

Protocol for the Examination of Specimens From Patients With Invasive Carcinoma of Renal Tubular Origin

Wilms tumors and tumors of urothelial origin are not included.

Based on AJCC/UICC TNM, 7th edition

Protocol web posting date: October 2013

Procedures

- Incisional Biopsy (Needle or Wedge)
- Partial Nephrectomy
- Radical Nephrectomy

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CAP Kidney Protocol Revision History

Version Code

The definition of the version code can be found at www.cap.org/cancerprotocols.

Version: Kidney 3.2.0.0

Summary of Changes

The following changes have been made since the June 2012 release.

Nephrectomy, Partial or Radical

Macroscopic Extent of Tumor

"Primary tumor cannot be assessed" and "No evidence of primary tumor" were added. "Major calyx" and "Minor calyx" were added beneath "Tumor extension in the pelvicaliceal system" as follows:

____ Tumor extension into pelvicaliceal system

- + ____ Major calyx
- + ____ Minor calyx

Microscopic Extent of Tumor

"Primary tumor cannot be assessed" and "No evidence of primary tumor" were added.

Primary Tumor (pT)

pT1, pT2, and pT3 were changed from selectable to nonselectable elements, as follows:

Primary Tumor (pT)

- ____pTX: Primary tumor cannot be assessed
- ____ pT0: No evidence of primary tumor
- pT1: Tumor 7 cm or less in greatest dimension, limited to the kidney
- ____pT1a: Tumor 4 cm or less in greatest dimension, limited to the kidney

____pT1b: Tumor more than 4 cm but not more than 7 cm in greatest dimension, limited to the kidney pT2: Tumor more than 7 cm in greatest dimension, limited to the kidney

- ____ pT2a: Tumor more than 7 cm but less than or equal to 10 cm in greatest dimension, limited to the kidney
- ____ pT2b: Tumor more than 10 cm, limited to the kidney
- pT3: Tumor extends into major veins or perinephric tissues but not into the ipsilateral adrenal gland and not beyond Gerota's fascia
- ____pT3a: Tumor grossly extends into the renal vein or its segmental (muscle containing) branches, or tumor invades perirenal and/or renal sinus fat but not beyond Gerota's fascia
- ____ pT3b: Tumor grossly extends into the vena cava below the diaphragm
- ____ pT3c: Tumor grossly extends into vena cava above diaphragm or invades the wall of the vena cava
- ____ pT4: Tumor invades beyond Gerota's fascia (including contiguous extension into the ipsilateral adrenal gland)

Surgical Pathology Cancer Case Summary

Protocol web posting date: October 2013

KIDNEY: Biopsy

Note: Use of case summary for biopsy specimens is optional.

Select a single response unless otherwise indicated.

+ Procedure

- + ____ Incisional biopsy, needle
- + ____ Incisional biopsy, wedge
- + ____ Other (specify): _____
- + ____ Not specified

+ Specimen Laterality

- + ____ Right
- + ____ Left
- + ____ Not specified

+ Histologic Type (Note A)

- + ___ Clear cell renal cell carcinoma
- + ____ Multilocular clear cell renal cell carcinoma
- + ____ Papillary renal cell carcinoma
- + ____ Chromophobe renal cell carcinoma
- + ____ Carcinoma of the collecting ducts of Bellini
- + ____ Renal medullary carcinoma
- + ____ Translocation carcinoma (Xp11 or others)
- + ____ Carcinoma associated with neuroblastoma
- + ____ Mucinous tubular and spindle cell carcinoma
- + ____ Tubulocystic renal cell carcinoma
- + ____ Renal cell carcinoma, unclassified
- + ____ Other (specify): _____

+ Sarcomatoid Features (Note B)

- + ____ Not identified
- + ____ Present

+ Specify percentage of sarcomatoid element: _____%

+ Histologic Grade (Fuhrman Nuclear Grade) (Note C)

- + ____ Not applicable
- + ____ GX: Cannot be assessed
- + ____ G1: Nuclei round, uniform, approximately 10 µm; nucleoli inconspicuous or absent
- + ____ G2: Nuclei slightly irregular, approximately 15 µm; nucleoli evident
- + ____ G3: Nuclei very irregular, approximately 20 µm; nucleoli large and prominent
- + ____ G4: Nuclei bizarre and multilobated, 20 µm or greater, nucleoli prominent, chromatin clumped

+ Additional Pathologic Findings

- + ____ None identified
- + ___ Other pathology present (specify): _____

+ Comment(s)

Surgical Pathology Cancer Case Summary

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KIDNEY: Nephrectomy, Partial or Radical

Select a single response unless otherwise indicated.

