Royal College of Pathologists

Standards and Minimum Datasets for Reporting Cancers

Minimum dataset for the histopathological reporting of pancreatic, ampulla of Vater and bile duct carcinoma

Acknowledgement

The working group acknowledges the use of the *Appraisal Instrument for Clinical Guidelines** and the assistance of the staff of the Clinical Audit and Effectiveness Unit and the Professional Standards Unit at The Royal College of Pathologists in the preparation of this booklet.

The Royal College of Pathologists acknowledges the support of the Department of Health in contributing towards the costs of this publication.

*Cluzeau F, Littlejohns P, Grimshaw J, Feder G. *Appraisal instrument for clinical guidelines*. London: St George's Hospital Medical School, 1997.

The Royal College of Pathologists
2 Carlton House Terrace
London
SW1Y 5AF

Registered Charity No. 261035

February 2002

Since the publication of the Calman-Hine Report, *A Policy Framework for Commissioning Cancer Services*, several national groups and committees have begun to define the standards that Cancer Centres and Units should attain.

- The Department of Health Clinical Outcomes Group is drawing up guidance on clinical services for site-specific cancers. This group employs a very elaborate, open and evidence-based approach and has already published guidelines on other clinical areas.[1,2]

- The NHS Advisory Committee on Cancer Registration and the UK Association of Cancer Registries are also making recommendations on the collection and coding of clinical and pathological data of diagnostic and prognostic importance for epidemiological and strategic purposes. The cancer registries are improving their links with histopathology departments that they see as timely, convenient and reliable sources of cancer data.

- The Royal Colleges' Intercollegiate Committee on Oncology has stated its intention to produce interdisciplinary guidance on diagnosing and managing patients with common cancers.

In addition, many working groups and committees throughout the UK are drawing up local guidelines and defining working practices and standards, including those for pathology.

The Royal College of Pathologists (RCPath) seeks an active role in this process. The RCPath Specialty Advisory Committee (SAC) on Histopathology approved the formation of a small working group to link with the various national committees and to produce a series of succinct evidence-based publications defining minimum standards of reporting common cancers to ensure that pathological standards are defined by histopathologists and to prevent the proliferation of numerous diverse and possibly conflicting local guidelines. There has been extensive consultation with specialist and general histopathologists, with multidisciplinary groups and societies, and with cancer registries in order to achieve the broadest possible consensus.

The standards and datasets are being published separately as individual booklets. This will have the major advantages of speed, by enabling documents to be published individually as soon as they become available, and ease of updating. They are also available on the College's website (www.rcpath.org.uk).

All these documents are evidence-based and define the minimum standards for reporting each group of tumours. They conform to a standard format and include a proforma that is intended to function as an *aide memoire* when reporting specific tumours. Although the data in the proforma may be presented as or supplemented by free text, the use of proformas in histopathological reporting is recommended: published audits have shown that they are very effective in ensuring that all necessary data are provided.[3,4]

This document will be reviewed in 2004, and before that if new evidence emerges.

Further copies of this dataset can be downloaded from the College website (www.rcpath.org).

The RCPath Working Group on Cancer Services recommends that:

- the minimum datasets for reporting tumours are used in the system of standard-setting, data collection, audit and feedback for those involved in caring for these patients
- histopathology laboratories nominate a lead pathologist for each of the main cancers with responsibility for liaising with relevant local committees and clinicians, and ensuring that the relevant cancers are examined, sampled and reported appropriately and in a consistent fashion
- histopathologists should be members of multidisciplinary teams, dedicated to the diagnosis and management of patients with specific cancers (and be involved in auditing the service)
- the SNOMED coding system is used to achieve as much uniformity as possible from centre to centre and to facilitate reliable cancer registration. Either the 1979 or 1993 version of SNOMED can be used, as there is currently no clear consensus for using one or the other
- histopathologists reporting cancers should participate in appropriate EQA schemes
- Cancer Centres and Units should be supported only by laboratories accredited with Clinical Pathology Accreditation (UK) Ltd and staffed in accordance with the recommendations of the Royal College of Pathologists and the Association of Clinical Pathologists.

Anyone wishing to make specific or general comments on this document should contact Dr Fiona Campbell, Department of Pathology, Royal Liverpool University Hospital, Duncan Building, Daulby Street, Liverpool L69 3GA. Email: f.campbell@liv.ac.uk

Royal College of Pathologists Working Group on Cancer Services

GT Williams (Chairman)
ID Ansell
SD Coghill
G Lawrence
P Quirke
JCE Underwood

REFERENCES

1. Cancer Guidance Subgroup of the Clinical Outcomes Group. *Improving Outcomes in Breast Cancer*. London: NHS Executive, 1996.

