

ORIGINAL ARTICLE

# Risk adjusted assessment of individual surgeon's pancreatic fistula outcomes

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## Abstract

**Background:** Post-operative pancreatic fistula (POPF) is a major cause of morbidity following pancreatoduodenectomy. The risk of POPF varies between individuals and thus assessment without risk adjustment is crude. However, despite the availability of numerous scores to determine risk, no study has provided a risk adjusted assessment of POPF outcomes.

**Methods:** The observed and risk adjusted occurrence of POPF from consecutive patients operated upon by eight surgeons were recorded. Surgeons varied in experience from newly appointed ( $n = 5$ ) to established ( $n = 3$ ). CUSUM (cumulative sum) analysis was used to assess performance.

**Results:** 104 POPF occurred among 519 patients (20.0%). The occurrence of POPF was significantly lower among experienced surgeons (20/186, 10.7% vs 84/333, 25.2%;  $p < 0.001$ ). Following risk adjustment surgeons observed 16.6 fewer to 6.5 excess POPF per 100 patients than predicted. Analysis of the CUSUM plots demonstrated the experienced surgeons performed steadily with a gradual reduction in observed POPF compared to what was predicted. The new surgeon's performance was less consistent and evidence of a learning curve was observed with steady improvement occurring after 50–70 patients.

**Conclusions:** Risk adjusted assessment of POPF demonstrates differences between experienced and less experienced surgeons. This method could be used to audit practice and observe effects of changes to technique.

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## Introduction

Pancreatoduodenectomy is associated with high levels of morbidity. Assessments of national datasets report post-operative mortality amongst 2–10% of patients.<sup>1–5</sup> A strong relationship exists between low volume centres and high post operative mortality.<sup>1–3,6,7</sup> Causes of excess mortality are multi factorial though the relationship between centre volume and mortality place institutions and the individuals working there in the spot light. In a move towards greater transparency NHS England is to report surgeon-specific mortality amongst various

medical and surgical specialities.<sup>8</sup> Pancreatoduodenectomy is yet to be scrutinised in terms of surgeon-specific mortality.

Surgery is a complex practical skill that requires amongst other things experience, insight, judgement and technical ability; this is particularly relevant among patients undergoing pancreatoduodenectomy where post operative pancreatic fistula (POPF) is both common and a major factor related to both morbidity and mortality.<sup>9</sup> Evidence that this procedure and complication is related to aspects of surgical technique is provided by the numerous clinical trials of surgical anastomotic technique. However, there are many variables that relate to POPF and consequently an individuals risk of POPF varies greatly dependent upon these. There are several scores available to predict

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POPF; one such score was validated in a multicentre UK cohort.<sup>10</sup> This score has advantages that it requires just two variables to determine risk and can be determined using pre-operative data. Despite wide variation in POPF risk, availability of scores to determine risk of POPF and an interest in using POPF to assess the success of surgery to date no study has reported risk adjusted outcomes of POPF.

The aim of this study was to explore the potential utility of using a POPF risk score to risk adjust and compare outcomes after pancreatoduodenectomy between surgeons with the hypothesis being that performance should differ between surgeons of varying experience.

## Methods

Consecutive patients undergoing pancreatoduodenectomy for any indication between September 2007 and May 2017 were identified from a prospectively maintained institutional database. Eight surgeons were operating at the end of the study period. These surgeons comprised of 3 who were already established consultant surgeons at the start of the study period or when they joined the department during the study period (Surgeons A to C having been consultant surgeons for 15, 15, 10 years prior to participation in the study); there were 5 surgeons who were appointed to the unit during the study period without prior experience of performing pancreatoduodenectomy as consultant surgeons (Surgeons D to H). Surgeons who had retired, moved or who were with the team temporarily were excluded, largely because numbers of operated patients were small.

There was no directed allocation of patients between surgeons with an equitable sharing of patients from referrals to the team.

