The impact of a centralised pancreatic cancer service; a case study of Wales, UK

Short title: Pancreatic cancer centralisation

Nicholas G Mowbray[1,2]
Rowena Griffiths[1,3]
Ashley Akbari[1,3]
Hayley Hutchings[1]
Gareth Jenkins[1]
Bilal Al-Sarireh[1,2]

[1] Swansea University Medical School, Swansea, SA2 8QA
[2] Morriston Hospital, Swansea Bay University Health Board, SA6 6NL
[3] Health Data Research UK, Swansea University, Swansea, SA2 8PP

Corresponding author: Mr. Nicholas Mowbray, Morriston Hospital, Swansea Bay University Health Board, SA6 6NL, email: ngmowbray@doctors.org.uk, Twitter:@nickmowbray13

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Abstract

Introduction

The centralisation of pancreatic cancer (PC) services still varies worldwide. This study aimed to assess the impact that a centralisation has had on patients in South Wales, UK.

Methods

A retrospective cohort analysis of patients in South Wales, UK, with PC prior to (2004-2009), and after (2010-2014) the formation of a specialist center. Patients were identified using record linkage of electronic health records.

Results

The overall survival (OS) of all 3413 patients with PC increased from a median (IQR) 10 weeks (3-31) to 11 weeks (4-35), $p = 0.038$, after centralisation. The OS of patients undergoing surgical resection or chemotherapy alone did not improve (93 weeks (39-203) vs 90 weeks (50-95), $p = 0.764$ and 33 weeks (20-57) vs 33 weeks (19-58), $p = 0.793$). Surgical resection and chemotherapy rates increased (6.1% vs 9.2%, $p < 0.001$, and 19.7% vs 27.0%, $p < 0.001$). The 30-day mortality rate trended downwards (7.2% vs 3.6%, $p = 0.186$). The percentage of patients who received no treatment reduced (75.2% vs 69.6%, $p < 0.001$).

Conclusion

The centralisation of PC services in South Wales is associated with a small increase in OS and a larger increase in PC treatment utilisation. It is concerning that many patients still fail to receive any treatments.

Key words: Pancreatic cancer, centralisation, pancreatic surgery,

Introduction

Increases in survival rates from pancreatic cancer (PC) have not accompanied the improvements seen in other solid organ cancers. The 5-year survival rates from colorectal cancer have doubled, from 24% to 59%, whereas the doubling of PC survival rates from 3.1% to 6.9% is less impressive (1, 2). Advancements in chemotherapy and immunotherapy may hold the key to significantly improving outcomes in the future, however, the greatest fundamental change in the management of PC has been a move to focus cancer care into high-volume centers led by specialist multi-disciplinary teams (MDTs) (3, 4).

Prior to centralisation in the UK, 85% of PC resections were performed by surgeons dealing with less than 1 case of new pancreatic cancer per month (5). Guidance in the 1990's suggested the use of specialist MDTs and the formation of specialist upper gastrointestinal cancer centers to serve a population of 2-3 million (6, 7). These recommendations for centralisation were largely based upon an observed decrease in operative mortality rates in high volume centers in the United States. Evidence from the Netherlands shows an improved overall survival (OS) after pancreaticoduodenectomy for all tumours after centralisation, but little exists on the effect of regional PC centers on all patients with PC (8).

A specialist PC MDT was created in South Wales in 2009 and included radiologists, surgeons, oncologists, and specialist cancer nurses to provide a consensus management opinion. Centralisation aimed to concentrate expertise, standardise care and hence improve patient outcomes. The objective of this study was to test the hypothesis that a centralised service would decrease the operative mortality associated with PC surgery and increase the OS of patients with PC. A secondary objective was to determine if centralisation resulted in any change in other treatment rates such as chemotherapy and palliative bypass operations.

Methods

Study population

Patients in North Wales, UK (Gwynedd, Anglesey, Conwy, Flintshire, Denbighshire, Wrexham and North Powys) are supported by PC services in Liverpool and therefore, this study concentrated on patients resident in the rest of Wales (based on lower layer super output area). All patients aged at least 18 years old with a diagnosis of PC (International Classification of Diseases, Tenth Revision, ICD-10 code C25) found between 1st January 2004 to 31st December 2014 were included. Patients with peri-ampullary or biliary tumors were excluded (ICD-10 code C24).