Procedure (Note D)

- Partial nephrectomy
- ____ Radical nephrectomy

___ Other (specify): _____

____ Not specified

Specimen Laterality

- ____ Right
- ____ Left
- ____ Not specified

+ Tumor Site (select all that apply)

- + ___ Upper pole
- + ____ Middle
- + ____ Lower pole
- + ____ Other (specify): _____
- + ____ Not specified

Tumor Size (largest tumor if multiple)

Greatest dimension: ___ cm

- + Additional dimensions: ____ x ___ cm
- ___ Cannot be determined (see "Comment")

Tumor Focality

- ____ Unifocal
- ___ Multifocal

Macroscopic Extent of Tumor (select all that apply) (Note E)

- ____ Primary tumor cannot be assessed
- ____ No evidence of primary tumor
- ____ Tumor limited to kidney
- ____ Tumor extension into perinephric tissues
- ____ Tumor extension into renal sinus
- ____ Tumor extension beyond Gerota's fascia
- ____ Tumor extension into major veins (renal vein or its segmental (muscle containing) branches, inferior vena cava)
- ____ Tumor extension into pelvicaliceal system
 - + ____ Major calyx
 - + ____ Minor calyx

_____ Tumor extension into adrenal gland

- ___ Direct invasion (T4)
- ____ Noncontiguous (M1)

____ Tumor extension into other organ(s)/structure(s) (specify): ____

Histologic Type (Note A)

- ____ Clear cell renal cell carcinoma
- ____ Multilocular clear cell renal cell carcinoma
- ____ Papillary renal cell carcinoma
- ___ Chromophobe renal cell carcinoma
- ___ Carcinoma of the collecting ducts of Bellini
- ____ Renal medullary carcinoma
- ____ Translocation carcinoma (Xp11 or others)
- ___ Carcinoma associated with neuroblastoma
- ____ Mucinous tubular and spindle cell carcinoma
- ____ Tubulocystic renal cell carcinoma
- ____ Renal cell carcinoma, unclassified
- ___ Other (specify): _____

Sarcomatoid Features (Note B)

- ____ Not identified
- ____ Present

Specify percentage of sarcomatoid element: _____%

+ Tumor Necrosis (any amount)

- + ____ Not identified
- + ____ Present

Histologic Grade (Fuhrman Nuclear Grade) (Note C)

- ___ Not applicable
- ____ GX: Cannot be assessed
- ____ G1: Nuclei round, uniform, approximately 10 µm; nucleoli inconspicuous or absent
- ____ G2: Nuclei slightly irregular, approximately 15 µm; nucleoli evident
- ____ G3: Nuclei very irregular, approximately 20 µm; nucleoli large and prominent
- ____ G4: Nuclei bizarre and multilobated, 20 µm or greater, nucleoli prominent, chromatin clumped
- ___ Other (specify): _____

Microscopic Tumor Extension (select all that apply)

- ____ Primary tumor cannot be assessed
- ____ No evidence of primary tumor
- ____ Tumor limited to kidney
- ____ Tumor extension into perinephric tissue (beyond renal capsule)
- ____ Tumor extension into renal sinus
- ____ Tumor extension beyond Gerota's fascia
- ____ Tumor extension into major vein (renal vein or its segmental (muscle containing) branches, inferior vena cava)
- ____ Tumor extension into pelvicalyceal system
- ____ Tumor extension into adrenal gland
 - ____ Direct invasion (T4)
 - __ Noncontiguous (M1)

____ Tumor extension into other organ(s)/structure(s) (specify): _____

Margins (select all that apply) (Note F)

- ___ Cannot be assessed
- ____ Margins uninvolved by invasive carcinoma
- ____ Margin(s) involved by invasive carcinoma
 - ____ Renal parenchymal margin (partial nephrectomy only)
 - ____ Renal capsular margin (partial nephrectomy only)
 - ____ Perinephric fat margin (partial nephrectomy only)
 - ____ Gerota's fascial margin
 - ____ Renal vein margin
 - ____ Ureteral margin
 - ___ Other (specify): _____

+ Lymph-Vascular Invasion

(excluding renal vein and its muscle containing segmental branches and inferior vena cava)