## Surgical technique

The nature of the pancreaticoenterostomy was at the discretion of the operating surgeon with all routinely performing pancreatojejunostomy (PJ). None of the experienced surgeons A to C changed their technique over the study period. Surgeon A performed a single layer continuous PJ; surgeons B, D and E a two layer interrupted anastomosis with the outer layer set back from the pancreatic cut surface and the inner layer to the cut surface and duct mucosa; surgeon C a single layer continuous anastomosis approximately one to two centimetres back from the cut surface of the pancreas to create a 'dunk' with placement of a short 6 or 8 French stent. Three of the newly appointed surgeons used more than one technique over the study period. Surgeon F initially performed an interrupted duct to mucosa PJ but changed to a single layer continuous pancreaticogastrostomy and finally to the same technique as surgeons B, D and E. Surgeon G initially performed an interrupted duct to mucosa PJ but changed to the technique of surgeons B, D and E and finally to the technique of surgeon C. Surgeon H did not change his technique over the study period but used two different techniques dependent upon his assessment of the intraoperative

findings. For patients where he assessed the risk of POPF to be low he performed a single layer end to side duct to mucosa interrupted PJ. For patients where he considered patients to be at high risk of POPF (narrow pancreatic duct and soft texture) he performed a two layer end to side duct to mucosa PJ with the outermost layer of sutures at the cut surface of the pancreas. These techniques and relationship to POPF are shown in the Figs. 1–3 and described in detail below.

The team perform pylorus preserving resections when possible. Venous resection was performed at the discretion of the operating surgeon. Hepaticojejunostomy was routinely performed with continuous 5.0 absorbable sutures and enteroenterostomy with one layer continuous 3.0 absorbable sutures to the same limb as the PJ.

All surgeons place one 28 French tube drain behind the hepaticojejunostomy and pancreaticoenterostomy. Surgeon G added a Jackson Pratt drain during the study period. This was wrapped around the pancreatic anastomosis.

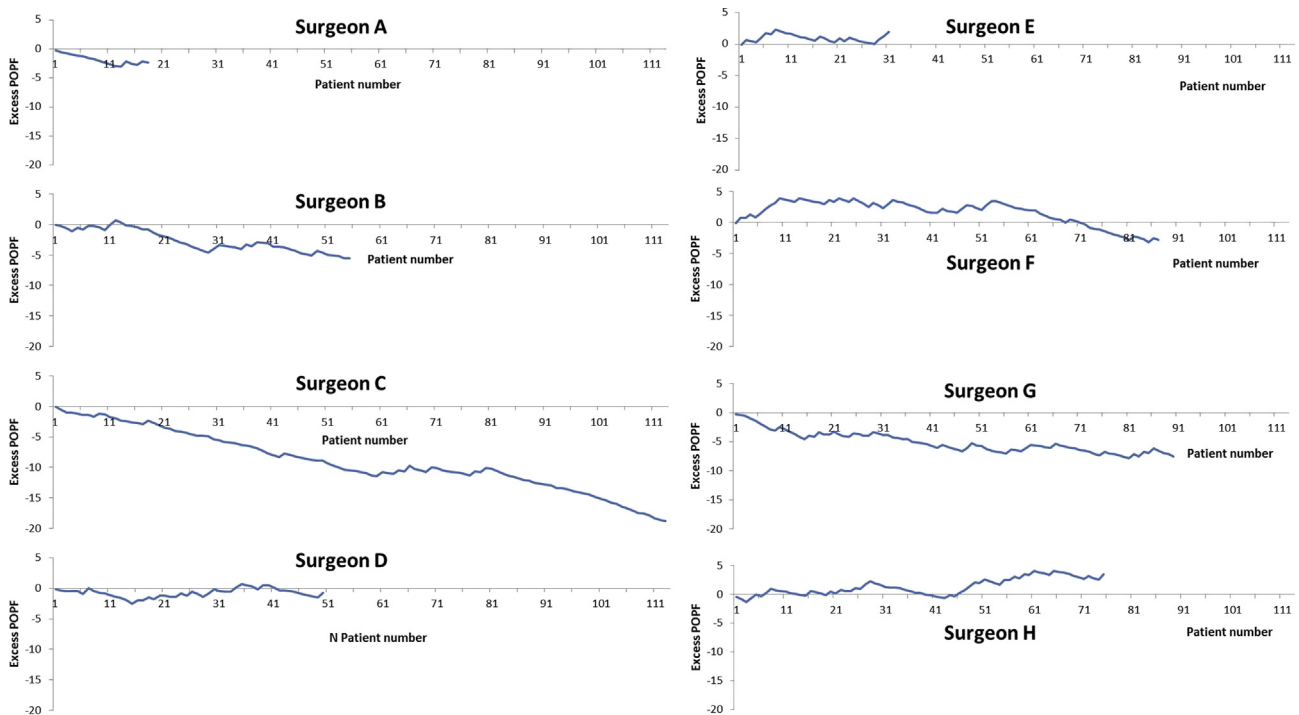
All patients received peri- and postoperative somatostatin analogues and were treated as part of a departmental enhanced recovery program<sup>11</sup> which was implemented in 2011. Prior to this time enteral feeding was instigated when drain fluid amylase levels were <300u/L at or after post operative day five. After 2011 drain fluid amylase was assessed on post operative day 1, 3 and 5. Patients began eating when the drain fluid amylase was <300u/L at the first time point. Drains were removed if the amylase was low at day 3. Nasojejunal feeding tubes were placed at the time of surgery and nasoenteric feeding instigated immediately post surgery until oral nutrition was established.