Information from national population electronic health record (EHR) administrative databases were compiled, stored and accessed through a secure data storage gateway; the Secure Anonymised Information Linkage (SAIL) Databank (9, 10). The SAIL Databank was developed, and validated, by the Health Informatics Group at Swansea University with support from the Farr institute of Health Informatics Research. The datasets included; Patient Episode Database for Wales (PEDW), Welsh Cancer Intelligence and Surveillance Unit (WCISU), Outpatient Dataset for Wales (OPDW), Emergency Department Dataset (EDDS), Welsh Longitudinal General Practice (WLGP) dataset, and the Annual District Death Extract (ADDE) provided by the Office for National Statistics (ONS) deaths registry. The data is linked using the patients unique NHS number but is immediately anonymised. Ethical approval was therefore not essential but was given by an Independent Governance Review Panel (IGRP) and registered as project 0623. PEDW, WCISU, EDDS, and OPDW are purely administrative datasets detailing diagnoses and Office of Population Censuses and Surveys (OPCS)

124 classification of surgical operations and procedures codes. The WLGP dataset contains primary
125 care data for diagnoses, prescriptions and prescribed medications.
126
127 **Study outcomes**
128 The study population was split into those diagnosed prior to the centralisation of pancreatic
129 cancer services, 1st January 2004 to 31st December 2008 (PreC), and those diagnosed post
130 centralisation, 1st January 2010 to 31st December 2014 (PostC). Patients diagnosed in 2009
131 were excluded from the analysis to allow for a transition period.
132
133 The SAIL Databank was interrogated for; patient demographics, date of diagnosis, date of
134 death or relocation out of Wales, Welsh Index of Multiple Deprivation version 2014 (WIMD)
135 score, and OPCS-4 (4th revision) codes listed in Appendix 1. The WIMD is a measure of
136 relative deprivation between areas in Wales using 8 domains; income, employment, education,
137 health, access to services, community safety, housing and physical environment.
138
139 Overall survival was defined as the time from diagnosis until death from any cause. 30- and
140 90-day operative mortality was defined as a death occurring within 30 or 90 days after a
141 surgical resection procedure. The last update from the ONS registry was 17th February 2017.
142
143 **Statistical analysis**
144 Age adjusted incidence was calculated using the crude incidence rate for the age group, divided
145 by the mid-year population for that year, multiplied by the European Standard Population
146 (ESP). The 95% confidence intervals were not calculated because data were analysed from the
147 whole population without sampling.
148

To aid comparisons, patients were grouped into 10-year age categories and also into quintiles based on the WIMD score (Q1 represents the most socioeconomically deprived and Q5 the least socioeconomically deprived patients) (11). Continuous variables were presented as median (interquartile range, IQR) and compared using the Mann-Whitney U test. Categorical variables were presented as frequencies and compared with Pearson's chi-square tests. Survival was estimated using Kaplan-Meier survival curve analysis with log rank testing. A multivariate Cox-proportional hazard model was used to identify prognostically significant factors. Tests were two-sided using a p-value < 0.05 as statistically significant. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 22.0 (IBM Corp, Armonk, NY).

Results

Between 1st January 2004 to 31st December 2014, 5,261 patients in Wales were diagnosed with PC, 638 with ampullary neoplasms and 456 patients with extrahepatic biliary neoplasms. For those with PC, data were available from WICSU (5042), PEDW (4,457 patients), WLGP (3,688 patients), OPDW (104 patients), EDDS (2443 patients) datasets. Only 48 patients had records within all 5 datasets. A total of 3,746 patients (71.2%) were from South Wales and exhibited an increase in the incidence of PC from 15.37 per 100,000 population in 2004 to 16.76 in 2014 (Figure 1). The 334 patients diagnosed with PC in 2009 were excluded such that the Pre-C group involved 1581 patients and the Post-C group 1832 patients.

Patient characteristics

The proportion of males did not differ between the Pre-C and Post-C groups (48.8% vs 51.4%, $p = 0.122$) and neither did the age distribution ($p = 0.109$). Table 1 illustrates the patient demographics and an increase in the number of patients from the most socioeconomically

deprived quintile (p = 0.002). There was a significant shift towards an even distribution of patients across the WIMD quintiles in the Post-C group (p=0.002). Tumor grade information was incomplete as overall, 2,524 patients (74.0%) did not have an associated tumor stage code. Amongst those that had a surgical resection, the proportion with a documented tumor grade increased after centralisation (49.5% vs 72.2%, p < 0.001). Only 1.8% of all patients had a tumor morphology code of adenocarcinoma.

Primary outcome

The OS of patients diagnosed with PC improved over the study period from 10 weeks (IQR 3-31) Pre-C to 11 weeks (4-35) Post–C (p = 0.038,). The 1, 3, and 5-year survival increased from 15.8%, 4.9% and 3.5% to 18.2%, 5.8% and 4.0% respectively. Figure 2 shows the OS for patients categorised by treatment group.

