Systematic evaluation of radiological findings in the assessment of resectability of peri-ampullary cancer by CT using different contrast phase protocols

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Abstract

Aims: To determine the relative significance of radiological signs in determining the resectability of peri-ampullary cancer (PC) and to assess the value of multi-phase imaging in detecting these findings.

Materials and Methods: Blinded, double re-reporting of pre-operative imaging from five hospitals was undertaken of 411 patients undergoing surgery for PC over an eight year period, of whom 119 patients were found to be inoperable at the time of surgery.

Results: The median tumour size was 26.7 mm and the proportion of patients reported to have regional lymphadenopathy (RL), venous (VI) and arterial involvement (AI) was 24.7%, 11.5% and 3.9% respectively and was similar regardless of the number of contrast phases undertaken. Significant associations were however noted between individual risk factors: VI was closely associated with tumour size ($p=0.002$) and AI ($p< 0.0001$). In multi-variable analysis AI, VI and RL were independently associated with resectability (relative risk of resection =0.05, 0.31 and 0.51 respectively). Tumour size however was not associated with resectability when VI was included in the multivariate model.

Conclusions: The use of multiple vascular contrast phases has no measureable impact on the rate of determination of tumour resectability of PC. In pre-operative staging AI is the most significant adverse finding for resectability. Large tumour diameter is not an adverse finding in isolation from other risk factors.

Key words

Ampulla, Bile duct, Cancer, CT scan, Pancreas

Abbreviations and acronyms

AI: Arterial involvement

PC: Peri-ampullary cancer

RL: Regional lymphadenopathy

VI: Venous involvement

Introduction

Determination of tumour resectability is a major aspect of the interpretation of pre-operative imaging of peri-ampullary cancer (PC). The findings of distant metastases and local invasion resulting in occlusion of major arteries or veins are contraindications to attempted surgical resection, whereas lesser degrees of arterial involvement (AI) and venous involvement (VI), including abutment and tapering, are relative contraindications, as imaging can sometimes be inaccurate in determining these findings (1-4), and vein resection can be undertaken where incomplete venous occlusion is noted (5-7). Tumour size (8) and regional lymphadenopathy (RL) (9, 10) have also been shown to be associated with unresectability, although RL is a relative contraindication as these nodes are removed as part of a Whipple procedure (11). This finding may however be a surrogate marker of an aggressive malignancy, which will progress rapidly to become inoperable.

Despite pre-operative imaging to exclude patients with contraindications to surgery a proportion of patients with PC proceeding to operation are found to be inoperable, either due to unresectable invasion of vascular structures or the presence of metastatic disease. This may result from either understaging by CT or rapid tumour progression in the interval between imaging and surgery.

Pre-operative staging of PC is commonly undertaken by contrast-enhanced CT scan. Some authorities recommend tri-phasic imaging (12), including pre-contrast phase, arterial phase and portal phase, although the benefits of this over monophasic scans (portal venous phase only) and biphasic scans (arterial and portal phases) have not been demonstrated. This has implications in terms of radiation exposure and resource utilisation. There have also been major improvements in CT scan technology in recent years with the development of multi-

detector imaging (13), which would be expected to lead to a reduction in the proportion of false negative findings, and may have reduced the need for multi-phase imaging.

The principal study aim is to determine a hierarchy of radiological findings in predicting the resectability of PC in patients undergoing surgery at a regional centre within a Cancer Network serving five hospitals (A-E) and to investigate the cause of unresectability (local invasion or metastatic disease) associated with these findings. Secondary aims were to explore the effect of varied imaging protocols in the detection of these findings to determine potential advantages of multi-phase imaging in clinical practice.

Material and Methods

Details of consecutive patients undergoing surgical exploration for suspected PC between January 2006 and January 2014 were collected in a prospective database. Patients were offered surgery following review of imaging at a specialist HPB MDT and all scans were performed on 64-slice multi-detector CT (MDCT). Relevant abdominal CT scans were retrieved from referring hospitals, anonymised and uploaded to a dedicated research hard-drive. Images were then re-reported independently by two radiologists with higher training in pancreatico-biliary imaging using standard criteria(14). The number of vascular contrast phases was recorded for each patient and the proportion of patients having mono, bi and tri-phasic imaging in each of the referring hospitals was determined, along with the association of the number of scan phases with the main radiological findings. Specific data fields were created to collect information relating to hospital of origin, the presence of a biliary stent inserted at ERCP, tumour size, regional nodal status (presence of lymph nodes >1cm in transverse diameter) and vascular involvement status. Radiological evidence of arterial and venous involvement were defined according to published criteria (14) (Figure 1). In the assessment of a binary variable (e.g. nodal status) a positive outcome was recorded only

when both radiologists agreed on the finding. For tumour size the mean of the two findings was taken.