2. Cancer Guidance Subgroup of the Clinical Outcomes Group. *Improving Outcomes in Colorectal Cancer*. London: NHS Executive, 1997.

3. Cross SS, Angel CA. Five audit cycles of the informational content of histopathological reports of bladder carcinoma. *J Pathol* 1997;181:7A.

4. Cross SS, Feeley KM, Angel CA. The effect of four interventions on the informational content of histopathology reports of resected colorectal carcinomas. *J Clin Pathol* 1998;51:481–482.

MINIMUM DATASET FOR THE HISTOPATHOLOGICAL REPOR TING OF PANCREATIC, AMPULLA OF VATER AND BILE DUCT CARCINOMA

Coordinators: Dr F Campbell, Royal Liverpool University Hospital
Dr M K Bennett, Freeman Hospital, Newcastle
Dr A K Foulis, Glasgow Royal Infirmary

These guidelines describe the core data that should be provided in histopathology reports of specimens for carcinoma of the pancreas, ampulla of Vater and distal bile duct. They should be implemented for the following reasons.

1. Certain features of these carcinomas (e.g. tumour grade, stage and resection margin status in pancreatic carcinoma) have been shown to be related to clinical outcome.[1-3] Consequently these features may be important in:
   a) providing prognostic information to clinicians and patients[2,3]
   b) providing accurate data for cancer registration
   c) providing feedback to the surgeon on the quality of the resection
   d) potentially selecting patients for future trials of adjuvant therapy
   e) auditing the cost-effectiveness of pre-operative staging procedures.

2. They allow the accurate and equitable comparison of surgical practice in different units and the comparison of patients in clinical trials.

The guidance and reporting proformas contained in this document have been approved by the Pancreatic Section of the British Society of Gastroenterology and the Pathology Section of the British Society of Gastroenterology.

INTRODUCTION

These guidelines mainly apply to the reporting of pancreatic exocrine carcinomas, 90% of which are ductal adenocarcinomas, but similar principles may be applied to the reporting of carcinomas arising in the ampulla of Vater or distal bile duct.

The reporting proformas and guidance in the following pages are based on the WHO *Classifications of Exocrine Pancreatic Tumours*[4] and *Extrahepatic Bile Duct Tumours*[5] and the UICC TNM staging system.[6] They follow consultation with histopathologists and hepatopancreaticobiliary surgeons.

The purpose of this document is to define the minimum set of data that should be provided by pathologists on resected carcinoma specimens. The proformas may be used as the main reporting format or may be combined with free text as required.

A detailed dissection protocol is beyond the scope of these guidelines and only a brief summary of dissection methods and block selection is included.

NOTES ON RECORDING DATA ITEMS

1. Type of specimen

The type of specimen should be recorded, e.g. a standard Kausch-Whipple's pancreato-duodenectomy (PD), a pylorus-preserving PD, a total PD, a subtotal or left pancreatectomy. The standard Kausch-Whipple's PD includes the head of pancreas, duodenum, distal bile duct, gall bladder and two thirds of the stomach; the pylorus-preserving PD does not include the stomach; the total PD also includes the body and tail of pancreas with or without the spleen and/or stomach; the subtotal pancreatectomy includes the body of the pancreas with or without stomach, and the left (or distal) pancreatectomy only consists of the body and tail of pancreas, with or without the spleen.

The type of operation will depend upon the site and size of the tumour. Although the type of operative procedure was a significant predictor of survival in one univariate analysis,[7] prognosis depends more upon the biology of the tumour rather than the particular surgical procedure.

2. Specimen handling

Specimens should preferably be opened and partially sectioned immediately after resection, to aid fixation and preservation of pancreatic parenchyma. The circumferential margins of the pancreas (including the anterior, medial and retroperitoneal aspects) should be painted, either when the specimen is fresh or when fixed, according to the preference of the examining pathologist, but before blocks are taken.

To aid fixation, the duodenum and/or stomach should be opened. The presence or absence of a stent, and of a named vessel (e.g. portal vein), should be noted. The pancreatic parenchyma should be partially sliced at 5 mm intervals, perpendicular to the long axis of the pancreas, or opened along the pancreatic duct and bile duct, according to the preference of the examining pathologist. The specimen may then be pinned to a cork board, placed in a large volume of formalin and allowed to fix for 24–48 hours.

3. Gross description

Specimen measurements

Record the lengths, in millimetres, of the duodenum, stomach (lesser curve and greater curve), gall bladder, cystic duct and extra-pancreatic bile duct and the maximum dimensions of the pancreas.