In patients that underwent surgical resection of a pancreatic tumor, there was no difference between the OS at 1, 3 and 5 years (67.0%, 34.0% and 21.7% Pre-C vs 75.0%, 35.1% and 22.0% Post-C) with a median survival of 93 weeks (46-203, p = 0.764). There was no difference in the survival of patients undergoing chemotherapy as the only treatment for PC, median survival 33 weeks (20–58, p = 0.793).

Secondary outcomes

There was an increased utilisation rate of both chemotherapy (p < 0.001) and surgical resection (p < 0.001) as well as a decreased use of surgical bypass (p < 0.001) (Table 1). Amongst the patients who underwent surgical resection, there was no difference in the gender (p = 0.890), age distribution (p = 0.742) or WIMD (p = 0.504) between the two cohorts. There was a higher rate of males resected in both patient cohorts and a trend towards decreased operative mortality

at both 30 and 90 days (Table 2). The yearly resection volume and associated mortality is displayed in Figure 3.

During the multivariable regression analysis, the 'surgery' covariate failed the proportional hazard assumption and so cox regression analysis with time varying covariate was performed. This accounted for the variance in surgical procedure and indicated, age greater than 70 years, surgical resection, and chemotherapy were all associated with a prolonged OS (Table 3).

4.1 Discussion

Calls for the centralisation of PC services have echoed across the world, but progress has been slow. Differing social, political and economic pressures result in a heterogeneous approach to healthcare provision. Countries that provide a central, single-payer system, such as in the UK, have been able to mandate change. Conversely, healthcare systems based on more complex fee-for-service model for instance, have struggled to significantly change practice (12, 13).

The Cancer Outcome Group guidance in 2001 was fundamental in driving change in the UK (7). Within 3-years of publication, the number of hospitals performing pancreaticoduodenectomies in the UK decreased by 29% (101 to 73), with an operative mortality rate that reduced from 6.7 to 5.7% (14). At the Bart's and the London HPB center, centralisation was also associated with a decreased operative mortality rate from 9.7% to 5.0% (15). The present study re-affirms this trend with a commendable 30-day mortality of 3.6%.

A recent meta-analysis by Hata et al quantified the inverse association between higher hospital volume and lower mortality with a pooled odds ratio of 2.37 (95%CI 1.95,2.88) (16). This

overall effect on the mortality rate is likely multifactorial; better pre-operative planning, more experienced surgeons and anesthetic staff, and the ability to 'rescue' patients with complications. Extrapolating further, the results could also explain the increase in 1-year survival rate (67.0% vs 75.0%) (17-19).

The increasing incidence of PC is a worldwide phenomenon and is associated with ageing populations, increased lifestyle risk factors (such as smoking and obesity) (20). The higher incidence in South Wales, in comparison to the rest of the UK, may relate to these risk factors and also to socioeconomic deprivation (21). Our analysis has shown that the distribution of patients across the WIMD quintiles has evened post-C and this may reflect better access to services to make the diagnosis of PC.

A study from the US by Gooiker et al also reported an increase in the number of patients undergoing treatment for PC after centralisation (22). As in our study, there was also no effect on OS. This should not be an unexpected statistical finding however, given that two thirds of our patients did not receive any form of treatment for PC and less than 10% undergo surgical resection. The oft-quoted historical 20% resectability rate is at the top of internationally published data and appears optimistic in comparison to the current findings (23). Our results appear consistent with English national data and therefore may represent the maximal advantage to be gained by surgery at present (24). To significantly impact the OS rate perhaps the advances needs to come from earlier detection, neo-adjuvant therapies or immunotherapy.

The strength of this study is the comprehensive identification of patients diagnosed with pancreatic cancer using a proven record linking methodology. The incidence of PC mirrors that published by Public Health Wales but a selection bias may be hidden within these retrospective

datasets (25). The diagnosis of pancreatic cancer could be challenged as only 23% of patients had staging information and less than 2% of patients had a tumor specifically labelled/coded as adenocarcinoma (10). Whilst this limited any multivariate survival analysis in the current study, one could also question whether the data includes bile duct cancers, ampullary cancers, pancreatic neuroendocrine tumours or cystic lesions. Obtaining a histological diagnosis is not without risk, however, and may not affect the management in patients for palliative treatment. More accurate data is required to here.

Future work needs to address the paucity of nationally held information on patients with pancreatic cancer and allow clearer comparisons between emerging treatment options and pancreatic units. Existing UK cancer registries could be improved with more comprehensive, and complete, data capture. The Netherlands Cancer Registry routinely extract and code for detailed information that includes one of eight reasons the patient declined a therapy (22, 26). Alternatively, a user led audit such as the UK Registry of Endocrine and Thyroid surgery could provide a prospective data capture. In the interim however, a recent national trainee led collaborative study (Ricochet) hopes to provide an insight into the case load and current practice of pancreatic cancer centers across the UK (27).

