http://dx.doi.org/10.1016/j.hpb.2017.06.010 HPB

ORIGINAL ARTICLE

Nationwide prospective audit of pancreatic surgery: design, accuracy, and outcomes of the Dutch Pancreatic Cancer Audit

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Abstract

Background: Auditing is an important tool to identify practice variation and 'best practices'. The Dutch Pancreatic Cancer Audit is mandatory in all 18 Dutch centers for pancreatic surgery.

Methods: Performance indicators and case-mix factors were identified by a PubMed search for randomized controlled trials (RCT's) and large series in pancreatic surgery. In addition, data dictionaries of two national audits, three institutional databases, and the Dutch national cancer registry were evaluated. Morbidity, mortality, and length of stay were analyzed of all pancreatic resections registered during the first two audit years. Case ascertainment was cross-checked with the Dutch healthcare inspectorate and key-variables validated in all centers.

Results: Sixteen RCT's and three large series were found. Sixteen indicators and 20 case-mix factors were included in the audit. During 2014–2015, 1785 pancreatic resections were registered including 1345 pancreatoduodenectomies. Overall in-hospital mortality was 3.6%. Following pancreatoduodenectomy, mortality was 4.1%, Clavien–Dindo grade $\geq$ III morbidity was 29.9%, median (IQR) length of stay 12 (9–18) days, and readmission rate 16.0%. In total 97.2% of >40,000 variables validated were consistent with the medical charts.

Conclusions: The Dutch Pancreatic Cancer Audit, with high quality data, reports good outcomes of pancreatic surgery on a national level.

Received 28 March 2017; accepted 22 June 2017

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Introduction

Monitoring quality of care has a long history in surgical practice.[1,2] The goal of measuring outcomes is usually to determine the optimal treatment by comparing interventions. Clinical auditing, however, aims at measuring and comparing outcomes of doctors or hospitals for a specific patient population. These results can then be used to improve current practice and increase transparency, which is increasingly demanded by society. Clinical auditing is increasingly being implemented throughout surgery, and prominent initiatives such as the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP) have already improved outcomes for patients.[3,4] Auditing is relevant especially to areas of surgery where there is much inter-hospital variation: in pancreatic surgery, differences in mortality between hospitals are among the highest.[5]

Performance indicators measure various aspects of the quality of care. Indicators are subdivided in structural, process, and patient outcome indicators. An example of a structural performance indicator is hospital volume. Process indicators are typically certain guideline recommendations. Patient outcomes may be divided into short-term (e.g. in-hospital mortality) or long-term (e.g. survival), subjective (e.g. quality of life), and intermediate (e.g. intra-operative blood loss) outcomes. Identifying the most important performance indicators is the main challenge of setting up an audit. Performance indicators should be relevant for the patient, have unambiguous definitions, and data collection should be straightforward. Fair comparison of performance indicators across hospitals (i.e. benchmarking) requires adjustment for differences in baseline characteristics. Therefore, baseline characteristics associated with performance indicators (e.g., tumor stage when comparing survival) should also be collected in the audit.[6,7]

Data collection for the mandatory Dutch Pancreatic Cancer Audit (DPCA) started in 2013. All patients undergoing surgical exploration for a suspected pancreatic or periampullary tumor in the Netherlands are included, as imposed by the Dutch Healthcare Inspectorate.[8] The DPCA aims to improve patient outcomes after pancreatic surgery by reducing practice variation and stimulating 'best practices'. In this study we describe the design, results, and validation of a nationwide evidence-based surgical audit in pancreatic cancer surgery.

Methods

Design of the audit

To identify relevant performance indicators and case-mix factors, a systematic literature search was conducted in PubMed in July 2011. Performance indicators and independent case-mix factors in pancreatic cancer surgery were identified by analyzing all randomized controlled trials (RCT's) and large case series ($n > 1000$) in pancreatic surgery published between 2000 and 2011 in core clinical journals. It was assumed that key performance indicators and case-mix factors are frequently reported by experts.