Site of tumour (see Table 1)

State, when possible, whether the tumour is in the ampulla of Vater, the bile duct or the head, body or tail of the pancreas. The head is that part of the pancreas to the right of the left border of the superior mesenteric vein (SMV); the uncinate process is considered part of the head; the body lies between the left border of the SMV and the left border of the aorta, and the tail lies to the left of the left border of the aorta. Carcinomas of the body or tail are usually more advanced than those of the head at the time of diagnosis, because of lack of obstructive symptoms and because they usually spread into extra-pancreatic tissue and metastasize before detection. They are, therefore, seldom resected. Note that pancreatic carcinomas may be multicentric (fill in separate proforma for each carcinoma).

Table 1 Coding for individual tumour sites

Tumour site	ICD10	SNOMed
Head of pancreas	C25.0	T-65100
Body of pancreas	C25.1	T-65200
Tail of pancreas	C25.2	T-65300
Whole pancreas	C25.8	T-65000
Extrahepatic bile ducts	C24.0	T-64000
Ampulla of Vater	C24.1	T-64700

Tumour size

Optimally, three dimensions should be measured but, for staging purposes, at least the maximum diameter of the tumour should be measured to the nearest millimetre. Tumour size is an independent prognostic factor in most studies.[3, 8-11] Note that lymph node involvement and portal vein, capsular or retroperitoneal involvement can be seen in small pancreatic (T1) tumours.[12]

Distance from tumour to nearest margin

Adequacy of excision should be assessed by the naked eye and confirmed by microscopic examination. Potential margins (see Figure 1) include the pancreatic transection margin (with main pancreatic duct), medial (SMV) margin, retroperitoneal margin (defined as the peripancreatic fat tissue behind the head of the pancreas), the anterior pancreatic capsule and the bile duct (common bile duct or common hepatic duct).

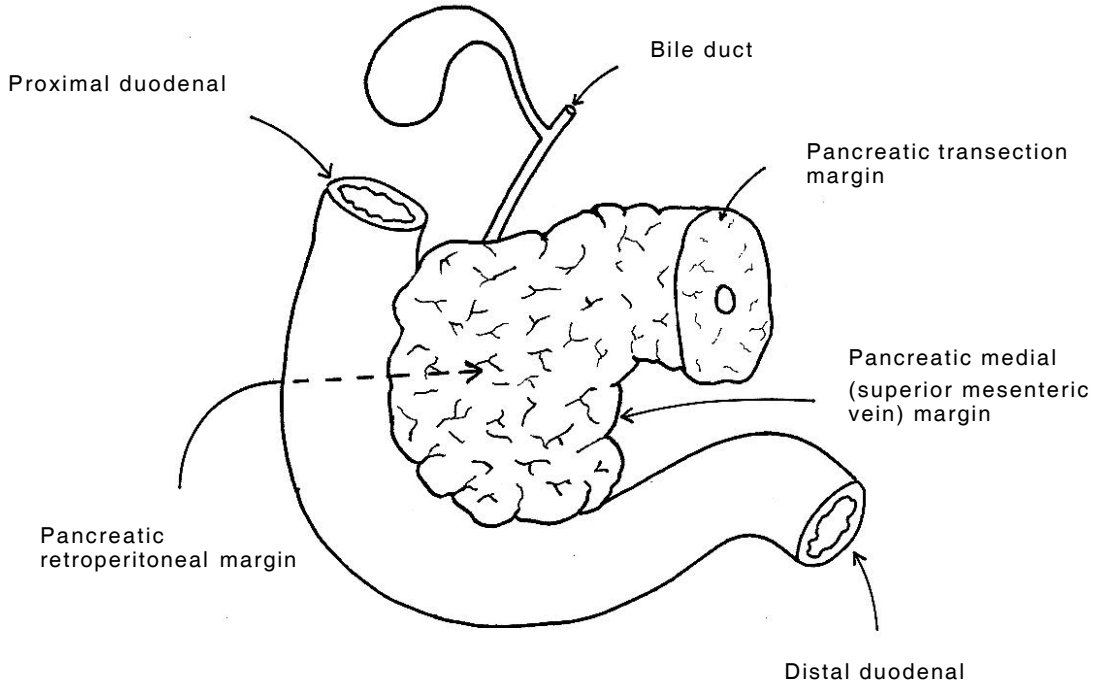

Figure 1 Resection margins

Sampling

The pancreatic transection margin, main bile duct and duodenal/gastric resection margins are sampled. Blocks are taken to include the tumour with pancreatic capsule and/or resection margins, duodenum, ampulla of Vater and/or bile duct. Blocks of ampulla of Vater, background pancreatic parenchyma, other organs and all lymph nodes (see Figure 2) should also be taken.