Conclusion

Patients with PC are often faced with few treatment options and a poor survival rate. By centralising PC services; chemotherapy rates and surgical resection rates have increased while operative mortality has decreased. Managing patients through these centers maximises current treatments but has not been enough to meaningfully raise the OS rates of patients with PC. As more effective treatments become available however, the regional MDTs will be ideally poised to deliver them.

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Table 1. Patient demographics, and the PC treatment, of all patients meeting the inclusion criteria

	Pre-centralisation n=1,581	Post-centralisation n=1,832	P (Pearson χ^2)
Gender			0.122
Male	771 (48.8%)	942 (51.4%)	
Female	810 (51.2%)	890 (48.6%)	
Age Group (years)			0.109
<50	68 (4.3%)	66 (3.6%)	
50-59	167 (10.6%)	161 (8.7%)	
60-69	374 (23.7%)	492 (26.9%)	
70-79	493 (31.2%)	553 (30.2%)	
80≥	479 (30.3%)	560 (30.6%)	
WIMD			0.002
1	396 (25.1%)	403 (22.0%)	
2	366 (23.2%)	354 (19.3%)	
3	293 (18.5%)	395 (21.6%)	
4	235 (14.9%)	296 (16.2%)	
5	291 (18.4%)	384 (21.0%)	
Chemotherapy	311 (19.7%)	496 (27.0%)	<0.001
Chemotherapy only	250 (15.8%)	377 (20.6%)	<0.001
Chemotherapy and surgical resection	40 (2.5%)	110 (6.0%)	<0.001
Surgical resection	97 (6.1%)	168 (9.2%)	<0.001
Surgical bypass	100 (6.3%)	65 (3.5%)	<0.001

Table 2. Patient demographics of patients undergoing surgical resection for PC.

	Pre-centralisation (n=97)	Post-centralisation (n=168)	P (Pearson χ^2)
Gender			0.890
Male	54 (7.0%)	95 (10.1%)	
Female	43 (5.3%)	73 (8.2%)	
Age group (years)			0.742
<50	8 (8.2%)	10 (5.9%)	
50-59	19 (19.6%)	31 (18.5%)	
60-69	42 (43.3%)	69 (41.1%)	
70-79	26 (26.8)	50 (29.8%)	
80≥	2 (2.1%)	8 (4.8%)	
WIMD			0.504
1	16 (4.0%)	33 (8.2%)	
2	24 (6.6%)	28 (7.9%)	
3	19 (6.5%)	39 (9.9%)	
4	15 (6.4%)	32 (10.8%)	
5	23 (7.9%)	36 (9.4%)	
Operative mortality			
30-day	7 (7.2%)	6 (3.6%)	0.186
90-day	11 (11.3%)	10 (6.0%)	0.118

380 **Table 3.** Multivariable proportional hazards analysis of patients with PC diagnosed
381 regression in 2004-2009 and 2010-2015.
382

	Hazard ratio	p
Gender		
Male	1.00 (reference)	
Female	0.924 (0.861,0.991)	0.027
Age		
<50	1.00 (reference)	
50-59	1.194 (0.960,1.059)	0.111
60-69	1.276 (1.047,1.556)	0.016
70-79	1.472 (1.209,1.791)	<0.001
80≥	1.588 (1.302,1.937)	<0.001
Study period		
Pre-Centralisation	1.00 (reference)	
Post-Centralisation	0.987 (0.920,1.059)	0.715
Chemotherapy		
No	1.00 (reference)	
Yes	0.519 (0.475,0.567)	<0.001
Surgery		
Not resected	1.00 (reference)	
Resected	0.448 (0.378,0.531)	<0.001