- + ____ Not identified
- + ____ Present
- + ___ Indeterminate

Pathologic Staging (pTNM) (Note G)

TNM Descriptors (required only if applicable) (select all that apply)

- ____ m (multiple primary tumors)
- ____r (recurrent)
- ____y (posttreatment)

Primary Tumor (pT)

- ____pTX: Primary tumor cannot be assessed
- ____pT0: No evidence of primary tumor
- pT1: Tumor 7 cm or less in greatest dimension, limited to the kidney
- ____pT1a: Tumor 4 cm or less in greatest dimension, limited to the kidney
- ____pT1b: Tumor more than 4 cm but not more than 7 cm in greatest dimension, limited to the kidney pT2: Tumor more than 7 cm in greatest dimension, limited to the kidney
- ____ pT2a: Tumor more than 7 cm but less than or equal to 10 cm in greatest dimension, limited to the kidney
- ____ pT2b: Tumor more than 10 cm, limited to the kidney
- pT3: Tumor extends into major veins or perinephric tissues but not into the ipsilateral adrenal gland and not beyond Gerota's fascia
- ____pT3a: Tumor grossly extends into the renal vein or its segmental (muscle containing) branches, or tumor invades perirenal and/or renal sinus fat but not beyond Gerota's fascia
- ____ pT3b: Tumor grossly extends into the vena cava below the diaphragm
- ___ pT3c: Tumor grossly extends into vena cava above diaphragm or invades the wall of the vena cava
- ____pT4: Tumor invades beyond Gerota's fascia (including contiguous extension into the ipsilateral adrenal gland)

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Regional Lymph Nodes (pN)

- ____ pNX: Regional lymph nodes cannot be assessed
- ____ pN0: No regional lymph node metastasis
- ____pN1: Metastasis in regional lymph node(s)

____ No nodes submitted or found

Number of Lymph Nodes Examined

Specify: ____

____ Number cannot be determined (explain): _____

Number of Lymph Nodes Involved

Specify: ____ Number cannot be determined (explain): _____

Distant Metastasis (pM)

____ Not applicable

____ pM1: Distant metastasis

Pathologic Findings in Nonneoplastic Kidney (select all that apply) (Note H)

Insufficient tissue (partial nephrectomy specimen with <5 mm of adjacent nonneoplastic kidney) _____ Significant pathologic alterations

- ____ None identified

___ Glomerular disease (specify type): _____ ___ Tubulointerstitial disease (specify type): ______

- ____ Vascular disease (specify type): _____
- ___ Other (specify): _____

+ Other Tumors and/or Tumor-like Lesions (select all that apply)

- + ___ Cyst(s) (specify type): ___
- + ____ Tubular (papillary) adenoma(s)
- + ___ Other (specify): _____
- + Comment(s)

Explanatory Notes

A. Histologic Type

The histopathologic classification published by the World Health Organization (WHO)¹ and the Armed Forces Institute of Pathology² is recommended for usage.

Clear cell renal cell carcinoma Multilocular clear cell renal cell carcinoma Papillary renal cell carcinoma[#] Chromophobe renal cell carcinoma Carcinoma of the collecting ducts of Bellini Renal medullary carcinoma Xp11 translocation carcinomas Carcinoma associated with neuroblastoma Mucinous tubular and spindle cell carcinoma Tubulocystic renal cell carcinoma ^{##} Renal cell carcinoma, unclassified

[#] Papillary carcinoma is commonly separated into type 1 and type 2 based mainly on cytomorphological features.¹

^{##} Tubulocystic carcinoma is a distinct low-grade variant of renal cell carcinoma that was not listed in the 2004 WHO classification. Recent papers have elucidated the nature of this tumor.³⁻⁵ This tumor had been previously referred to as a low-grade collecting duct carcinoma.⁶ Additionally, there are a variety of other uncommon and emerging carcinomas described in the recent literature.⁷

Occasionally more than one histologic type of carcinoma occurs within the same kidney specimen. Each tumor type should be separately recorded along with its associated prognostic factors.

B. Sarcomatoid Features

Sarcomatoid carcinoma is not a specific morphogenetic subtype of renal cell carcinoma but is considered as a pattern of dedifferentiation.^{1,2} Sarcomatoid change in a renal cell carcinoma is associated with an adverse outcome.⁸ Sarcomatoid morphology may be found in renal cell carcinomas of clear cell, papillary, chromophobe, collecting duct, and unclassified subtypes.⁹⁻¹⁴ When the background carcinoma subtype is recognized, it should be specified under histologic type (see Note A). Pure sarcomatoid carcinoma or sarcomatoid carcinoma associated with epithelial elements that do not conform to usual renal carcinoma cell types should be considered as unclassified renal cell carcinoma.