## POPF analysis

The score used to quantify a patients risk of POPF in this study utilises their body mass index and pancreatic duct width being based upon multivariable logistic regression<sup>12</sup> and subsequently modified following multicentre validation.<sup>10</sup> It is reported as a continuous variable with risk presented as a value between 0 and 1. A web based calculator is available for use (<http://www.uhb.nhs.uk/preoperative-prediction-of-pancreatic-fistula-calculator.htm>).

Cumulative sum (CUSUM) analysis has since been used to monitor the outcomes of surgical procedures.<sup>13,14</sup> It transforms raw data and cumulates an observed deviation from the expected outcome with sequential procedures. Patients were ordered chronologically and for each a predicted risk of POPF were calculated. The observed outcome (POPF or no POPF) was then plotted with a positive value in the case of a POPF (1 minus predicted risk of POPF) or negative value in the case of no POPF (0 minus predicted risk of POPF). This recursive process was repeated so the overall difference in expected versus observed POPF could be identified by the value on the y axis.

POPF was identified prospectively and defined according to the International Study Group on Pancreatic Surgery definitions.<sup>15,16</sup> To standardise the recording of POPF, all POPF prior



**Figure 1** Individual surgeons CUSUM plots for post operative pancreatic fistula during the study period (surgeons A–C experienced; surgeons D–F newly appointed during the study period)

to the recent modification of the definition, were reclassified in line with the more recent definition.<sup>16</sup>

### Statistical analysis

Data describing the cohorts is expressed as the median (interquartile range), or as a number and percentage, with Mann–Whitney and Fisher's exact tests used to compare between patients with and without POPF.

All analyses were performed using IBM SPSS 21 (IBM SPSS Inc.), with  $p < 0.05$  deemed to be indicative of statistical significance. A medical statistician provided advice during study design and performed the CUSUM analyses (JH).

### Results

Some 519 patients underwent pancreatoduodenectomy during the study period. Of these, 186 and 333 were operated upon by the three experienced and five new surgeons respectively.

Characteristics of the cohort are summarised in Table 1. Patients operated upon by new surgeons were older and more likely to be smokers or undergo a pylorus preserving resection. Importantly there was no difference in BMI and pancreatic duct width between patients operated upon by new or experienced surgeons given that these are the components of the POPF risk score. The increased age and non-smoking habit of the patients operated upon by new surgeons likely reflects a change in practice over time given that the median age of patients has