383 Values in parentheses are 95% confidence intervals
384
385
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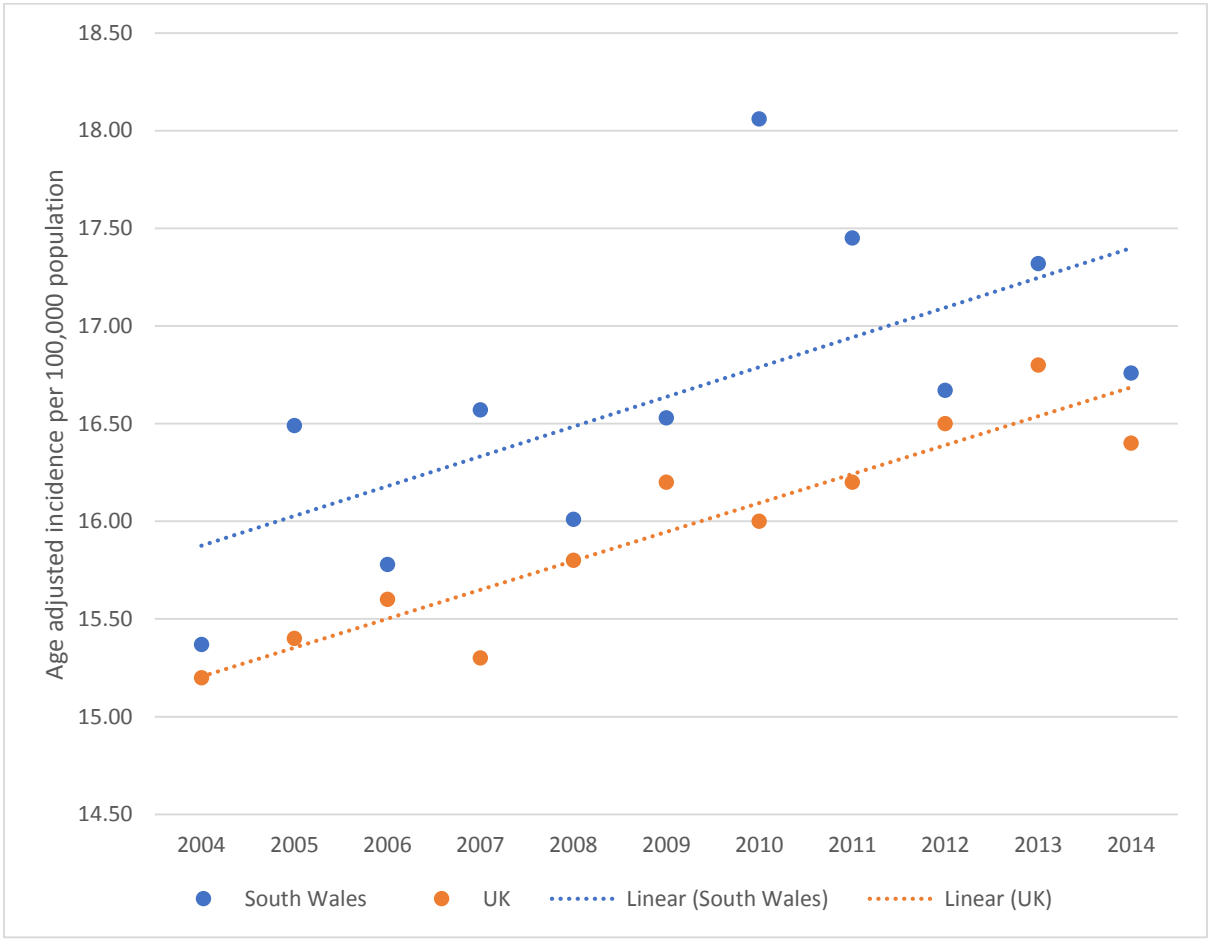
Figure 1. Age adjusted incidence of pancreatic cancer in South Wales and in the UK

Figure 2. Overall survival of all patients with pancreatic cancer by period of diagnosis (log rank test). **a**, All patients (p = 0.038), **b**, Resected patients (p = 0.764), **c**, Un-resected patients (p = 0.695).

Figure 3. Surgical resection and operative mortalities for patients with pancreatic cancer in South Wales, UK