There is some indication that the percentage of sarcomatoid component in a renal cell carcinoma has prognostic importance.^{13,14}

C. Histologic Grade

The following grading scheme for renal cell carcinoma developed by Fuhrman et al is recommended and shown below.¹⁵ Beyond clear cell renal cell carcinoma, Furhman grading has not been fully established for each histologic subtype of renal parenchymal neoplasia.¹⁶ The protocol does not preclude the use of other grading schemes.^{16,17} The system of grading should be specified in the pathologist's report. Scoring is based on the worst (highest) grade present in the tumor even if it constitutes only a minor component.

Fuhrman Grading System

- Grade X Cannot be assessed
- Grade 1 Nuclei round, uniform, approximately 10 µm in diameter; nucleoli inconspicuous or absent
- Grade 2 Nuclei slightly irregular, approximately 15 µm in diameter; nucleoli evident
- Grade 3 Nuclei very irregular, approximately 20 µm in diameter; nucleoli large and prominent
- Grade 4 Nuclei bizarre and multilobated, 20 µm or greater in diameter, nucleoli prominent, chromatin clumped

D. Specimen Type

A standard radical nephrectomy specimen consists of the entire kidney including the calyces, pelvis, and a variable length of ureter. The adrenal gland is usually removed en bloc with the kidney. The entire perirenal fatty tissue is removed to the level of Gerota's fascia, a membranous structure that is similar to the consistency of the renal capsule that encases the kidney in perirenal fat. Variable lengths of the major renal vessels at the hilus are submitted.

Regional lymphadenectomy is not generally performed even with a radial nephrectomy. A few lymph nodes may occasionally be seen in the renal hilus around major vessels. Other regional lymph nodes (eg, paracaval, para-aortic, and retroperineal) may be submitted separately.

A partial nephrectomy specimen may vary from a simple enucleation of the tumor to part of a kidney containing variable portions of calyceal or renal pelvic collecting system. The perirenal fat immediately overlying the resected portion of the kidney but not to a level of Gerota's fascia is usually included.

E. Macroscopic Extent of Tumor

A careful gross analysis and description of tumor extension in a nephrectomy specimen is important and should guide blocking of tissue samples for histologic assessment. Careful documentation of the tumor extension beyond kidney into perinephric fat and Gerota's fascia provides important staging information. Renal sinus fat involvement in renal cell carcinoma is an under-recognized phenomenon.¹⁸ The renal sinus is an important pathway of spread of renal cell carcinoma (Figure 1, A and B). The renal sinus fat should be carefully assessed and generously sampled in order to detect renal sinus fat involvement. There is evolving literature suggesting that renal sinus fat involvement predicts a more aggressive outcome than peripheral perinephric fat invasion.^{19,20} When renal carcinoma involves adrenal gland, it is important to document whether the involvement is contiguous spread of tumor or a separate (noncontiguous) nodule of carcinoma, the latter representing metastatic disease (pM1) (Figure 2).

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Figure 1. A, Diagram showing the renal sinus fat (S) and its rich venous system that envelops the collecting system. The renal capsule terminates (arrow) just inside the vestibule of the hilus. B, A renal malignancy is constrained by the renal capsule (arrow), yet no fibrous capsule impedes its growth into the vascular tissue of the renal sinus (curved arrows). From Bonsib et al.¹⁸ Reproduced with permission of the American Journal of Surgical Pathology. © 2000 Wolters Kluwer Health.



Figure 2. Diagram showing relationship between local tumor extension and pT designation. When a tumor shows direct invasion into the perirenal fat or renal sinus fat it is designated as pT3a. A tumor that directly invades the adrenal gland is designated as pT4 while a tumor that shows discontinuous (noncontiguous) involvement of the adrenal gland is considered metastatic (M1).

F. Margins

In a partial nephrectomy specimen, the renal parenchymal margin should be inked and histologically assessed. Most partial nephrectomy specimens also contain a portion of perinephric fat overlying the tumor site. The perirenal fat margin should also be assessed. In situations where no perirenal fat is present, the renal capsular margin should be inked and examined histologically.