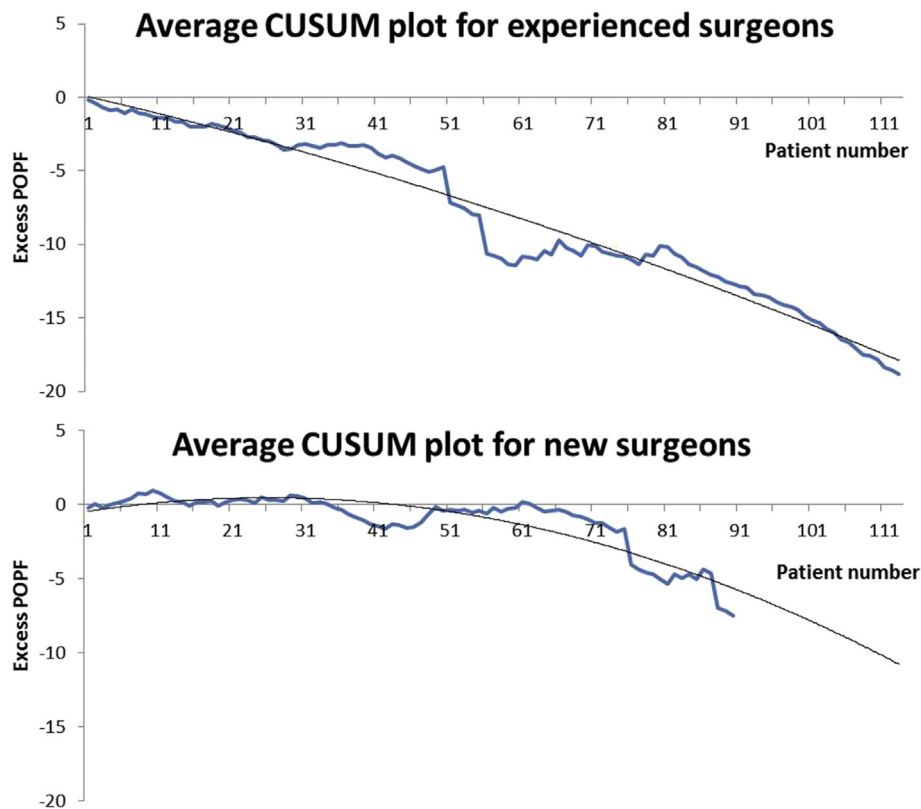
increased over time (during the first and last 2 year periods of the study the median age of the patients were 66.6 and 68 respectively); similarly patients were more likely to be smokers early in the study period (data not shown); only experienced surgeons were operating at the start of the study period.

### Post-operative pancreatic fistula

Among 104 patients with a POPF (20.0%) 44, 36 and 24 were classified as ISGPF grades biochemical leak, B and C respectively (Table 2). There was no significant difference in the proportion of patients with expected POPF based upon the predictive POPF score between the 'new' and 'experienced' surgeons. However, there was a significant difference in the observed rate of POPF (new  $n = 84$ , 25.2% vs experienced  $n = 20$ , 10.7%;  $p = 0.001$ ). Interestingly, there was no significant difference in the distribution of grades of POPF or of clinically significant POPF between patients operated upon by new or experienced surgeons (Table 2). There was no significant difference in 90 day mortality between surgeons. Though experienced surgeons had lower rates of POPF they were significantly more likely to let a trainee perform part or the entire pancreatic reconstruction than new surgeons.

### Individual surgeon's performance

The estimated expected and observed rates of POPF varied from 24.2 to 28.5 and 8 to 32.3 POPF per 100 patients respectively (Table 3). The risk adjusted (observed – expected) rate of POPF



**Figure 2** These figures represents the mean CUSUM plots for experienced ( $n = 3$ ) and new ( $n = 5$ ) surgeons together with polynomial trend lines. Experienced surgeons appear to demonstrate consistent performance with a trend line that is nearly linear and a steady reduction in the observed: expected rate of POPF. New surgeon's performance is more erratic and it takes around 50 patients for the trendline to drop below 0 or 67 patients for the CUSUM to drop consistently below 0; after this point performance seems to improve with a gradual reduction in the observed: expected rates of POPF

varied from 16.6 fewer POPF to 6.5 more POPF per 100 patients than expected.