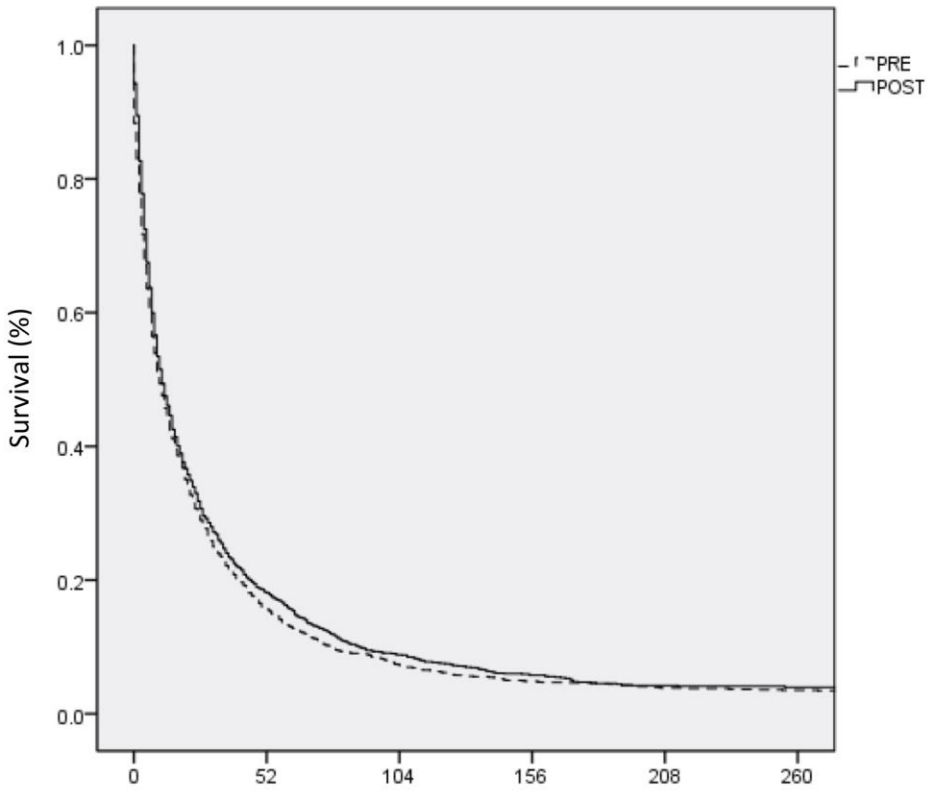
415 **Figure 1.** Age adjusted incidence of pancreatic cancer in South Wales and in the UK



416

Figure 2. Overall survival of all patients with pancreatic cancer by period of diagnosis. **a**, p = 0.038, **b**, p = 0.764, **c**, p = 0.695 (log rank test).

a, All patients



No at risk						
Pre-centralisation	1,581	250	112	77	60	55
Post-centralisation	1,832	333	161	106	79	73

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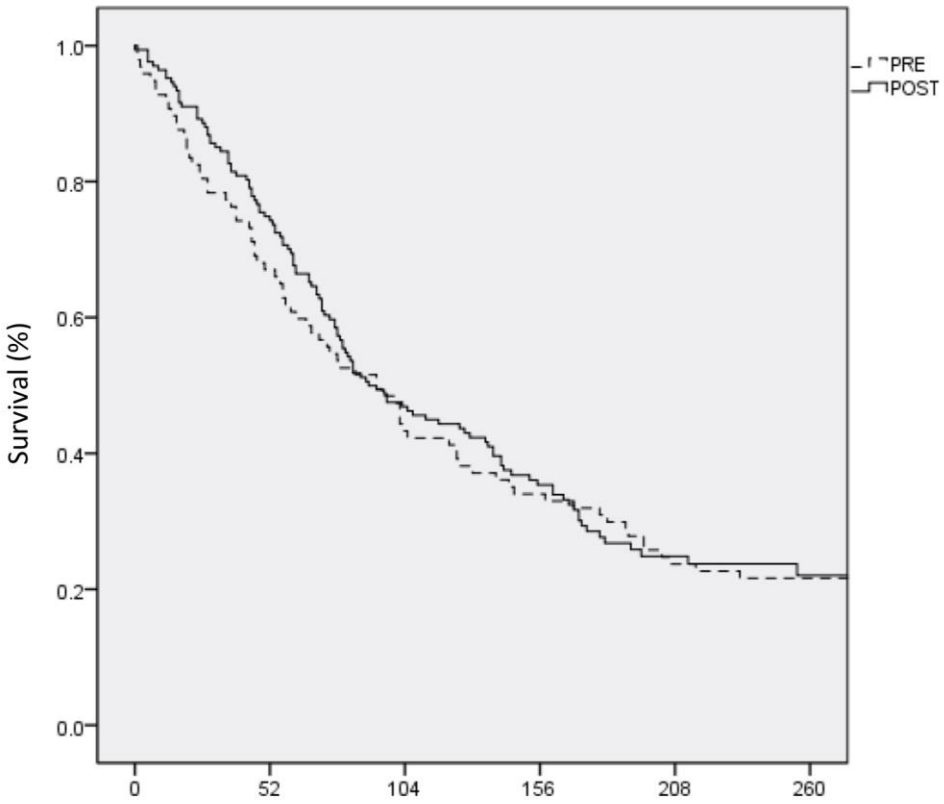
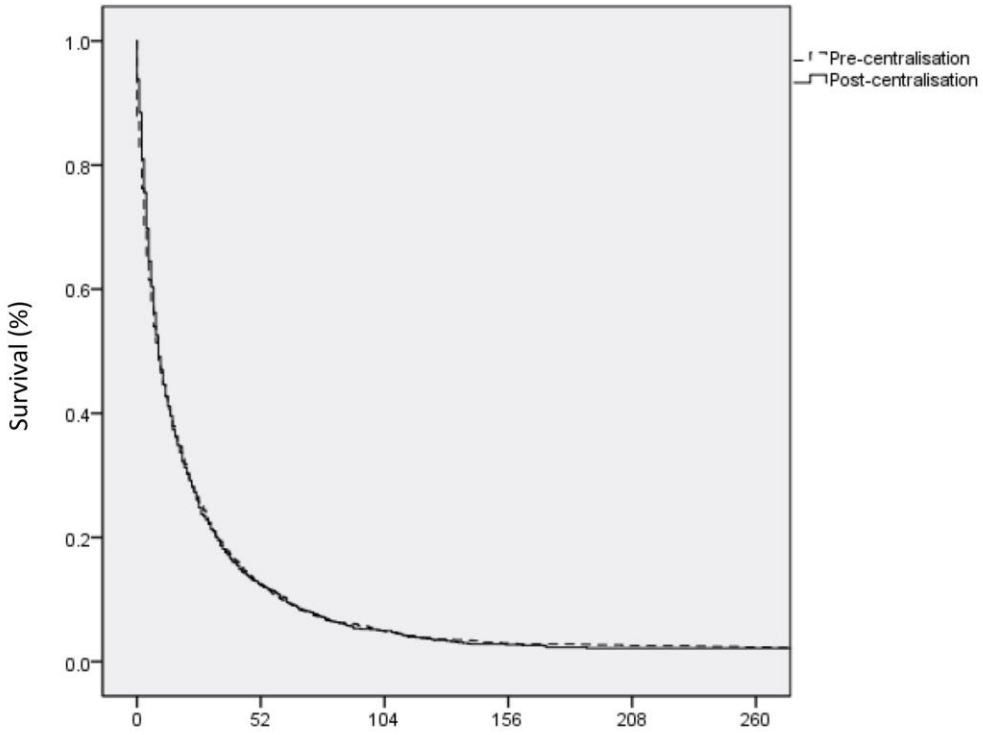
b, Resected patients