In radical nephrectomy specimens the ureteric, major vascular (renal vein, renal artery) and soft tissue (Gerota's fascia, renal sinus) margins should be examined and documented in the report.

G. TNM and Stage Groupings

The TNM staging system of the American Joint Committee on Cancer (AJCC) and the International Union Against Cancer (UICC) for renal cell carcinoma is recommended.^{21,22}

By AJCC/UICC convention, the designation "T" refers to a primary tumor that has not been previously treated. The symbol "p" refers to the pathologic classification of the TNM, as opposed to the clinical classification, and is based on gross and microscopic examination. pT entails a resection of the primary tumor or biopsy adequate to evaluate the highest pT category, pN entails removal of nodes adequate to validate lymph node metastasis, and pM implies microscopic examination of distant lesions. Clinical classification (cTNM) is usually carried out by the referring physician before treatment during initial evaluation of the patient or when pathologic classification is not possible.

Pathologic staging is usually performed after surgical resection of the primary tumor. Pathologic staging depends on pathologic documentation of the anatomic extent of disease, whether or not the primary tumor has been completely removed. If a biopsied tumor is not resected for any reason (eg, when technically unfeasible) and if the highest T and N categories or the M1 category of the tumor can be

confirmed microscopically, the criteria for pathologic classification and staging have been satisfied without total removal of the primary cancer.

Stage Gr	oupings		
Stage I	T1	N0	M0#
Stage II	T2	N0	MO
Stage III	T1 or T2	N1	MO
	T3	N0 or N1	MO
Stage IV	T4	Any N	MO
	Any T	Any N	M1

M0 is defined as no distant metastasis.

TNM Descriptors

For identification of special cases of TNM or pTNM classifications, the "m" suffix and "y," "r," and "a" prefixes are used. Although they do not affect the stage grouping, they indicate cases needing separate analysis.

<u>The "m" suffix</u> indicates the presence of multiple primary tumors in a single site and is recorded in parentheses: pT(m)NM.

<u>The "y" prefix</u> indicates those cases in which classification is performed during or following initial multimodality therapy (ie, neoadjuvant chemotherapy, radiation therapy, or both chemotherapy and radiation therapy). The cTNM or pTNM category is identified by a "y" prefix. The ycTNM or ypTNM categorizes the extent of tumor actually present at the time of that examination. The "y" categorization is not an estimate of tumor prior to multimodality therapy (ie, before initiation of neoadjuvant therapy).

The "r" prefix indicates a recurrent tumor when staged after a documented disease-free interval, and is identified by the "r" prefix: rTNM.

The "a" prefix designates the stage determined at autopsy: aTNM.

Additional Descriptors

Residual Tumor (R)

Tumor remaining in a patient after therapy with curative intent (eg, surgical resection for cure) is categorized by a system known as R classification, shown below.

- RX Presence of residual tumor cannot be assessed
- R0 No residual tumor
- R1 Microscopic residual tumor
- R2 Macroscopic residual tumor

For the surgeon, the R classification may be useful to indicate the known or assumed status of the completeness of a surgical excision. For the pathologist, the R classification is relevant to the status of the margins of a surgical resection specimen. That is, tumor involving the resection margin on pathologic examination may be assumed to correspond to residual tumor in the patient and may be classified as macroscopic or microscopic according to the findings at the specimen margin(s).

Lymph-Vascular Invasion

By AJCC/UICC convention, vessel invasion (lymphatic or venous) does not affect the T category indicating local extent of tumor unless specifically included in the definition of a T category. In all other cases, lymphatic and venous invasion by tumor are coded separately.

H. Pathologic Findings in Nonneoplastic Kidney

It is important to recognize that medical kidney diseases may be present in nonneoplastic renal tissue in nephrectomy and nephroureterectomy specimens.^{23,24} Arterionephrosclerosis (or hypertensive nephropathy) and diabetic nephropathy are seen in approximately 30% and 20% of cases, respectively. Other medical renal diseases that have been identified include thrombotic microangiopathy, focal segmental glomerulosclerosis, and IgA nephropathy. The findings of greater than 20% global glomerulosclerosis or advanced diffuse diabetic glomerulosclerosis are predictive of significant decline in renal function 6 months after radical nephrectomy.²⁴ Evaluation for medical renal disease should be performed in each case; PAS and/or Jones methenamine silver stains should applied if necessary. Consultation with a nephropathologist should be pursued as needed.

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