Performance indicators and case-mix factors found in these studies were cross-checked with existing registries. Data dictionaries of two foreign national audits (United Kingdom HPB audit, Swedish HPB registry), and the Dutch national cancer registry (NCR) were also scrutinized, as well as the prospective registries of three pancreatic centers: the Heidelberg University Hospital in Heidelberg (Germany), the Academic Medical Center in Amsterdam (the Netherlands), and Utrecht Medical Center in Utrecht (the Netherlands).

Next, the selection of the most frequently identified performance indicators and independent case-mix factors was based on a consensus process. The identified performance indicators and case-mix factors were first discussed with (inter)national field experts (see acknowledgements). The data model was developed hereafter in a plenary consensus with all members of the Dutch Pancreatic Cancer Group; the national multidisciplinary working group on pancreatic tumors with active members from all involved medical specialties including surgical oncology, medical-oncology, pathology, gastroenterology, radiology, dietary specialist, and nursing specialist. Formalized definitions were established and provided to the data collectors.

The DPCA includes all patients who are eligible for pancreatic surgery because of a (suspected) pancreatic- or periampullary tumor, or pancreatic cysts. Excluded are pancreatic resections for chronic pancreatitis, and pancreatic resections for tumors arising outside the pancreas. Patients discussed within a multidisciplinary team meeting, but not undergoing surgical exploration can be registered on a voluntary basis.

Governance

The DPCA is a collaboration of the Dutch Pancreatic Cancer Group (DPCG) and the Dutch Institute of Clinical Auditing (DICA) and endorsed by the Association of Surgeons of The Netherlands (Nederlandse Vereniging voor Heelkunde, NVvH).[9] The Dutch Pancreatic Cancer Audit has been implemented in all 18 centers performing pancreatic surgery in the Netherlands. The minimum requirement in the Netherlands is to perform at least 20 pancreatoduodenectomies annually per center. Each center is responsible for entering their own data. This is typically performed by a research fellow, study nurse, or surgeon. Ownership of the data remains with each individual center, each with a contract with the data processing agency (Medical Research Data Management; MRDM, Deventer, the Netherlands). The DPCG scientific committee supervises the data analysis and writes annual auditing reports. The data collected for auditing is also available for scientific research to all DPCA participants.

Results of the audit

Morbidity, mortality, length of stay, and readmission rate was examined in all patients undergoing pancreatic surgery in 2014

and 2015, and registered in the DPCA. Mortality was defined as in-hospital mortality. Overall morbidity consisted of all surgical and non-surgical morbidity. Major morbidity was defined as any Clavien–Dindo grade III or more morbidity.[10] Procedure specific complications were recorded according to the International Study Group on Pancreatic Surgery (ISGPS) definitions for postoperative pancreatic fistula (POPF), delayed gastric emptying (DGE), and post-pancreatectomy hemorrhage (PPH), respectively.[11–13] Clinically relevant (CR) complications were defined as grade B or grade C procedure specific complications. Length of stay was defined as the number of days between surgery, and initial discharge from the hospital. Readmissions were registered up to 30 days postoperatively. Additionally, assessment of a patient within a multidisciplinary team (MDT) meeting was noted. The influence of sex, age, procedure type and diagnosis on morbidity, mortality, length of stay, and readmission rate was analyzed. The number of surgical explorations was noted, which did not include diagnostic laparoscopy.

Data verification

Two trained auditors (MJZ and LBR) verified data entered for each pancreatoduodenectomy registered in 2014 and 2015. All participating centers were visited and all relevant medical charts were cross-checked with the audit data. Cross-checked baseline variables included length, weight, WHO performance status, neoadjuvant therapy, and comorbidities. Intra-operative variables included the use of minimally invasive surgery, vascular resection, additional resection(s), and drain placement. Complications included: mortality, morbidity, grading of morbidity as described by the International Study Group of Pancreatic Surgery (ISGPS) for postoperative pancreatic fistula,[11] post-pancreatectomy hemorrhage,[12] and delayed gastric emptying,[13] or by the International Study Group on Liver Surgery (ISGLS) for bile leakage.[14] Re-interventions (radiologic, surgical or endoscopic), ICU admission, and single- or multi-organ failure were also verified.