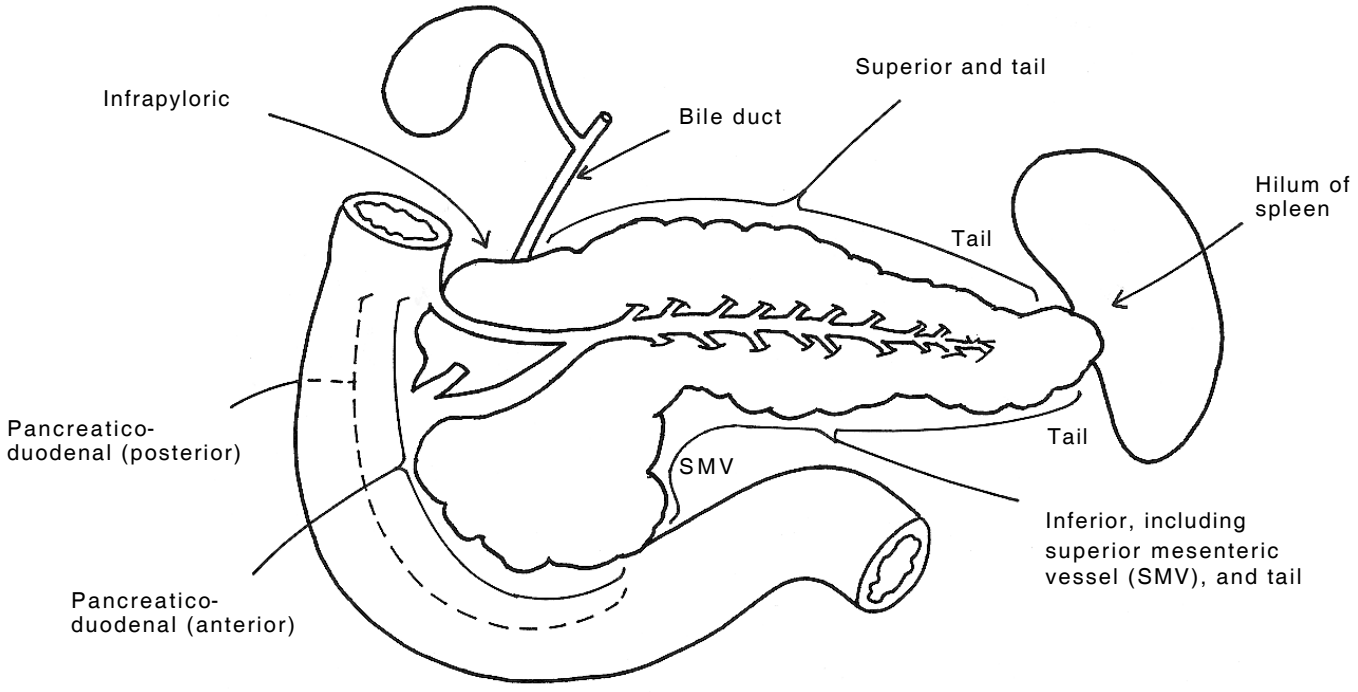

Figure 2 Regional lymph nodes for pancreas and ampulla of Vater (for bile duct regional lymph nodes see Table 5)

4. Histology

Histological type

The histological classification is based on the WHO typing of exocrine pancreatic tumours[4] and tumours of the extrahepatic bile ducts[5] (Tables 2 and 3). Ductal adenocarcinoma, including its variants, accounts for 90% of the pancreatic tumours.

Table 2 WHO classification of malignant exocrine pancreatic tumours[4]

Description	SNOMed code
Ductal adenocarcinoma (infiltrating duct carcinoma)	M8500
Mucinous noncystic carcinoma (mucinous adenocarcinoma)	M8480
Signet-ring cell carcinoma	M8490
Adenosquamous carcinoma	M8560
Undifferentiated (anaplastic) carcinoma	M8020 (M8021)
Mixed ductal-endocrine carcinoma	M8154
Osteoclast-like giant cell tumour	M8030
Serous cystadenocarcinoma	M8441
Mucinous cystadenocarcinoma	M8470
Intraductal papillary-mucinous carcinoma	M8503/2
Invasive papillary-mucinous carcinoma	M8503/3
Acinar cell carcinoma	M8550
Pancreatoblastoma	M8971
Solid-pseudopapillary carcinoma	M8452
Extremely rare carcinomas	
Clear cell carcinoma (clear cell adenocarcinoma)	M8310
Oncocytic carcinoma (oxyphilic adenocarcinoma)	M8290
Choriocarcinoma (NOS)	M9100

Table 3 WHO classification of tumours of the extrahepatic ducts and ampulla of Vater[5]

Description	SNOMed code
Adenocarcinoma (NOS)	M8140
Papillary adenocarcinoma	M8260
Adenocarcinoma, intestinal type	M8144
Mucinous adenocarcinoma	M8480
Clear cell adenocarcinoma	M8310
Signet-ring cell carcinoma	M8490
Adenosquamous carcinoma	M8560
Squamous cell carcinoma (NOS)	M8070
Small cell carcinoma (NOS)	M8041
Undifferentiated carcinoma	M8020
Mixed carcinoid-adenocarcinoma (adenocarcinoid tumour)	M8244
Carcinosarcoma (NOS)	M8980

Tumour differentiation

Histological grading of pancreatic ductal adenocarcinoma into 'well', 'moderately', and 'poorly differentiated', according to the criteria of Kloppel *et al*[13] (Table 4), has been found to be of prognostic significance on multivariate analysis.[7,14–16] The tumour is graded according to the least differentiated area, regardless of prevalence.