At surgery initially a search for metastatic disease was undertaken before an attempt at dissection of the primary tumour. The tumour was considered to be unresectable due to local invasion when the operating surgeon was unable to resect the tumour after trial dissection without undertaking arterial resection or where there was occlusion or extensive invasion of the portal or superior mesenteric vein. Data retrieved from the database included the operative finding of either unexpected distant metastases or local invasion by tumour into vascular structures. The proportion of resectable tumours was recorded for consecutive quartiles (two year intervals) of the study period. To explore further the predictive value of radiological findings the operative outcome among patients where the tumours were found to be unresectable were categorised into the finding of metastatic disease or local invasion.

Discrete variables and interdependence of radiological findings were analysed by Chi-square test and continuous variables by Mann-Whitney. Estimates of the relative value of radiological parameters in the prediction of resectability of PC were determined by logistic regression analysis.

Ethical approval for the study was obtained from the South West Health Research Authority Research Ethics Committees. No patient consent was required for this study because patient data were collected in the course of normal hospital care and were anonymised for research purposes.

The study is registered with ClinicalTrials.gov (unique identifier NCT02296736).

Results

Operative details and relevant pre-operative imaging were available in 409 patients (Figure 2), of median age 66.9 (28-86) years, of whom 55.8% were male. The median age (66.7 v 67.5 years), percentage of male patients (54.5% v 59.8%) and median interval between imaging and surgery (42 v 39 days, p=0.419) did not differ between patients proceeding to resection and those where the lesion was found to be unresectable.

Analysis of images revealed a similar proportion of mono-, bi- and tri-phasic scans. There was variation in the number of vascular contrast phases undertaken in scans from different hospitals; however the rate of detection of the main radiological end-points did not differ according to the number of contrast phases undertaken (Table 1). In particular the proportion of patients noted to have AI did not differ between patients where only portal venous imaging was performed (3 of 134) and those where additional arterial phase imaging (bi- and tri-phasic scans) was also performed (13 of 275) (p=0.223). The primary tumour was visible in 250 patients (61.1%), with no difference in the rate of detection in patients having different contrast phase protocols (Table 1). Similarly the median tumour size was 26.7 (8-70) mm and did not differ between patients having different scan phases (p= 0.39). Where a tumour was visible RL, VI and AI were noted in 101 (40.4%), 47 (18.8%) and 16 (6.4%) of patients respectively. Among the 159 patients where no primary tumour was visible, RL was noted in 40 (25%) patients. Tumour size was noted to be greater in patients with RL (28.5mm v 26mm), AI (30.7mm v 26.5mm) and VI (33mm v 25.5mm) than in those without these findings (p= 0.02, 0.03 and 0.0001 respectively). In evaluation of interdependence of pre-operative risk factors VI was noted to be strongly associated with AI (p=0.000). Of the 16 patients with AI, 8 (50%) also were noted to have VI. The finding of RL was not significantly associated with either AI (p=0.472) or VI (p=0.108).

Biliary stents had been inserted prior to CT scan in 73 (17.8%) patients. The proportion of patients with radiologically detectable RL did not differ between those who had (17/72, 23.6%) and those who had not (84/337, 25%) had a stent inserted prior to CT scan (p=0.814).

Surgical resection of the PC was completed in 292 patients (71.4%). Resection was completed more commonly among the 159 patients where no lesion was visible (126, 79%) than among the 250 patients where the tumour was visible (166, 66.4%) (p=0.005). Among the 155 patients with a visible tumour and no adverse risk factors (RL, AI or VI) on pre-operative imaging, the median tumour size did not differ between the 121 patients where the tumour was resectable (24.5 mm, IQR 20.5-30.42) and the 34 patients where the tumour was not resectable (26.7mm, IQR 20-28.5mm) (p=0.55).