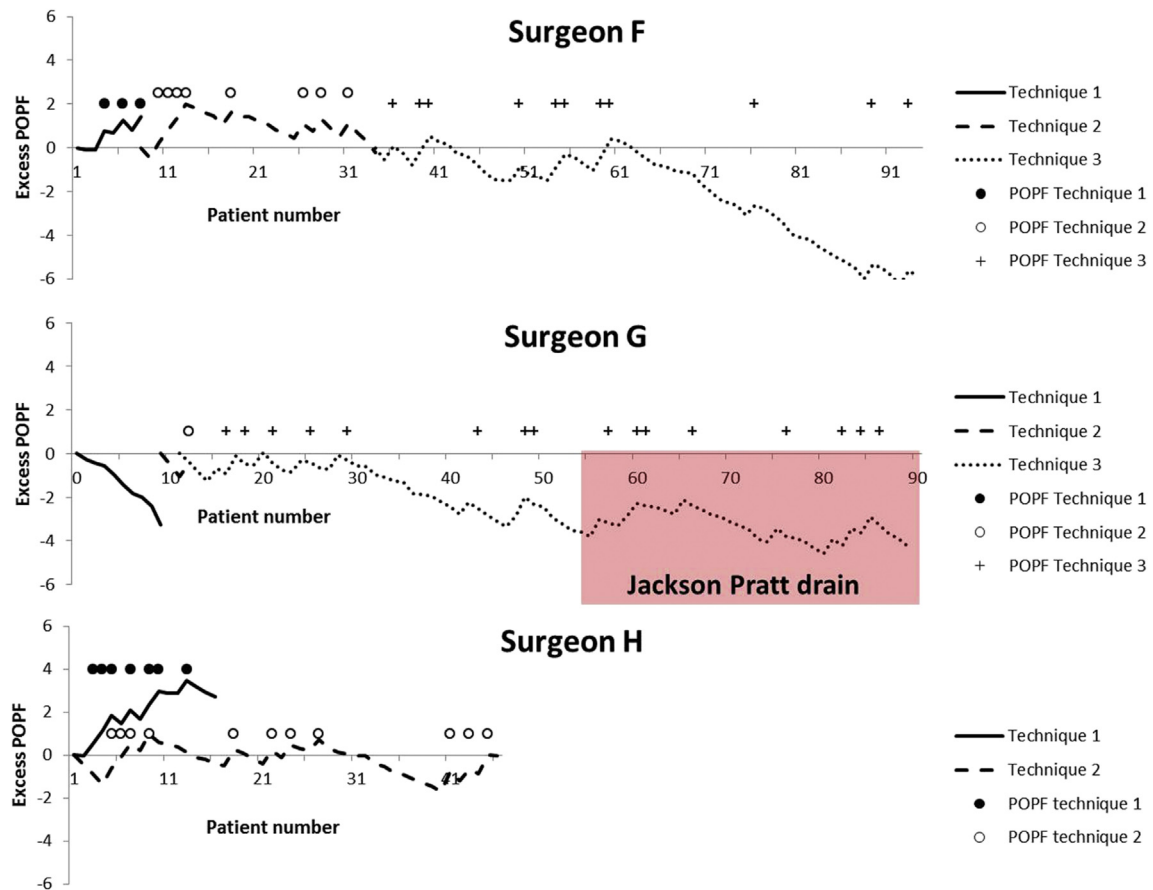
A review of CUSUM plots demonstrates different characteristics in the risk adjusted occurrence of POPF between patients operated upon by new or experienced surgeons (Figs. 1, 2). Fig. 1 demonstrates individual surgeons performance and it can be seen that experienced surgeons tend to display consistent practice in that the CUSUM plots tend to be more linear and less erratic than those of the new surgeons. A review of the combined CUSUM plots for new and experienced surgeons (Fig. 2) is suggestive of a learning curve. The number of risk adjust POPF began to fall consistently after 67 operated cases; the trend line suggests this may occur after around 50 patients.

### Changes in surgical technique and POPF

Using CUSUM analysis the effect of changing technique or practice upon POPF can be observed. Three of five new surgeons used at least two techniques whilst none of the experienced surgeons changed their technique over the study period; these details are shown in Fig. 3.

### Discussion

This is the first observational study to report individual surgeons risk adjusted post-operative pancreatic fistula (POPF) rates following pancreatoduodenectomy with CUSUM analysis. Risk adjustment was performed using an externally validated predictive score of POPF<sup>10</sup> which controlled for variables affecting POPF occurrence. The main finding was that experienced surgeons with many years of clinical practice demonstrated consistent good performance with an observed rate of POPF below which was expected. Five surgeons who had been appointed during the study period and without prior experience of performing pancreatoduodenectomy as a consultant were used as a comparison and they displayed less consistent performance with more variation in the occurrence of POPF and an observed rate of POPF much closer to the predicted rate of POPF occurrence than the experienced surgeons. Risk adjusted analyses of surgeon and institution POPF rates has been reported previously by the North American group using the Fistula Risk Score where variation was observed.<sup>17</sup> However, in that study clinical



**Figure 3** Effect of change of technique over time. The combination of the POPF risk score and CUSUM analysis can be used to observe how changing technique affects outcome. Three surgeons, all new, used more than one technique during the study period. All other surgeons did not change their technique

experience of the surgeons was not described and CUSUM analyses not used. What is therefore clear is that risk adjustment is possible using validated scores of POPF.