Table 4 Histological grading of pancreatic ductal adenocarcinoma[13]

Differentiation	Duct structures	Nuclei	Mitotic figures per 10 high power fields*	Mucin production
Well	Well formed	Basal	< 5	Marked
Moderate	Some well formed	Loss of polarization, anisonucleosis	5–10	Variable
Poor	Very irregular or absent	Marked anisonucleosis, clumped chromatin	> 10	Minimal

*High power field of Kloppel *et al*[13] measured 1356 μ m^2

Local invasion

UICC TNM staging requires assessment of whether or not pancreatic carcinoma invades the duodenum, ampulla of Vater, bile duct or peripancreatic tissues (T3) or invades the stomach, spleen, colon or adjacent large vessels (T4). Peripancreatic tissue invasion has been reported in up to 90% of cases[17] and correlates with poor prognosis. Note that UICC TNM staging of carcinomas of the bile duct and ampulla of Vater is different from that of pancreatic carcinoma[6] (Table 5).

Margins

Pancreatic tumour involvement of the standard surgical margins (see Figure 1), or anterior pancreatic capsule, is associated with a high rate of local recurrence and is an important negative prognostic factor.[10,18,19] The peripancreatic circumferential margin is the most commonly involved margin,[20] with the pancreatic transection margin and bile duct margin less commonly involved. Carcinoma less than 1 mm from a margin is considered to be incompletely excised.

Lymph node spread

Multivariate analysis has shown lymph node involvement to be a negative prognostic indicator in pancreatic carcinoma,[8,11,15,16,18] with patients with a single group of involved lymph nodes surviving significantly longer than those with multiple groups of involved lymph nodes.[10] In ampullary carcinoma, the metastatic/dissected lymph node ratio is an independent prognosticator on multivariate analysis.[21] The regional lymph nodes for the pancreas and ampulla of Vater (see Figure 2) can be grouped into anterior pancreaticoduodenal, posterior pancreaticoduodenal, inferior (including the lymph nodes around the superior mesenteric vessels), bile duct, infrapyloric (for tumours of head of pancreas or ampulla) and superior.[6] Coeliac lymph nodes (sent separately) are regional lymph nodes for tumours of the head of the pancreas only. Lymph nodes in the hilum of the spleen and tail of the pancreas are regional lymph nodes for tumours of the body and tail only.

Table 5 UICC TNM classification[6]

General	
TX	Primary tumour cannot be assessed
T0	No evidence of primary tumour
Tis	Carcinoma *in situ*
NX	Regional lymph nodes cannot be assessed
N0	No regional lymph node metastasis
MX	Distant metastasis cannot be assessed
M0	No distant metastasis
M1	Distant metastasis
Pancreas	
T1	Tumour limited to the pancreas, 20 mm or less in greatest dimension
T2	Tumour limited to the pancreas, > 20 mm in greatest dimension
T3	Tumour extends directly into duodenum, bile duct or peripancreatic tissues
T4	Tumour extends directly into stomach, spleen, colon or adjacent large vessels
N1	Regional lymph node metastasis
N1a	Metastasis in single regional lymph node
N1b	Metastasis in multiple regional lymph nodes
Ampulla of Vater	
T1	Tumour limited to ampulla of Vater or sphincter of Oddi
T2	Tumour invades duodenal wall
T3	Tumour invades 20 mm or less into pancreas
T4	Tumour invades > 20 mm into pancreas and/or other adjacent organs
N1	Regional lymph node metastasis
Bile duct	
T1	Tumour invades subepithelial connective tissue or fibromuscular layer
T1a	Tumour invades subepithelial connective tissue
T1b	Tumour invades fibromuscular layer
T2	Tumour invades perifibromuscular connective tissue
T3	Tumour invades adjacent structures: liver, pancreas, duodenum, gall bladder, colon or stomach
N1	Metastasis in cystic duct, pericholedochal, and/or hilar lymph nodes (i.e. in hepatoduodenal ligament)
N2	Metastasis in peripancreatic (head only), periduodenal, periportal, coeliac, superior mesenteric, posterior pancreatico-duodenal lymph nodes

The different nodal stages (N1, N2) for bile duct tumours depend upon which specific bile duct regional lymph nodes (listed in Table 5 and the bile duct proforma) are involved. On average, a Whipple's resection should yield 10–20 lymph nodes.