Of the 17 patients with VI on pre-operative imaging where resection was completed, partial venous resection was necessary in three (17.6%) patients. Vein resection was also required in five of the 348 patients (1.4%) where VI was not noted pre-operatively.

The final pathological diagnosis of resected specimens is shown in Table 2.

In univariate analysis the presence of a visible tumour, tumour size, RL, AI and VI on pre-operative imaging were all associated with unresectability of the tumour (Table 3). However in multivariate analysis the strongest association with tumour resectability was with the presence of AI (Table 3). Tumour size and VI were found to be mutually exclusive for significance in the multi-variate model.

In the 117 patients where the tumour was not resected this was due to the finding of hepatic metastatic disease in 45 patients (37.8%) or local invasion of vascular structures in 72 patients (60.5%). The proportion of patients with unresectable disease was 16/67 (23.8%), 35/93 (37.6%), 32/119 (26.2%) and 34/130 (26.1%) (p=0.17) in consecutive time quartiles of

the study. No difference was noted in the reasons for unresectability (local invasion or metastatic disease) among patients with different pre-operative radiological findings (Table 4).

Discussion

This study allows the determination of a hierarchy of relative contraindications to resection of peri-ampullary cancer, based on a systematic assessment of radiological findings. In multivariable analysis the likelihood of completing surgical resection was reduced by a factor of 0.05, 0.31 and 0.51 by a finding of AI, VI and RL respectively, compared to a patient with none of these findings. In the absence of these findings tumour size was not associated with resectability. The study also revealed significant interdependence of radiological signs, with VI closely associated with tumour size ($p<0.0001$) and with AI ($p=0.000$). The study demonstrated that the proportion of patients with unresectable disease at the time of surgery has not declined over the eight year period of the study, and that the radiological findings are similar regardless of the number of scan phases undertaken. In addition pre-operative radiological findings were not able to predict the reason the pancreatic tumour was not resectable at the time of surgery (metastatic disease or local progression).

Many studies have shown that AI and VI are risk factors for non-resection of pancreatic tumours (15-17). Most have focussed on assessing the accuracy of MDCT in identifying these risk factors in comparison with operative findings or histology (18-20). This study has used a structured reporting protocol to assess the relative risk that pre-operative identification of these findings entails for individual patients in terms of tumour resectability. AI is shown to be the most significant adverse finding, with a relative risk of resection of 0.05 compared to a patient without this finding. This may be due to the hepatic and superior mesenteric

arteries lying further from the duodenal ampulla than venous structures, denoting a greater degree of invasion. The observation that the radiological findings of AI and VI are associated with each other may also reflect the spatial relationship of these structures, with VI occurring first followed by AI.

The significance of radiological evidence of RL has been less well investigated previously. It is interesting to note that the presence of RL was not influenced by the insertion of biliary stents, so this finding should be attributed to a malignant, rather than inflammatory process. RL was also not associated with other signs of local tumour progression, and is only weakly associated with primary tumour size. The development of lymph node metastases in PC may therefore depend on different biological processes to primary tumour enlargement and local invasion. RL was however independently associated with tumour unresectability. This is probably due to this finding being a marker of a more aggressive malignancy. In a large proportion (69%) of patients with RL however the tumour remains resectable at surgery.

Our study confirms that although tumour size is associated with invasion of vascular structures, size alone does not lead to an increased risk of non-resection in the absence of other adverse findings. This is significant as some centres have used tumour size alone as a factor in the decision to offer surgery for PC(8).

The observation that 20% of patients with no detectable tumour radiologically are found to be inoperable at the time of surgery is an interesting finding. This suggests that although the interval from imaging to surgery has only a small impact on resectability in large series(21) there may be a more aggressive subset where progression proceeds rapidly. Similarly among the 271 patients where no adverse radiological signs were identified 54 (19.9%) were still found to be inoperable at the time of surgery. Caution must be exercised therefore in the interpretation of radiological findings when counselling patients. In addition although vein

resection was required in 17.6% of patients undergoing resection where VI was noted on pre-operative imaging it was also necessary in 1.4% of cases without VI on pre-operative imaging. These observations emphasize the limitations of pre-operative imaging in planning surgery for PC.