Each year, the Dutch Healthcare Inspectorate requests the number of performed pancreatoduodenectomies from each Dutch center regardless of indication (including benign disease, which is excluded from the DPCA). These data are published publicly online and were crosschecked to the number of pancreatoduodenectomies in the audit in 2014 and 2015.[15]

Statistical analysis

Dichotomous data were presented as proportions. Continuous data were presented as medians with interquartile range (IQR). Differences in binary postoperative outcomes were analyzed using Chi-square test. Unpaired t-test and one-way ANOVA were used in the comparison of postoperative length of stay between two groups, or more than two groups, respectively. P values of less than 5% were considered significant. Statistical analysis was performed using SPSS Statistics for Windows (Version 20.0; IBM, Armonk, NY).

Results

Performance indicators and case-mix factors

The literature search retrieved 16 RCT's,[16–31] and three large case series of pancreatic surgery.[6,7,32] A total of 112 individual performance indicators and 111 independent case-mix factors were identified from RCT's, case series and (inter)national registries. After multidisciplinary comments and international advice, 16 indicators and 20 case-mix factors were selected. The final selection of variables was implemented in June 2013 in all 18 pancreatic centers in The Netherlands. Performance indicators and case-mix factors in the audit are shown in Table 1. Performance indicators were categorized into morbidity, severity of morbidity, and clinical consequences. Morbidity was graded with

Table 1 Variables in the Dutch Pancreatic Cancer Audit: Performance indicators (A) and Case-mix factors (B)

A. Performance indicators	
Morbidity[a]	Postoperative pancreatic fistula (POPF),[b] delayed gastric emptying (DGE),[b] post-pancreatectomy hemorrhage (PPH),[b] bile leakage (BL)[c]
Clinical consequence	Mortality (in-hospital), re-interventions (radiologic, surgical, endoscopic), ICU admission, length of stay, 30-day readmission
Process indicators	Structured imaging (CT/MRI) report, structured pathology report, EUS for unexplained bile duct obstruction,[d] surgery within 3 weeks after final MDT meeting
B. Case-mix factors	
Patient history	Age, sex, BMI, ASA, ECOG/WHO performance status, comorbidity, other malignancy
Laboratory and imaging	CA 19-9, cTNM, MPD diameter, venous involvement on CT, arterial involvement on CT
Surgery and pathology	Margin status (R stage), tumor location, pancreatic texture, tumor diameter, pTNM, tumor histology, number of evaluated lymph nodes, number of positive lymph nodes, tumor grade

BMI, body mass index; ASA, American Society of Anesthesiologists; ECOG, Eastern Cooperative Oncology Group; WHO, World Health Organization; CA, carbohydrate antigen; CTNM, clinical TNM; MPD, main pancreatic duct; VPMS, vena porta mesenteric vein; CT, computed tomography; pTNM, pathology TNM; ICU, intensive care unit; ISGPS, International Study Group on Pancreatic Surgery; ISGLS, International Study Group on Liver Surgery.
[a] Graded by Clavien–Dindo.
[b] Graded by International Study Group on Pancreatic Surgery (ISGPS).
[c] Graded by International Study Group on Liver Surgery (ISGLS).
[d] If CT/MRI shows no tumor, as recommended by the Dutch guideline on pancreatic carcinoma.

the Clavien–Dindo scale, International Study Group of Pancreatic Surgery (ISGPS), and International Study Group on Liver Surgery (ISGLS).[10–14] Independent case-mix factors were categorized into patient history, laboratory and imaging, and surgery and pathology.

Results of the audit

A total of 2107 patients underwent a surgical exploration. Of all patients, 2016 (95.7%) patients had been discussed within a MDT meeting preoperatively. Of 2107 patients, 84.7% (1785 patients) underwent a pancreatic resection. Of these 1785 patients, 45.8% were female. The proportion of elderly (≥75 years) patients was 20.8%. Of patients undergoing pancreatic resection 75.5% (1347 patients) underwent pancreatoduodenectomy. Most patients (39.1%) were diagnosed with pancreatic adenocarcinoma, 24.6% were diagnosed with periampullary (distal bile duct, duodenum, ampulla) adenocarcinoma (Table 2). Other histopathologic diagnosis included mainly pancreatic neuroendocrine tumor (8.9%), intraductal papillary mucinous neoplasma (8.1%), and chronic pancreatitis (3.3%).