Immunohistochemistry to detect micrometastases in haematoxylin and eosin (H&E) stained tumour-free lymph nodes is not currently recommended.

Vascular invasion
Large named-vessel involvement (e.g. portal vein, superior mesenteric artery or vein, and/or common hepatic artery or vein) is a major factor determining survival after resection.[17]

Neural invasion
Perineural invasion is a histological characteristic of pancreatic carcinoma. There is a significant correlation between intrapancreatic neural invasion and extrapancreatic plexus invasion,[22] which is a major cause of local (retroperitoneal) recurrence.

Other markers
At present, the use of special techniques to assess DNA ploidy,[11,23–25] proliferation markers, oncogenes (including growth factors and their receptors) or nuclear morphometry[26–28] are not considered justifiable in a minimum dataset.

Metastases
If known, the presence or absence of distant metastases (Table 5) is stated.[6]

5. Pathological staging

Multivariate analysis shows that tumour stage is the most significant factor in predicting long-term survival in pancreatic carcinoma.[1-3,29] The UICC TNM classification obtained from the histopathological data can be converted to a pathological stage,[6] but full clinical data will need to be taken into account before the final stage can be determined.

6. Needle biopsies

Only limited information can be obtained from pre-operative pancreas or liver needle biopsy. All the tissue should be fixed in formalin and routinely processed. Multiple sections should be cut and some left unstained for additional special histochemical and immunohistochemical staining. Histological reports of such specimens should state whether or not carcinoma is present.

7. Use of frozen section diagnosis

Histological confirmation of the primary diagnosis, assessment of the presence or absence of carcinoma at the pancreatic surgical transection margin, or histological confirmation of a potentially metastatic nodule in the liver, peritoneum or a lymph node are the commonest indications for intra-operative frozen section diagnosis. While it will usually be possible to identify a liver metastasis, the distinction between adenocarcinoma and pancreatitis in the pancreas may be impossible to determine on frozen section, because of the distortion and reactive nuclear atypia in small residual ductules in chronic pancreatitis.

REFERENCES

1. Gall FP, Kessler, H, Hermanek P. Surgical treatment of ductal pancreatic carcinoma. *Eur J Surg Oncol* 1991;17:173–181.

2. Allema JH, Reinders ME, van Gulik TM *et al.* Prognostic factors for survival after pancreaticoduodenectomy for patients with carcinoma of the pancreatic head region. *Cancer* 1995;75:2069–2076.

3. Cameron JL, Crist DW, Sitzmann JV *et al.* Factors influencing survival after pancreaticoduodenectomy for pancreatic cancer. *Am J Surg* 1991;161:120–125.

4. Kloppel G, Solcia E, Longnecker DS *et al. Histological typing of tumours of the exocrine pancreas, 2nd ed. WHO international histological classification of tumours.* Berlin: Springer-Verlag, 1996.

5. Albores-Saavedra J, Henson DE, Sobin LH. *Histological typing of tumours of the gall bladder and extrahepatic bile ducts, 2nd ed. WHO international histological classification of tumours.* Berlin: Springer-Verlag, 1991.

6. Sobin LH, Wittekind C (eds). *International Union Against Cancer TNM classification of malignant tumours*, 5th ed. New York: John Wiley & Sons Inc, 1997.

7. Takahashi T, Niino N, Ishikura H *et al.* Predictive factors for long-term survival in patients with pancreatic carcinoma. *Hepato-Gastroenterol* 1997;44:1463–1468.

8. Geer RJ, Brennan MF. Prognostic indicators for survival after resection of pancreatic adenocarcinoma. *Am J Surg* 1993;165:68–73.

9. Fortner JG, Klimstra DS, Senie RT, Maclean BJ. Tumor size is the primary prognosticator for pancreatic cancer after regional pancreatectomy. *Ann Surg* 1996;223:147–153.

10. Griffanti-Bartoli F, Arnone GB, Ceppa P *et al.* Malignant tumors in the head of the pancreas and the periampullary region. Diagnostic and prognostic aspects. *Anticancer Res* 1994;14:657–666.

11. Allison DC, Bose KK, Hruban RH *et al.* Pancreatic cancer cell DNA content correlates with long-term survival after pancreatoduodenectomy. *Ann Surg* 1991;214:648-656

12. Furukawa H, Okada S, Saisho H *et al.* Clinicopathologic features of small pancreatic adenocarcinoma. *Cancer* 1996;78:989–990.