No at risk						
Pre-centralisation	97	65	42	33	23	21
Post-centralisation	168	126	79	59	42	37

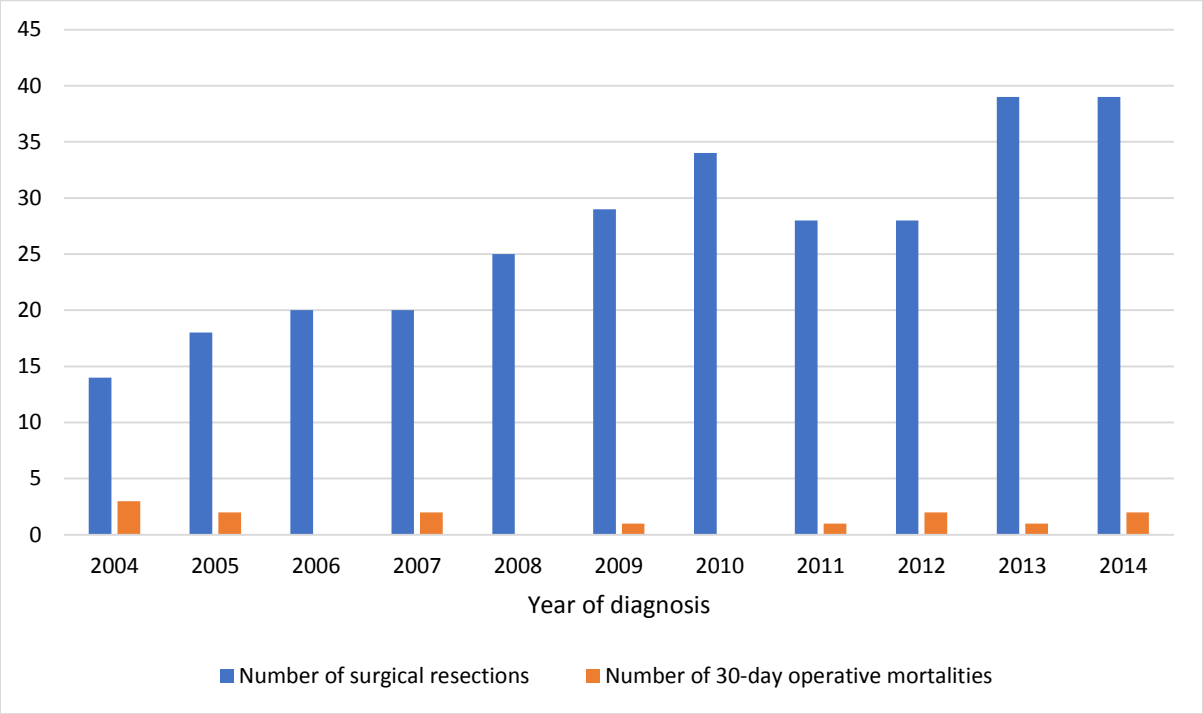
418

c, Un-resected patients



No at risk	Time from surgery (weeks)					
Pre-centralisation	1484	184	73	44	37	34
Post-centralisation	1664	208	83	45	37	37