The weaknesses of this study mainly relate to the non-standardised imaging protocols undertaken in different centres, and its retrospective nature. This study however represents an analysis of the value of pre-operative imaging in routine clinical practice, rather than under trial conditions, and the results are therefore likely to be relevant to other centres undertaking this type of surgery. Of particular interest is the finding that the radiological findings and resection rate are similar regardless of the number of contrast phases. Although multi-phase pancreatic–protocol CT is considered the 'gold-standard' in assessing resectability of PC(12), our results indicate that the resectability rate is unaltered by the CT technique used. It is possible that with a larger study the use of arterial phase contrast may lead to greater sensitivity in the detection of AI. This however does not seem necessary in patients with small tumours and no evidence of VI, where the risk of AI is very low. The study is also limited by the number of radiologists undertaking rereporting (two). The agreement between radiologists is being addressed seperately and it is possible that the results have been biased by individual radiologists performance.

The analysis of surgical outcomes has revealed the most common cause for non-resection was invasion of vascular structures (60.5%), with metastatic disease a less common finding (37.8%). Patients noted to have AI or VI on pre-operative imaging had a similar likelihood of being inoperable due to metastatic disease or local invasion at the time of surgery, suggesting that these findings are markers of aggressive malignancy. CT has a high resolution for hepatic metastases, which has increased in recent years(22). Despite this the proportion of patients with unresectable disease has remained largely unchanged over the period of study.

This finding suggests that disease progression between imaging and the time of surgery may be a more significant cause of inoperability than understaging by CT. There may therefore be an irreducible number of patients with rapidly progressive disease who will be unresectable at the time of surgery, regardless of the quality of the imaging and reporting undertaken.

The strength of this study lies in its large size and in the assessment of imaging of heterogeneous technique from different hospitals. Other studies have shown similar risk factors for non-resection(23, 24), and a similar rate of non-resection (23, 24) at the time of surgery, and there is little available evidence that this rate has declined with improved imaging. This may be due to alterations in the threshold for undertaking surgery in borderline cases and improvements in surgical technique. The study however reveals significant limitations in the ability of MDCT to predict the presence of surgically significant operative findings.

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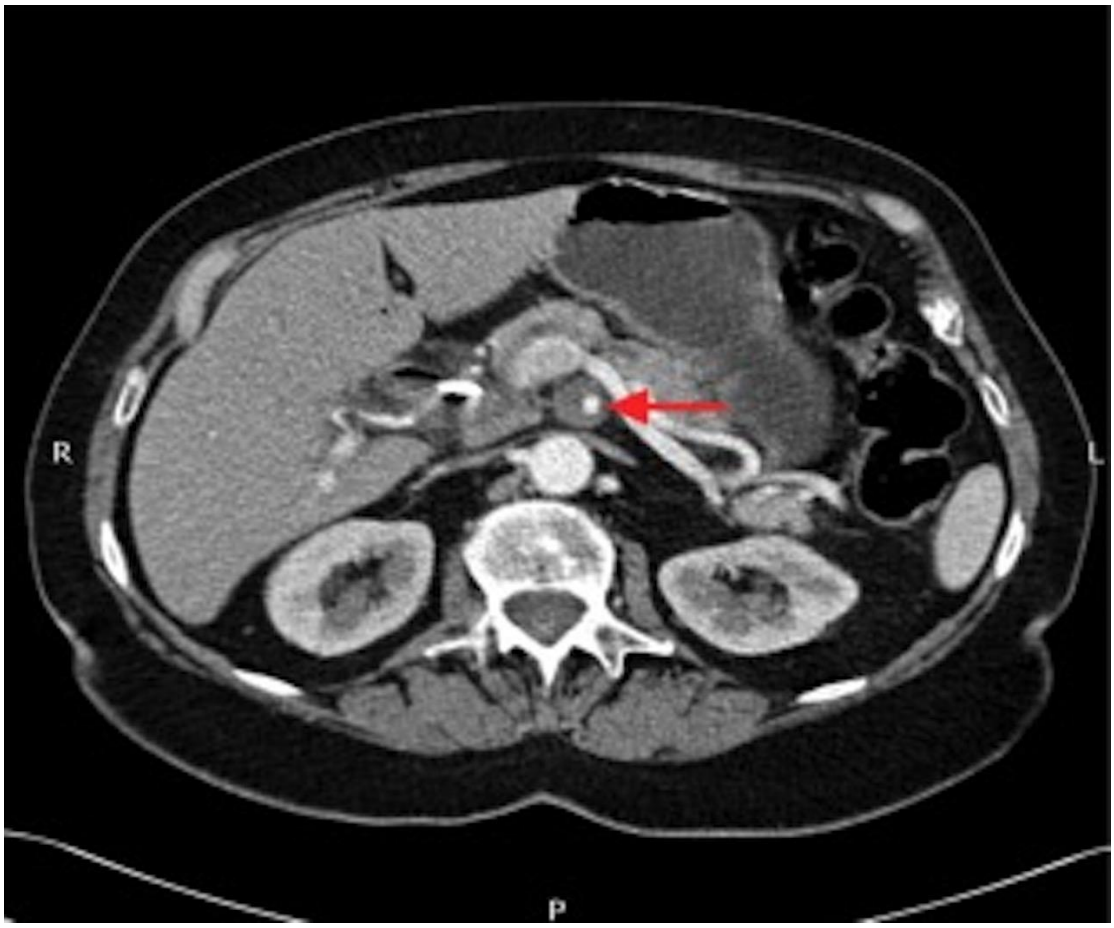