Postoperative outcomes following pancreatic resection for suspected malignancy are shown in Table 2 as well. In-hospital mortality following pancreatic resection was 3.6%. There was a significantly higher mortality among males (4.6%) compared to females (2.4%, p = 0.04). There was a significantly higher mortality with increasing age categories: 1.7% in patients aged <65 years, 4.0% in patients aged 65–74 years, and 6.5% in patients aged ≥75 years (p < 0.001). Mortality was significantly higher in patients with periampullary carcinoma (6.2%) compared to patients with pancreatic adenocarcinoma (3.2%), or another diagnosis (2.3%, p = 0.02).

Overall morbidity rate was 57.6% and the rate of Clavien–Dindo grade ≥ III morbidity was 27.3%. Major morbidity rate was higher in patients with periampullary carcinoma (36.5%), compared to patients with another diagnosis (25.8%) or patients with pancreatic adenocarcinoma (22.9%, p < 0.001). Pancreatoduodenectomy was the procedure type with highest rate of major morbidity (29.9%, p < 0.001) compared to distal pancreatectomy (17.2%) or other types of pancreatic resection (24.4%). A diagnosis of periampullary carcinoma was more often associated with major morbidity (36.5%) compared to pancreatic carcinoma (22.9%), or other diagnosis (25.8%, p < 0.001). In total, 231 (12.9%) patients had a grade B/C POPF, 114 (6.4%) a grade B/C PPH, and 250 (14.0%) patients a grade B/C DGE. These numbers were 175 (13.0%), 100 (7.4%), and 223 (16.6%) after pancreatoduodenectomy, respectively.

Median length of postoperative stay following pancreatic resection was 11 (IQR: 8–17) days. After PD median length of postoperative stay was 12 (IQR: 9–18) days and this was 8 (IQR: 6–11) days after distal pancreatectomy. Only type of procedure, but not sex, age category, or diagnosis predicted length of stay.

Readmission rate was 15.7% after pancreatic resection. Readmission rate was slightly higher following pancreatoduodenectomy (16.0%). Sex, age category, procedure type or diagnosis did not predict readmission rate.

Table 2 Postoperative outcomes after pancreatic resection for malignant and pre-malignant disease in the Netherlands, 2014–2015

	N	Mortality	P value	Overall morbidity	P value	Major morbidity[b]	P value	Length of stay (median days (IQR))	P value	Readmission	P value
All pancreatic resections	1785	64 (3.6%)		1028 (57.6%)		487 (27.3%)		11 (8–17)		281 (15.7%)	
Sex			0.04		0.13		0.003		0.11		0.30
Male	966	44 (4.6%)		575 (59.7%)		292 (30.2%)		11 (8–18)		162 (16.8%)	
Female	818	20 (2.4%)		453 (55.5%)		195 (23.8%)		11 (8–16)		119 (14.5%)	
Age			<0.001		0.22		0.91		0.16		0.15
<65 years	746	13 (1.7%)		420 (56.3%)		206 (27.6%)		10 (8–16)		124 (16.6%)	
65–74 years	667	27 (4.0%)		384 (57.8%)		178 (26.7%)		11 (8–18)		109 (16.3%)	
≥75 years	372	24 (6.5%)		224 (60.5%)		103 (27.7%)		13 (9–19)		48 (12.9%)	
Procedures			0.11		<0.001		<0.001		0.004		0.64
Pancreatoduodenectomy[a]	1347	55 (4.1%)		830 (61.9%)		403 (29.9%)		12 (9–18)		216 (16.0%)	
Distal pancreatectomy	319	5 (1.6%)		139 (43.6%)		55 (17.2%)		8 (6–11)		49 (15.4%)	
Other	119	4 (3.4%)		59 (49.6%)		29 (24.4%)		13 (8–19)		16 (13.5%)	
Diagnosis			0.02		<0.001		<0.001		0.15		0.45
Pancreatic adenoc.	698	22 (3.2%)		375 (53.7%)		160 (22.9%)		11 (8–16)		110 (15.8%)	
Periampullary adenoc.	439	27 (6.2%)		295 (67.2%)		160 (36.5%)		13 (9–20)		68 (15.5%)	
Other	648	15 (2.3%)		358 (55.7%)		167 (25.8%)		10 (7–16)		103 (15.9%)	

[a] Either classic Whipple or pylorus-preserving procedure.
[b] Defined as Clavien–Dindo grade ≥ III.

