.001
Age	<64	Reference category				Reference category			
	64–71	1.30	1.19	1.43	<0.001	1.30	1.19	1.43	<0.001
	72–77	1.52	1.39	1.67	<0.001	1.52	1.39	1.67	<0.001
	78–83	1.73	1.59	1.89	<0.001	1.73	1.59	1.89	<0.001
	>83	2.70	2.48	2.94	<0.001	2.70	2.48	2.94	<0.001
Deprivation Quintile	1	1.21	1.11	1.32	<0.001	1.20	1.10	1.30	<0.001
*1 is the most deprived	2	1.11	1.02	1.20	0.018	1.10	1.01	1.19	0.029
	3	1.11	1.02	1.20	0.013	1.10	1.02	1.19	0.019
	4	1.09	1.00	1.18	0.040	1.08	1.00	1.17	0.054
	5	Reference category				Reference category			
	Unknown	0.36	0.08	1.52	0.164	0.35	0.08	1.50	0.158
Ethnic Group	White	Reference category				Reference category			
	Asian or Asian British	0.87	0.72	1.06	0.139	0.87	0.72	1.06	0.162
	Black or Black British	0.93	0.76	1.15	0.528	0.94	0.76	1.16	0.575
	Mixed	1.01	0.62	1.65	0.977	1.01	0.62	1.65	0.969
	Other Ethnic Group	0.83	0.64	1.07	0.147	0.83	0.64	1.07	0.150
	Unknown	1.26	1.16	1.37	<0.001	1.27	1.17	1.37	<0.001
Comorbidities	0	Reference category				Reference category			
	1–5	1.16	1.08	1.23	<0.001	1.16	1.08	1.23	<0.001
	6–10	1.38	1.26	1.50	<0.001	1.38	1.26	1.51	<0.001
	11–15	1.81	1.63	2.00	<0.001	1.81	1.63	2.00	<0.001
	16–20	2.20	1.92	2.52	<0.001	2.20	1.92	2.53	<0.001
	>20	3.36	2.94	3.84	<0.001	3.36	2.94	3.84	<0.001
Type of Cancer	Pancreatic	Reference category				Reference category			
	Small Intestine	1.45	1.22	1.72	<0.001	1.45	1.22	1.72	<0.001
	Liver and Intrahepatic Bile Ducts	1.10	1.03	1.17	0.005	1.09	1.03	1.17	0.006
	Gallbladder	1.11	0.97	1.28	0.112	1.11	0.97	1.27	0.130
	Extrahepatic and unspecified biliary tract	0.67	0.61	0.73	<0.001	0.67	0.61	0.74	<0.001
Year of ERCP	2006/2007	1.37	1.22	1.55	<0.001	1.38	1.22	1.55	<0.001
	2007/2008	1.33	1.18	1.50	<0.001	1.33	1.17	1.50	<0.001
	2008/2009	1.27	1.13	1.44	<0.001	1.28	1.13	1.44	<0.001
	2009/2010	1.24	1.10	1.40	0.001	1.24	1.10	1.40	0.001
	2010/2011	1.23	1.09	1.39	0.001	1.23	1.09	1.39	0.001
	2011/2012	1.19	1.06	1.35	0.004	1.20	1.09	1.39	0.004
	2012/2013	1.18	1.04	1.33	0.008	1.18	1.04	1.33	0.008
	2013/2014	1.07	0.94	1.20	0.315	1.07	0.94	1.21	0.304
	2014/2015	1.16	1.03	1.31	0.016	1.16	1.03	1.31	0.016
	2015/2016	1.03	0.91	1.17	0.613	1.03	0.91	1.17	0.605
	2016/2017	Reference category				Reference category			
Mean annual ERCP volume tertile	<204	Reference category							
	204–318	0.99	0.92	1.07	0.845				
	>318	0.91	0.84	0.98	0.010				
Mean annual ERCP volume for unresectable cancer	<23					Reference category			
	23–40					0.95	0.88	1.03	0.216
	>40					0.91	0.85	0.98	0.014

should the complication occur during the same episode as the ERCP procedure, the complication may not be recorded during coding and therefore the number of complications may under represent the actual number of such events.

Chemotherapy has previously been considered to be under coded in HES. A recent validation study of chemotherapy in lung cancer split patients into 4 groups, those with evidence of chemotherapy in; HES, the national lung cancer audit (NCLA), both HES and NCLA, and evidence in neither. Outcomes were similar with codes in NCLA, HES and both, compared to patients with evidence in neither data set, who had worse outcomes. This suggests that chemotherapy coded in HES has a strong positive predictive value. Unfortunately, chemotherapy still appeared to be under coded in HES and therefore correlation with audit data for case finding was recommended [17]. A comparison of chemotherapy for head and neck cancers from the national cancer data registry (NCDR) to HES between 2004 and 2006 demonstrated good concordance. Overall 89.3% (2096/2346) of patients receiving chemotherapy in the NCDR were also coded on HES. The quality of chemotherapy coding appeared to improve in that study in HES up to 2006 [18]. In the present study the observed 8.9% increase in chemotherapy provision over the study period is likely attributable to both improving coding and increasingly common use in clinical practice.