Figure 1-a. MDCT imaging demonstrating SMA involvement by PC (Arrow)

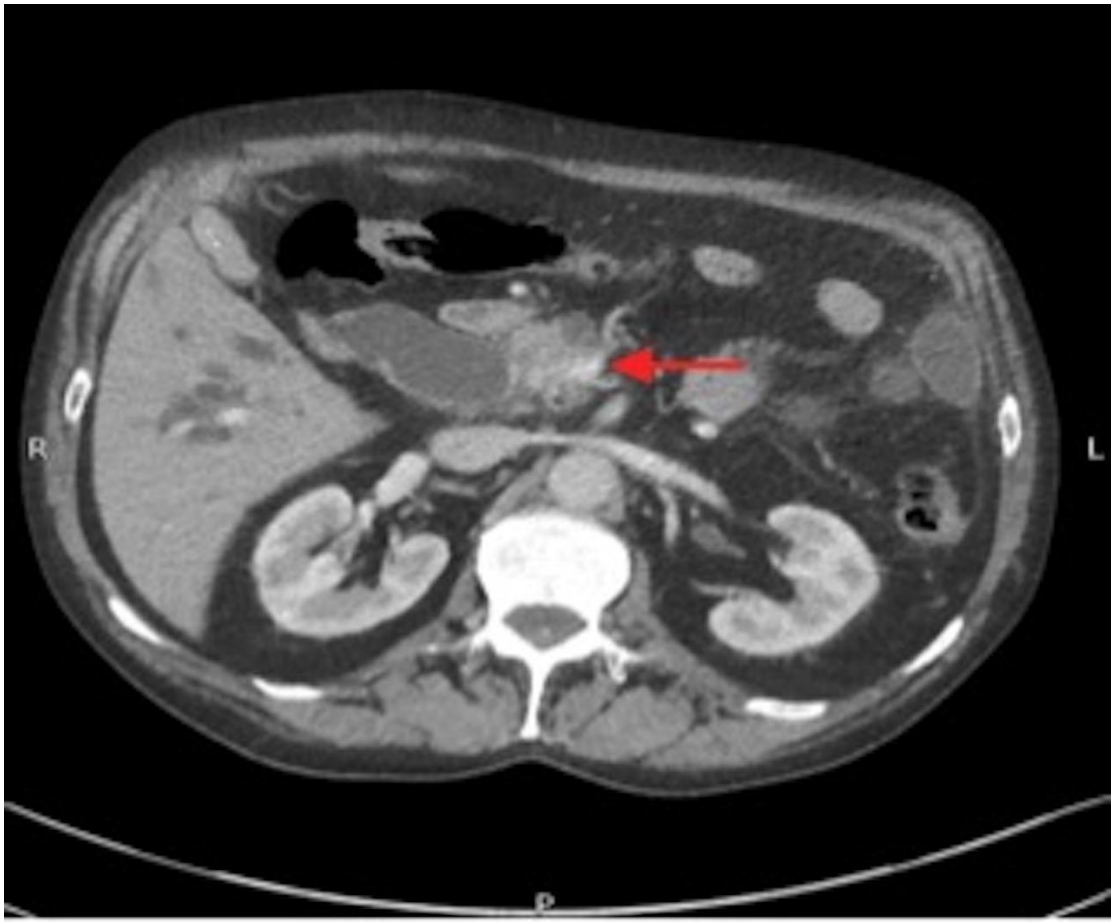
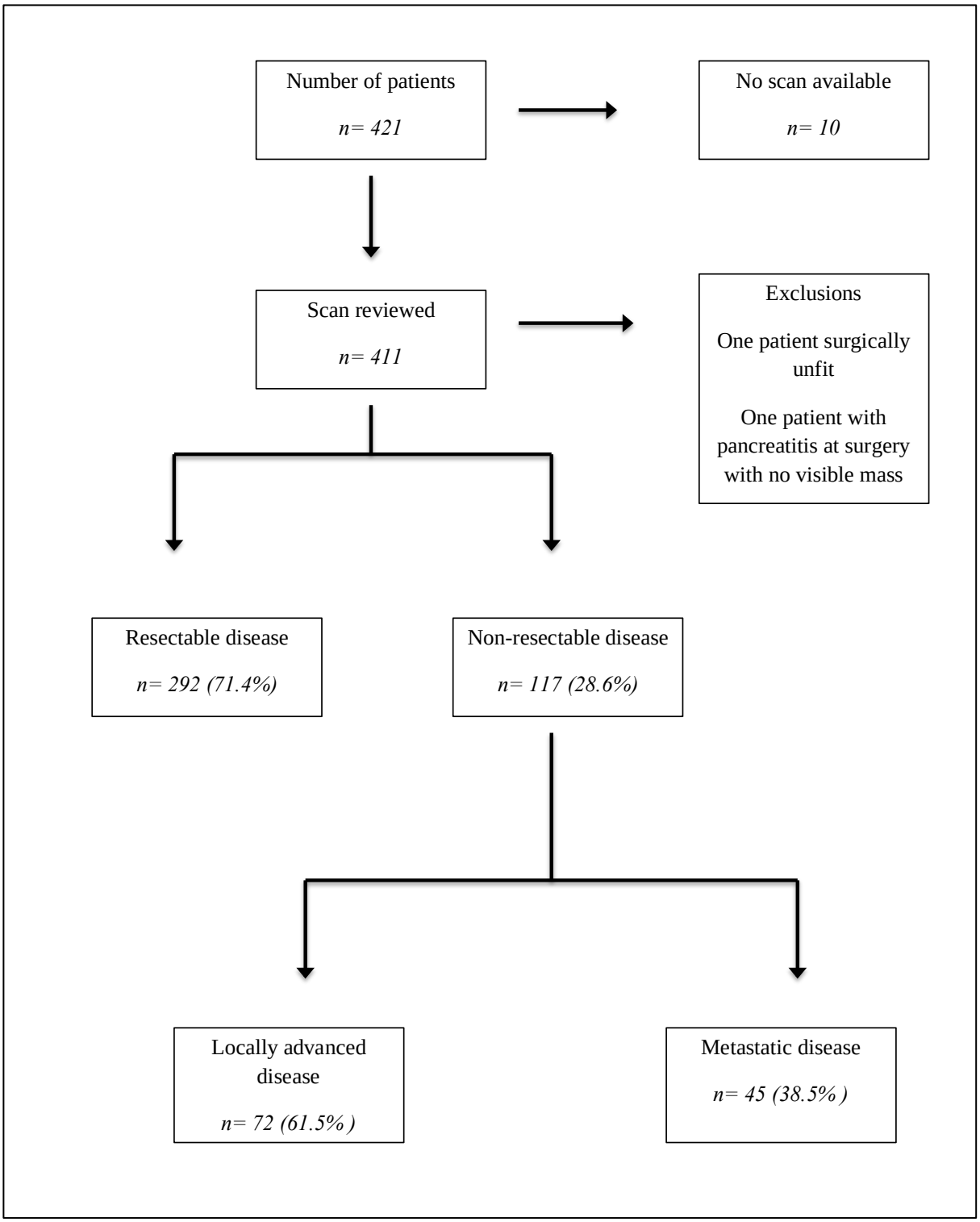