A review of practice and outcomes offers insights not possible without risk adjustment. Two of the new surgeons changed their technique of pancreatic reconstruction a total of four times during the study period, though only one change followed an actual excess of observed POPF. This suggests a lack of objective assessment into their performance and perhaps a desire to try different techniques regardless of actual outcomes. A further observation comes from the one surgeon who chose two different techniques dependent upon his intraoperative assessment of POPF risk based upon characteristics of the gland (surgeon H). As expected he experienced more POPF when operating on high risk glands; however, with risk adjustment an excess of POPF remained. The technique on high risk glands was performed less frequently than the other technique (24 vs 52). Perhaps the observed rates of POPF for this surgeon relate to his experience with each technique.

It is interesting to observe that when new surgeons switched to the same anastomotic techniques used by the experienced

surgeons the number of risk adjusted POPF did not improve to the same degree as that of the experienced surgeons. This suggests that it is not simply the adoption of one technique or another but perhaps the experience over ones career that more strongly influences surgical performance. This is important for the conduct of surgical trials of technique – one may not be able to simply assume that adopting techniques shown to be associated with low rates of POPF from a clinical trial will translate into similar outcomes – and that it is important that surgeons who take part in clinical trials use studied techniques with enough frequency to overcome any related learning curve otherwise results are likely to be biased towards favouring the technique they are most used with.

Although there are limited numbers of newly appointed surgeons within this study a review of the cumulative experience of the new surgeons suggests that a learning curve exists between around 50 to 67 patients. After this point a steady state of performance appears to be achieved.

A recent systematic review identified studies reporting the effect of self-assessment upon surgical performance.<sup>28</sup> All but one study used trainees and was based upon laboratory or animal

**Table 1** Summary of the whole cohort and of those patients operated upon by new or experienced surgeons

	All patients n = 519	New surgeons n = 5; patients n = 333	Experienced surgeons n = 3; patients n = 186	P value new vs experienced <sup>a</sup>
Age (median, range)	68, 20-87	67, 20-81	69, 31-87	<b>0.001</b>
Gender (male, %)	282, 54.3%	102, 54.8%	180, 54.0%	0.927
BMI (median, range)	25.3, 15.6–45	25.4, 16.4–40.5	25.3, 15.6–45.0	0.469
Jaundice (n, %)	416, 80.1%	143, 76.9%	273, 82.0%	0.170
Biliary stent (n, %)	301, 58%	110, 59.1%	191, 57.4%	0.711
Neoadjuvant therapy (n, %)	11, 2.1%	4, 2.1%	7, 2.1%	1.00
CCI (median, range)	2, 0-6	2, 0-6	2, 0-6	0.273
Smoker (n, %)	61, 11.8%	29, 15.6%	32, 9.6%	<b>0.047</b>
PPPD/Whipple (n, %)	479/40, 92.3%	165/21, 88.7%	314/19, 94.2%	<b>0.026</b>
PJ/PG (n, %)	482/37, 92.9%	173/13, 93.0%	309/24 92.8%	1.00
Venous resection (n, %)	86, 16.6%	28, 15.0%	58, 17.4%	0.454
Width PD (median, range)	4, 0-24	4, 0-12	4, 0-24	0.277
Pathology (n, %)				0.485
Pancreatic adenocarcinoma	255, 49.1%	168, 50.4%	87, 46.8%	
Ampullary cancer	103, 19.8%	58, 17.4%	45, 24.2%	
Cholangiocarcinoma	52, 10%	37, 11.1%	15, 8.1%	
Duodenal cancer	27, 5.2%	17, 5.1%	10, 5.4%	
Neuroendocrine tumour	20, 3.9%	14, 4.2%	6, 3.2%	
Benign/other	62, 11.9%	39, 11.7%	23, 12.4%	

BMI – body mass index, CCI – charlson comorbidity index, PPPD – pylorus preserving pancreatoduodenectomy, PJ – pancreatojejunostomy, PG – pancreatogastrostomy, PD pancreatic duct.