13. Kloppel G, Lingenthal G, von Bulow M, Kern HF. Histological and fine structural features of pancreatic ductal adenocarcinomas in relation to growth and prognosis: studies in xenografted tumours and clinico-pathological correlation in a series of 75 cases. *Histopathology* 1985;9:841–856.

14. Griffin JF, Smalley SR, Jewell W *et al.* Patterns of failure after curative resection of pancreatic carcinoma. *Cancer* 1990;66:56–61.

15. Sperti C, Bonadimani B, Pasquali C *et al.* Ductal adenocarcinoma of the pancreas: clinicopathologic features and survival. *Tumori* 1993;79:325–330.

16. Pedrazzoli S, DiCarlo V, Dionigi R *et al.* Standard versus extended lymphadenectomy associated with pancreatoduodenectomy in the surgical treatment of adenocarcinoma of the pancreas. *Ann Surg* 1998;228:508–517.

17. Luttges J,Vogel I, Menke M *et al.* The retroperitoneal resection margin and vessel involvement are important factors determining survival after pancreatico-duodenectomy for ductal adenocarcinoma of the head of the pancreas. *Virchows Arch* 1998;433:237–242.

18. Kayahara M, Nagakawa T, Konishi I *et al.* Histopathologic prognostic factors for ductal carcinoma of the head of the pancreas. *Oncol Rep* 1994;1:145–148.

19. Manabe T, Ohshio G, Baba N, Tobe T. Factors influencing prognosis and indications for curative pancreatectomy for ductal adenocarcinoma of the head of the pancreas. *Int J Pancreatol* 1990;7:187–189.

20. Willett CG, Lewandrowski K, Warshaw AL *et al.* Resection margins in carcinoma of the head of the pancreas. Implications for radiation therapy. *Ann Surg* 1993;217:144–148.

21. Bottger TC, Boddin J, Heintz A, Junginger T. Clinicopathologic study for the assessment of resection for ampullary carcinoma. *World J Surg* 1997;21:379–383.

22. Kayahara M, Nagakawa T, Konishi I *et al.* Clinicopathological study of pancreatic carcinoma with particular reference to the invasion of the extrapancreatic neural plexus. *Int J Pancreatol* 1991;10:105–111.

23. Hyoty M, Visakorpi T, Kallioniemi O-P *et al.* Prognostic value of analysis of DNA in pancreatic adenocarcinoma by flow cytometry. *Eur J Surg* 1991;157:595–600.

24. Rugge M, Sonego F, Sessa F *et al.* Nuclear DNA content and pathology in radically treated pancreatic carcinoma. The prognostic significance of DNA ploidy, histology and nuclear grade. *Cancer* 1996;77:459–466.

25. Bottger TC, Storkel S, Wellek S *et al.* Factors influencing survival after resection of pancreatic cancer. *Cancer* 1994;73:63–73.

26. Nagami H, Tamura K, Kin S *et al.* Nucleolar organizer regions in invasive ductal carcinoma of the pancreas: quantitative and qualitative evaluation in predicting biologic potential and prognosis. *J Exp Clin Cancer Res* 1996;15:71–76.

27. Eskelinen M, Lipponen P, Marin S *et al.* Prognostic factors in human pancreatic cancer, with special reference to quantitative histology. *Scand J Gastroenterol* 1991;26:483–490.

28. Coppola D, Lu L, Fruehauf JP *et al.* Analysis of p53, p21(WAF1), and TGF-beta 1 in human ductal adenocarcinoma of the pancreas. TGF-beta 1 protein expression predicts longer survival. *Am J Clin Pathol* 1998;110:16–23.

29. Sperti C, Pasquali C, Piccoli A, Pedrazzoli S. Survival after resection for ductal adenocarcinoma of the pancreas. *Br J Surg* 1996;83:625–631.

NATIONAL MINIMUM DATASET

PANCREATIC CARCINOMA HISTOPATHOLOGY REPORT

Surname ..... Forenames ..... Date of birth ..... Sex.....

Hospital ..... Hospital no ..... NHS no .....

Date of request ..... Date of reporting..... Report no.....

Pathologist ..... Surgeon .....

Type of specimen: .....

Specimen dimensions

Length of duodenum ..... mm
Length of lesser curve ..... mm
Length of greater curve..... mm
Length of gall bladder ..... mm
Length of bile duct ..... mm
Size of pancreas ..... x ..... x ..... mm

Site of tumour .....
Maximum tumour diameter ..... mm
Other organs .....
Named vessel identified Yes No
Which vessel? .....
Stent in place Yes No

Type of tumour Ductal adenocarcinoma Other (see Table 2) .....

Differentiation: Well Moderate Poor

Maximum depth of invasion (T)

Tis: Carcinoma *in situ*
T1: Tumour limited to the pancreas, 20 mm or less in greatest dimension
T2: Tumour limited to the pancreas, more than 20 mm in greatest dimension
T3: Tumour extends directly into any of the following: duodenum, bile duct, peripancreatic tissues
T4: Tumour extends directly into any of the following: stomach, spleen, colon, adjacent large vessels.