Although provider volume is the focus of the present study, demographic factors had a larger effect on 30 day mortality. Demographic factors are important for clinical decision making and patient selection but they cannot be modified therefore the potentially modifiable impact of provider volume has been the focus of the present study.

In conclusion this study, the largest study to date of outcomes for ERCP in unresectable malignant biliary obstruction, demonstrates high 30 day mortality. Mortality was associated with increasing age, deprivation and co-morbidity. Mortality fell over the study period and was higher in low volume providers of both ERCP for all indications and

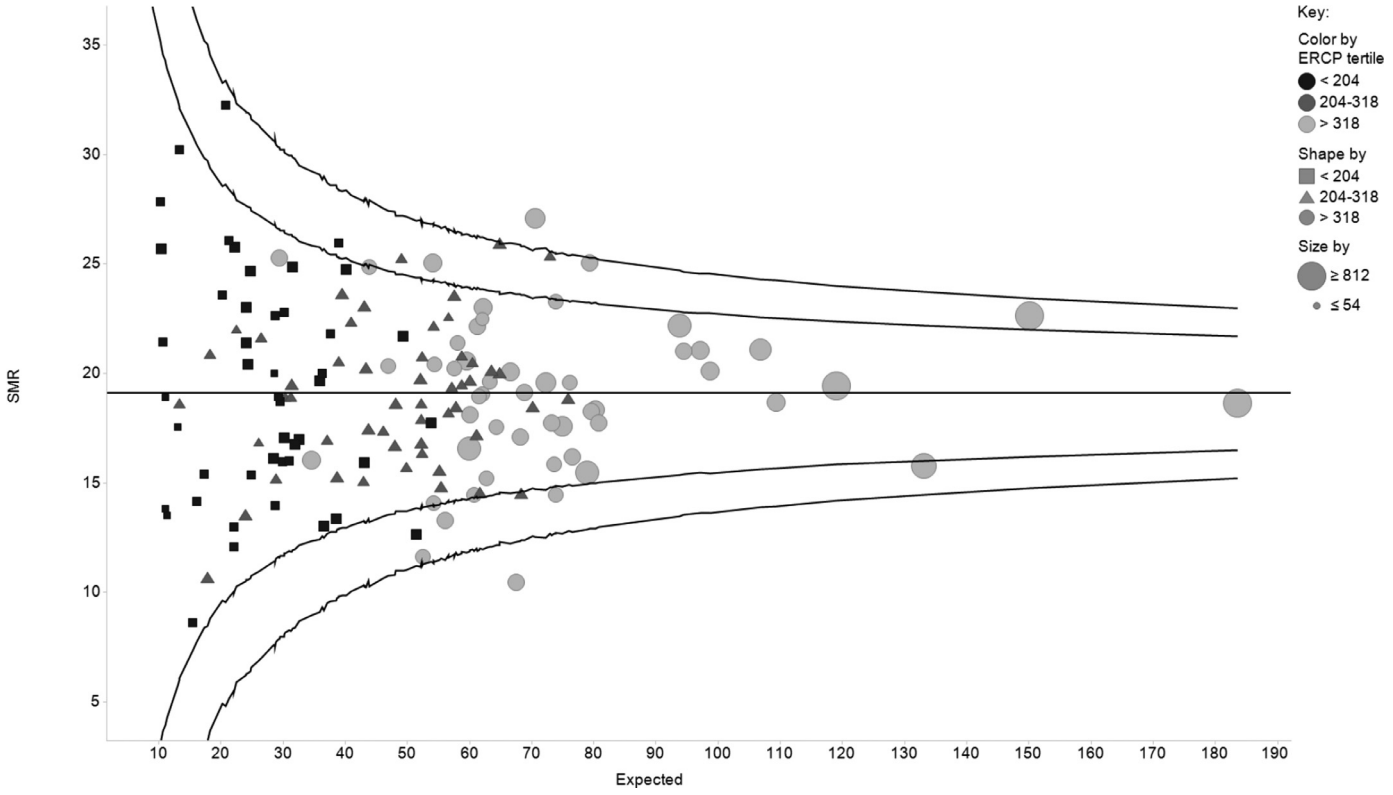

Fig. 2. Funnel plot of standardised 30 day mortality rate following ERCP for palliative malignant biliary obstruction. *Lines represent 2SD and 3SD.*

ERCP for malignant biliary obstruction. Future research should focus on the reasons for variable mortality in those with malignant biliary obstruction. Identifying those patients most likely to benefit from ERCP and performing ERCP for malignancy only in higher volume centres may reduce the number of ERCPs undertaken within 30 days prior to death in this palliative cohort.

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Disclosures

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Supplementary materials

Supplementary material associated with this article can be found in the online version at doi:10.1016/j.eclinm.2019.11.005.

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