<sup>a</sup> Mann Whitney or Chi square analyses.

models to assess their technical ability. One study assessed ‘experts’ performance at laparoscopic cholecystectomy using hierarchical task analysis to review live operations.<sup>29</sup> It thus appears that established surgeons do not participate in critical self-assessment of surgical technique in ways that have been subject to scientific analysis. The use of a risk adjusted POPF score could be used by surgeons to audit outcomes over their career and critically evaluate effects of changes to technique. It is however difficult to quantify the exact contribution of the surgeon to development of POPF. In every published risk score, not once

has the surgeon been considered a variable within the studied models. One strategy to define this would be to include surgeons within the development of prediction models but, as shown here, there is a learning curve so the magnitude of impact would change over time. A more pragmatic solution would be the development of a database where surgeons input their outcomes. If that database was large enough (and the number of prior procedures the surgeon had performed was known) a more critical analysis of the role of the surgeon upon POPF could be performed. Such a database would allow critical self-analysis of

**Table 2** Summary of post operative pancreatic fistula (POPF)

	All patients n = 519	New surgeons n = 5; patients n = 333	Experienced surgeons n = 3; patients n = 186	P value new vs experienced <sup>a</sup>
POPF risk score (median, range)	0.254, 0.001–0.557	0.266, 0.001–0.557	0.230, 0.03–0.538	0.152
Expected POPF (n, %)	136, 26.3%	90, 26.9%	47, 25.1%	0.740
Observed POPF (n, %)	104, 20.0%	84, 25.2%	20, 10.7%	<b>&lt;0.001</b>
POPF Biochemical leak/B/C	44/36/24	35/30/19	9/6/5	0.891
POPF B/C (n, % of all POPF)	60/104, 57.7%	49/84, 58.3%	11/20, 55.0%	1.00
Trainee performed anastomosis	67, 12.9%	17, 5.4%	50, 36.8%	<b>&lt;0.001</b>
90 day mortality	22, 4.2%	15, 4.5%	7, 3.8%	0.92

<sup>a</sup> Mann Whitney or Chi square analyses.

**Table 3** Individual surgeons experience and occurrence of post operative pancreatic fistula (POPF)

	Experienced surgeons			New Surgeons				
	A	B	C	D	E	F	G	H
N Pancreatoduodenectomy	18	55	113	50	31	87	90	75
Observed POPF	2	9	9	12	10	22	17	23
Expected POPF based on POPF score	4.4	14.6	27.8	12.7	8	24.8	24.5	19.5
Observed POPF (per 100 patients)	11.1	16.4	8	24	32.3	25.3	18.9	30.7
Expected POPF (per 100 patients) <sup>a</sup>	24.4	26.5	24.6	25.4	25.8	28.5	27.2	26
Risk adjusted POPF/100 patients <sup>b</sup>	-13.3	-10.1	-16.6	-1.4	6.5	-3.2	-8.3	4.7
Observed grade BL POPF per 100 pts	5	4	5	4	10	12	5	21
Observed grade B + C POPF per 100 pts	6	12	3	20	19	13	14	10
Trainee performed anastomosis	0, 0%	9, 16.4%	41, 36.7%	5, 10%	0, 0%	4, 5.3%	8, 8.9%	0, 0%
90 day mortality	0, 0%	2, 3.6%	5, 4.4%	3, 6%	1, 3.2%	6, 6.9%	2, 2.2%	3, 4%

<sup>a</sup> Expected POPF rates derived from use of the POPF risk score. To provide comparison between surgeons observed and expected rates of POPF were also estimated upon each surgeon operating upon 100 patients.

<sup>b</sup> Risk adjusted POPF is the observed number of POPF minus expected rate of POPF. BL – biochemical leak.

performance. Such performance data could be used to inform patients or healthcare providers of a surgeon's performance. However, given that learning curves are necessary and there is no proven way to reduce the learning curve associated with pancreatoenteric anastomoses, the authors would not support the use of these analyses for this purpose. Rather than encourage surgeons to conduct critical self-evaluation this system could serve as a barrier to its use if it is perceived as a threat. Whether this system should be used to report outcomes among established surgeons is open to debate but critical self-evaluation should be part of a surgeons practice. Establishing a freely accessible database would permit this.