Perineural invasion Yes No
Named vessel involved Yes No

Margins

Resection margin involvement Yes No If yes, which margin .....

Lymph node involvement (N)

Total number of nodes .....
Number of nodes involved .....

NX: Cannot be assessed
N0: Regional lymph nodes* not involved
N1: Regional lymph nodes* involved
N1a: Metastasis in a single group of regional lymph nodes
N1b: Metastasis in multiple groups of regional lymph nodes

Distant metastasis (M)

MX: Cannot be assessed
M0: No distant metastasis
M1: Distant metastasis

** Please see text and Figure 2 for definition of regional nodes*

Comments

Pathological staging pT pN pM **Completely excised at all margins?** Yes No

Signature:..... Date:..... SNOMed codes:.....

NATIONAL MINIMUM DATASET

AMPULLARY CARCINOMA HISTOPATHOLOGY REPORT

Surname ..... Forenames ..... Date of birth ..... Sex.....

Hospital ..... Hospital no ..... NHS no .....

Date of request ..... Date of reporting..... Report no.....

Pathologist ..... Surgeon .....

Type of specimen: .....

Specimen dimensions

Length of duodenum ..... mm
Length of lesser curve ..... mm
Length of greater curve..... mm
Length of gall bladder ..... mm
Length of bile duct ..... mm
Size of pancreas ..... x ..... x ..... mm

Maximum tumour diameter ..... mm
Other organs .....
Named vessel identified Yes No
Which vessel? .....
Stent in place Yes No

Type of tumour Adenocarcinoma Other (see Table 3) .....

Differentiation: Well Moderate Poor

Maximum depth of invasion (T)

- Tis: Carcinoma *in situ*
- T1: Tumour limited to ampulla of Vater or sphincter of Oddi
- T2: Tumour invades the duodenal wall
- T3: Tumour invades 20 mm or less into pancreas
- T4: Tumour invades more than 20 mm into pancreas and/or into other adjacent organs

Perineural invasion Yes No

Named vessel involved Yes No

Margins

Resection margin involvement Yes No If yes, which margin .....

Lymph node involvement (N)

Total number of nodes .....
Number of nodes involved .....

- NX: Cannot be assessed
- N0: Regional lymph nodes* not involved
- N1: Regional lymph nodes* involved

Distant metastasis (M)

- MX: Cannot be assessed
- M0: No distant metastasis
- M1: Distant metastasis

** Please see text and Figure 2 for definition of regional nodes*

Comments

Pathological staging pT pN pM **Completely excised at all margins?** Yes No

Signature:..... Date:..... SNOMed codes:.....

NATIONAL MINIMUM DATASET

BILE DUCT CARCINOMA HISTOPATHOLOGY REPORT

Surname ..... Forenames ..... Date of birth ..... Sex.....

Hospital ..... Hospital no ..... NHS no .....

Date of request ..... Date of reporting..... Report no.....

Pathologist ..... Surgeon .....

Type of specimen: .....

Specimen dimensions

Length of duodenum ..... mm
Length of lesser curve ..... mm
Length of greater curve ..... mm
Length of gall bladder ..... mm
Length of bile duct ..... mm
Size of pancreas ..... x ..... x ..... mm

Maximum tumour diameter ..... mm
Other organs .....
Named vessel identified Yes No
Which vessel? .....
Stent in place Yes No

Type of tumour Adenocarcinoma Other (see Table 3) .....

Differentiation: Well Moderate Poor

Maximum depth of invasion (T)

Tis: Carcinoma *in situ*
T1a: Tumour invades subepithelial connective tissue
T1b: Tumour invades fibromuscular layer
T2: Tumour invades perifibromuscular connective tissue
T3: Tumour invades adjacent structures: liver, pancreas, duodenum, gall bladder, colon or stomach

Perineural invasion Yes No
Named vessel involved Yes No

Margins

Resection margin involvement Yes No If yes, which margin .....

Lymph node involvement (N)

Total number of nodes .....
Number of nodes involved .....

NX: Cannot be assessed
N0: Regional lymph nodes not involved
N1: Metastasis in cystic duct, pericholedochal and/or hilar lymph nodes
N2: Metastasis in peripancreatic (head), periduodenal, periportal, coeliac, superior mesenteric, posterior pancreatico-duodenal lymph nodes

Distant metastasis (M)

MX: Cannot be assessed
M0: No distant metastasis
M1: Distant metastasis

Comments

Pathological staging pT pN pM **Completely excised at all margins?** Yes No

Signature:..... Date:..... SNOMed codes:.....