Figure 1-b. MDCT imaging demonstrating SMV involvement by PC (Arrow)



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394 Figure 2. Flow chart of patients undergoing surgery for PC between January 2006 and
395 January 2014

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n = 409		Monophasic (134, 32.7%)	Biphasic (149, 36.4%)	Triphasic (126, 31%)	P
Hospital	A (119)	20 (16.8)	52 (43.7)	46 (38.6)	0.0001
	B (97)	45 (46.4)	50 (51.5)	2 (2.1)	
	C (78)	24 (30.7)	9 (11.5)	45 (57.7)	
	D (71)	24 (33.8)	21(29.5)	26 (36.6)	
	E (44)	21 (47.7)	17 (38.6)	6 (13.6)	
AI (16)		3 (2.4)	8 (5.4)	5 (4)	0.398
VI (47)		20 (15)	11 (7.4)	16 (12.7)	0.122
RL (101)		28 (21)	42 (28.2)	31 (24.6)	0.83
Tumour visible (250)		72 (53.7)	99 (66.4)	79 (62.7)	0.83
Median tumour size (average)		25.25 (11.5-70)	26.25 (10.5-58)	27.75 (8-64.5)	0.39
Resection completed (292)		102 (76.1)	107 (71.8)	83 (65.8)	0.187

Table 1. Radiological findings and surgical resection rate according to the number of CT scan phases for 409 patients undergoing attempted surgical resection for PC

Tumour origin	N (%)	Median tumour size (range) mm	Histological lymph node involvement (%)
Pancreatic adenocarcinoma	132 (45.2)	30 (12-65)	122 (92.4)
Ampullary adenocarcinoma	66 (22.6)	25 (5-80)	37 (56)
Bile duct adenocarcinoma	47 (16.1)	25 (10-70)	25 (53.2)
Duodenal adenocarcinoma	7 (2.4)	40 (30-55)	4 (47)
Tubulo-villous adenoma	15 (5.1)	30 (24-55)	
Inflammatory disease	12 (4.1)		
Neuroendocrine tumour	6 (2)	18 (10-25)	3 (50)
Metastasis	4 (1.4)	35 (25-45)	
Gastro Intestinal Stromal cell tumour (GIST)	1 (0.03)		0 (0)
Others (Benign)	2 (0.6)		

Table 2. Histological outcome of 292 patients undergoing surgical resection for presumed PC.

Imaging characteristic	Tumour resectability		UVA	MVA		
	Yes (292)	No (117)	p	Exponent	95% CI of Exponent	p
Median tumour size (mm)(range)	25.5 (8-70)	28 (11.5-64.5)	0.01	0.46	(0.193-1.084)	0.076
RL (101) (%)	63 (21.6)	39 (32.8)	0.017	0.51	(0.272-0.949)	0.047
AI (16) (%)	2 (0.68)	14 (11.7)	0.000	0.05	(0.007-0.445)	0.007
VI (47) (%)	17 (5.82)	30 (25.2)	0.000	0.31	(0.152-0.638)	0.001

Table 3. Univariate and multivariate analysis of the association of the preoperative radiological risk factors and surgical resectability of PC in 409 patients

n=117 Radiological finding	Local progression (*n*= 72)	Metastatic disease (*n*= 45)	Chi Sq	P
Tumour visible (84, 71.8%)	49 (58.3)	35 (41.6)	1.3	0.256
Median tumour size (mm) (range)	28.25 (11.5-64.5)	27.75 (16.5-55.5)	0.838	0.36
RL (38, 32.5%)	23 (60.5)	15 (39.5)	0.024	0.876
AI (16, 13.7%)	9 (56.2)	5 (31.25)	0.051	0.822
VI (30, 25.6%)	22 (73.3)	8 (26.6)	2.37	0.123
No adverse radiological findings (54, 46.1%)	32 (59.2)	22 (40.7)	0.22	0.639

Table 4. Reasons for non-resection (local invasion or metastatic disease) among 117 patients undergoing attempted surgical resection for PC with different pre-operative radiological findings