The use of POPF, as a measure of surgical performance, is attractive for several reasons. Firstly, its occurrence is roughly 6–10 times more frequent than mortality; a recent analysis of prospective studies reported POPF using the ISGPF definition among 25.5% of patients undergoing pancreatoduodenectomy.<sup>25</sup> POPF is strongly related to subsequent adverse outcomes including mortality<sup>9,26</sup> and is therefore an excellent measure of surgical performance and is clinically relevant. Furthermore, by adjusting for the effect of patient variables related to POPF, its occurrence should not be affected by factors other than surgical technique. POPF risk has also been related to the volume of intraoperative haemorrhage.<sup>27</sup> It is difficult to avoid the assumption that better surgical technique should be associated with both reduced rates of POPF and intraoperative haemorrhage. Indeed, a root cause analysis of perioperative deaths following pancreatoduodenectomy concluded that risk prediction should emphasise operative factors.<sup>9</sup> In that study, operation-related complications and POPF were identified as the two most important factors related to mortality. That in-depth analysis of causes of death clearly supports assessment of POPF as an important surgical outcome following pancreatoduodenectomy. Mortality however, as a marker of surgeons

performance, is affected by factors outside of the control of the surgeon such as anaesthesiology, intensive care, radiology and the management of sepsis and by a lack of adequate risk adjustment. General surgical models for risk adjustment such as POSUM<sup>9</sup> are very poor and although more recent procedures specific models have been developed<sup>4,22–24</sup> they lack validation and though perform better than general surgical models they lack discriminatory power. In a study of 184 post-pancreatoduodenectomy deaths the vast majority of patients who died (94%) were not predicted to do so.<sup>9</sup>

There are clear limitations of this study. This is a single centre study and it would be desirable to observe/validate the potential utility of this method in other centres. Colleagues were invited but data was not forthcoming. Reasons for this were not explored. The score used to perform risk adjustment was designed at this centre and so is expected to perform strongly in the current study cohort; the score itself was validated in a multicentre cohort but nevertheless validation of this method in other centres is required and validation between countries cannot be guaranteed to be successful. There is no evidence that critical analysis of POPF occurrence will be of any practical use. However, it would be hoped that if a surgeon were to critically appraise their risk adjusted performance their outcomes would continue to evolve accordingly rather than simply by accumulating practical experience over their career. Whether improvement would increase more rapidly by permitting critical self-appraisal remains to be seen.

In conclusion this study demonstrates the application of a risk adjusted analysis of POPF occurrence as a potential way to assess surgeons performance after pancreatoduodenectomy. This study also suggests there is a learning curve of around 50 cases before surgeons outcomes steadily improve and that is experience more than technique which determines POPF after PD. Use of this score with risk adjustment could help surgeons critically appraise

their outcomes and monitor effects of changes to their practice over their career.

Three surgeons, all new, changed their technique of pancreaticoenterostomy during the study period. Surgeon F changed his technique after 3 occurrences of POPF occurred within his first 7 patients (risk adjusted CUSUM = 1.4; 20 per 100 patients). After 26 further patients and 7 occurrences of POPF (risk adjusted CUSUM = 0.2; 0.8 per 100 patients) he changed again and observed 11 POPF amongst 61 patients (risk adjusted CUSUM = -5.8; -9.5 per 100 patients). Surgeon G changed his technique after operating upon 9 patients despite having no POPF (risk adjusted CUSUM = -3.3; -36.3 per 100 patients) and then again after another 3 patients after a severe occurrence of POPF (ISGPF grade C) (risk adjusted CUSUM = -0.5; -16.5 per 100 patients). He then continued with the third technique amongst the remaining 79 patients observing 16 cases of POPF (risk adjusted CUSUM = -4.3; -5.4 per 100 patients). During this third technique, after 46 patients (risk adjusted CUSUM = -3.3; -7.7 per 100 patients) he added a Jackson Pratt drain wrapped around the pancreatic anastomosis. For the 33 subsequent patients the risk adjusted CUSUM was -1.1 (-3.3 per 100 patients). Surgeon H did not change over the study period though used two different anastomoses depending on his intra-operative assessment of POPF risk observing 13 POPF amongst 24 patients deemed high risk (risk adjusted CUSUM = 5.9; 24.6 per 100 patients) and 10 POPF amongst 52 patients he deemed low risk (risk adjusted CUSUM = -2.4; -4.8 per 100 patients).

#### Conflicts of interest

The authors have not received any research funding and declare have no conflicts of interest. Reprints should be addressed to the corresponding author.

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