Data verification

In total, 42 179 variables were cross-checked with medical charts. A total of 1162 (2.8%) variables recorded in the audit was missing or different then recorded in the medical charts (Table 3). Type of procedure was incorrectly registered in 9.5% of cases, involving mainly whether or not the pylorus was preserved. In-hospital mortality was correctly registered in all patients.

Crosscheck with the inspectorate data revealed that >90% of performed pancreatoduodenectomies (1347 registered in the audit, compared to 1448 reported to the inspectorate) were included in the first two registration years.

Discussion

This study demonstrates the evidence-based design, outcomes and validation of the Dutch Pancreatic Cancer Audit as well as its governance structure. Accuracy, as determined by an internal audit was very high (97.2% variables correct), as well as case ascertainment with the Dutch healthcare inspectorate (>90% of all procedures registered). The outcomes of the first two full audit years reveal low in-hospital mortality, especially considering the nationwide level of these data: 3.6% for all pancreatic resection, 4.1% for PD, and 1.6% for distal pancreatectomy. Following pancreatic resection, major morbidity rate was 27.3% and median postoperative length of stay was 11 days.

The DPCA includes all 18 hospitals performing pancreatic surgery in the Netherlands, each performing a minimum of 20 PDs annually. It is a unique nationwide audit because it covers 100% of the population of 17 million. Other noticeable population based registries originate mainly from the U.S. including the Surveillance, Epidemiology, and End Results (SEER), Medicare, and NSQIP programs. While each includes a greater absolute number of patients and hospitals, coverage is far below 100%. For example, the SEER program includes only 28% of the total population and the Medicare database contains only patients aged over 65 years.[33,34]

Table 3 Data validation of all pancreatoduodenectomies registered in the Dutch Pancreatic Cancer Audit during 2014–2015

Variables verified	No. discordant values/no. values verified	Percentage discordant[b]
Baseline variables	514/25 593	2.0%
Comorbidities	307/20 205	1.5%
Intraoperative variables	332/8082	4.1%
Procedure type	123/1 298[a]	9.5%
Postoperative variables	316/8504	3.7%
Complication grading	134/3320	4.0%
Re-intervention scoring	71/830	8.6%
Mortality	0/1347	0.0%
TOTAL	1162/42 179	2.8%

[a] Operative notes were not retrievable in 49 (3.6%) cases.
[b] Discordant variables defined as missing or different than recorded in medical charts.

The nationwide in-hospital mortality rate after PD was 4.1%. Few other studies report population-based outcomes after pancreatic surgery. A NSQIP study reported 30-day mortality of 2.9% for PD.[33] Two notable other large population based reports from the U.S. reported in-hospital mortality rates of 6.6% and 7.9% for PD.[35,36] A recent study from Germany (n = 31 293, 2009–2013) reported a 7.7% in-hospital mortality rate after PD.[37] Other nationwide European reports are more than 10 years old, with reports from Belgium (n = 1794, 2000–2004), England (n = 1905, 2002–2005) and Italy (n = 1576, 2003) describing in-hospital mortality rates after PD of 8.4%, 5.7%, and 8.1% respectively.[38–40] Low mortality rates are reported from Asian countries. Nationwide reports from South-Korea (n = 4975, 2005–2008) and Japan (n = 10 652, 2007–2010) have reported in-hospital mortality rates after PD of 2.1% and 3.3%, respectively.[41,42] The relatively low mortality rate in the Netherlands, as compared to for example Germany, may be explained by the centralization of pancreatic surgery in the Netherlands which has lowered mortality.[43]

The rate of major morbidity (Clavien–Dindo score above III) in this study was 27.3%. Other registries show similar rates although different definitions were used. NSQIP has reported major morbidity rate of 24%.[44] Defined as Modified Accordion severity grade $\geq$3, in another study this was 27.8%.[45] Beside the obvious implications, postoperative morbidity also dominates costs.[46] The nationwide rate of grade B/C POPF was 12.9% (13.0% after pancreatoduodenectomy), comparable to other studies.[47,48] As of 2017, the DPCA will register the new definition and grading system of POPF.[48]