Figure 3. Surgical resections and operative mortality of patients with pancreatic cancer in South Wales, UK



Appendix 1 - OPCS codes used in the SAIL Databank search

OPCS4.8 Code	Description
J27.1	Excision of ampulla of Vater and replantation of common bile duct into duodenum
J27.2	Partial excision of bile duct and anastomosis of bile duct to duodenum
J27.3	Partial excision of bile duct and anastomosis of bile duct to jejunum
J27.4	Partial excision of bile duct and end to end anastomosis of bile duct
J27.5	Excision of extrahepatic bile ducts HFQ
J27.8	Other specified excision of bile duct
J27.9	Unspecified excision of bile duct
J36.1	Excision of ampulla of Vater using duodenal approach
J36.8	Other specified other operations on ampulla of Vater using duodenal approach
J36.9	Unspecified other operations on ampulla of Vater using duodenal approach
J55.1	Total pancreatectomy and excision of surrounding tissue
J55.2	Total pancreatectomy NEC
J55.3	Excision of transplanted pancreas
J55.8	Other specified total excision of pancreas
J55.9	Unspecified total excision of pancreas
J56.1	Pancreaticoduodenectomy and excision of surrounding tissue
J56.2	Pancreaticoduodenectomy and resection of antrum of stomach
J56.3	Pancreaticoduodenectomy NEC
J56.4	Subtotal excision of head of pancreas with preservation of duodenum and drainage HFQ
J56.8	Other specified excision of head of pancreas
J56.9	Unspecified excision of head of pancreas
J57.1	Subtotal pancreatectomy
J57.2	Left pancreatectomy and drainage of pancreatic duct
J57.3	Left pancreatectomy NEC
J57.4	Excision of tail of pancreas and drainage of pancreatic duct
J57.5	Excision of tail of pancreas NEC
J57.8	Other specified other partial excision of pancreas
J57.9	Unspecified other partial excision of pancreas
G32.1	Bypass of stomach by anastomosis of stomach to transposed jejunum
G33.1	Bypass of stomach by anastomosis of stomach to jejunum NEC
G51.1	Bypass of duodenum by anastomosis of stomach to jejunum
G51.2	Bypass of duodenum by anastomosis of duodenum to duodenum
G51.3	Bypass of duodenum by anastomosis of duodenum to jejunum

G51.4	Bypass of duodenum by anastomosis of duodenum to colon
G51.8	Other specified bypass of duodenum
G51.9	Unspecified bypass of duodenum
G58.4	Partial jejunectomy and anastomosis of jejunum to ileum
G58.5	Partial jejunectomy and anastomosis of duodenum to colon
G58.8	Other specified excision of jejunum
G58.9	Unspecified excision of jejunum
J29.1	Anastomosis of hepatic duct to transposed jejunum and insertion of tubal prosthesis HFQ
J29.2	Anastomosis of hepatic duct to jejunum NEC
J30.1	Anastomosis of common bile duct to duodenum
J30.2	Anastomosis of common bile duct to transposed jejunum
J30.3	Anastomosis of common bile duct to jejunum NEC
J30.4	Revision of anastomosis of common bile duct
J30.8	Other specified connection of common bile duct
J30.9	Unspecified connection of common bile duct
X72.1	Delivery of complex chemotherapy for neoplasm including prolonged infusional treatment at first attendance
X72.2	Delivery of complex parenteral chemotherapy for neoplasm at first attendance
X72.3	Delivery of simple parenteral chemotherapy for neoplasm at first attendance
X72.4	Delivery of subsequent element of cycle of chemotherapy for neoplasm
X72.8	Other specified delivery of chemotherapy for neoplasm
X72.9	Unspecified delivery of chemotherapy for neoplasm
X73.1	Delivery of exclusively oral chemotherapy for neoplasm
X73.8	Other specified delivery of oral chemotherapy for neoplasm
X73.9	Unspecified delivery of oral chemotherapy for neoplasm
X74.1	Cancer hormonal treatment drugs Band 1
X74.2	Cancer supportive drugs Band 1
X74.8	Other specified other chemotherapy drugs
X74.9	Unspecified other chemotherapy drugs

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