Median length of postoperative stay was 11 days. While high-volume centers are reporting a LOS in the 8-day range now,[49] previous population-based studies from the U.S. have reported a median postoperative length of stay of 13 days, compared to (older studies reporting) 18–23 days in Europe, or 30–40 days in Asia.[38,40,42,50,51] Enhanced recovery after surgery (ERAS) programs are rapidly being implemented worldwide.[52] Implementation of ERAS did not appear to be related to increased readmission rates; 16% in this study versus 20% in previous database studies.[36,49] Length of postoperative stay depends not only on the quality of care but also on local, cultural, and regional aspects.

In the current study, data on mortality was 100% correctly registered. Data accuracy was 97.2% for other indicators and covariates. These results compare favorably to other equivalents.[53,54] The high accuracy at validation is important because of potential criticism that data are entered in the DPCA by health care providers rather than by independent data managers. To guarantee high quality data in the future a formal data validation program will be launched involving trained independent data managers.

The DPCA will be further improved in the coming years. Patients will be involved in the selection of indicators,

comparable to the initiatives of the International Consortium for Health Outcomes Measurement (ICHOM).[55] Registration burden will be reduced by implementation of synoptic reports which we have developed for operation note, discharge letter, and pathology and radiology reports.[9] Real-time feedback to individual health care providers of their outcomes in will be introduced. Data sharing initiatives will allow the DPCA to be merged with the National Cancer Registry, hosted by the Netherlands Comprehensive Cancer Organization. This will establish extensive follow-up data, e.g. adjuvant chemotherapy.

Auditing may be seen as a PDCA (plan-do-check-act) cycle. First, quality of care is defined, for example an evidence-based guideline. Second, care is evaluated, i.e. is there compliance to various guideline recommendations and what are the patient related outcomes. Third, areas of lagging compliance are identified and changes are implemented to increase compliance. Furthermore, feedback on results is essential to the effect of auditing.[56] The main objective of the DPCA is not ranking hospitals based on performance indicators, but facilitate PDCA cycles in which best practices are identified and hospitals can learn from each other. The first transparent outcome indicators (mortality and serious complications) for the DPCA will be released in 2018, after appropriate case-mix adjustment.

This study presents the design, completeness, accuracy, and outcomes of an evidence-based nationwide surgical audit in Europe. Case ascertainment and accuracy of the audit was very high. Outcomes were good compared to other nationwide registries, but additional room for improvement remains. Future focus is on independent quality control and feedback systems to individual centers.

Collaborators

The Dutch Pancreatic Cancer Group is grateful for all multidisciplinary collaborators who supported the development of the Dutch Pancreatic Cancer Audit, including Thomas L. Bollen, MD PhD (department of Radiology, St. Antonius Hospital, Nieuwegein, The Netherlands); Marco J. Bruno, MD PhD (department of Gastroenterology, Erasmus Medical Center, Rotterdam, The Netherlands); G. van Tienhoven, MD PhD (department of Radiotherapy, Academic Medical Center, Amsterdam); A. Norduyn, MD PhD (pathologist, Dordrecht, The Netherlands). The Dutch Pancreatic Cancer Group is deeply indebted to our international collaborators and advisors D.P. Berry, MD PhD (Leicester General Hospital, Leicester, UK); B. Tingstedt, MD PhD (Skåne University Hospital, Lund, Sweden); J.F. Tseng, MD PhD (Beth Israel Deaconess Medical Center, Boston, MA); and C.L. Wolfgang, MD PhD (The Johns Hopkins School of Medicine, Baltimore, MD)

Acknowledgements

The Dutch Pancreatic Cancer Group wishes to thank the Dutch Institute for Clinical Auditing and the Netherlands Comprehensive Cancer Organisation for the collaboration.

Conflicts of interest and source of funding

No conflicts of interest. This research was partially funded by a grant from the Dutch Cancer Society (grant number UVA2013-5842)

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