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European Association of Urology

Platinum Priority – Kidney Cancer

Editorial by Jean-Jacques Patard on pp. 794–795 of this issue

Preoperative Aspects and Dimensions Used for an Anatomical (PADUA) Classification of Renal Tumours in Patients who are Candidates for Nephron-Sparing Surgery

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Article info

Article history:

Accepted July 27, 2009

Published online ahead of
print on August 4, 2009

Keywords:

Renal cell carcinoma
Anatomical classification
Nephron-sparing surgery
Complications



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Abstract

Background: Besides clinical tumour size, other anatomical aspects of the renal tumour are routinely considered when evaluating the feasibility of elective nephron-sparing surgery (NSS).
Objective: To propose an original, standardised classification of renal tumours suitable for NSS based on their anatomical features and size and to evaluate the ability of this classification to predict the risk of overall complications resulting from the surgery.

Design, setting, and participants: We enrolled prospectively 164 consecutive patients who underwent NSS for renal tumours at a tertiary academic referral centre from January 2007 to December 2008.

Intervention: Open partial nephrectomy without vessel clamping.

Measurements: All tumours were classified by integrating size with the following anatomical features: anterior or posterior face, longitudinal, and rim tumour location; tumour relationships with renal sinus or urinary collecting system; and percentage of tumour deepening into the kidney. We generated an algorithm evaluating each anatomical parameter and tumour size (the preoperative aspects and dimensions used for an anatomical [PADUA] score) to predict the risk of complications.

Results and limitations: Overall rates of complication were significantly correlated to all the evaluated anatomical aspects, excluding clinical size and anterior or posterior location of the tumour. By multivariate analysis, PADUA scores were independent predictors of the occurrence of any grade complications (hazard ratio [HR] for score 8–9 vs 6–7: 14.535; HR for score ≥ 10 vs 6–7: 30.641). Potential limitations were the limited number of patients with T1b tumours included in the study and the lack of laparoscopically treated patients. Further external validation of the PADUA score is needed.

Conclusions: The PADUA score is a simple anatomical system that can be used to predict the risk of surgical and medical perioperative complications in patients undergoing open NSS. The use of an appropriate score can help clinicians stratify patients suitable for NSS into subgroups with different complication risks and can help researchers evaluate the real comparability among patients undergoing NSS with different surgical approaches.

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1. Introduction

Clinical tumour size currently is the most relevant parameter used to plan surgical treatment in patients with localised renal cancer. Specifically, open partial nephrectomy (OPN) is considered the gold standard of treatment for patients with tumours ≤ 4 cm (American Joint Committee on Cancer tumour category: T1a), but guidelines highlight the possible role of radical nephrectomy in patients in whom partial nephrectomy is not technically feasible, as determined by the urologic surgeon [1,2].

A few nonrandomised, comparative studies, however, reporting similar cancer-specific survival probabilities in patients who underwent OPN or radical nephrectomy, suggest that nephron-sparing surgery (NSS) can be performed in selected patients with tumours ranging from 4.1–7 cm [3–5]. However, these studies suffer from selection bias in favour of patients who were candidates for conservative treatment. That is, it is likely that the surgeon's judgement on the feasibility of the procedure played a paramount role in the decision on which type of surgery to choose.

Beyond clinical tumour size, other anatomical aspects of the renal tumour are routinely considered in the planning of conservative surgery. In particular, we believe that polar and rim location, relationship with renal sinus or urinary collecting system (UCS), or the tumour deepening into the renal parenchyma can provide more detailed information on how to select patients suitable for partial nephrectomy and predict the risk of complications, regardless of clinical tumour size [6]. At the same time, a more detailed definition of the anatomical location of the renal tumour could improve the information concerning the real comparability between different groups of patients in the context of comparative studies between open and pure laparoscopic or robot-assisted partial nephrectomy.

The objectives of this study were (1) to propose a standardised and original classification system of renal tumours suitable for conservative treatment based on their anatomical aspects and dimensions; (2) to evaluate the ability of this classification system to predict the risk of overall complications in a series of patients who underwent NSS; and (3) to define a complication risk-group stratification of patients according to the different score of anatomical classification.

2. Materials and Methods

2.1. Patients and tumours

We evaluated prospectively 164 patients who underwent NSS for clinical tumour stage 1 (cT1) renal tumours between January 2007 and December 2008. Preoperatively, all patients were staged using computed tomography (CT) or magnetic resonance imaging (MRI). Looking at the imaging examinations, three surgeons assigned the following anatomical parameters to every tumour: (1) anterior or posterior face, (2) longitudinal location, (3) rim location; (4) relationships with sinus; (5) relationships with the UCS; (6) percentage of tumour deepening into the kidney; and (7) maximal diameter in centimetres. All three urologists were blinded to the final outcome of the patients.

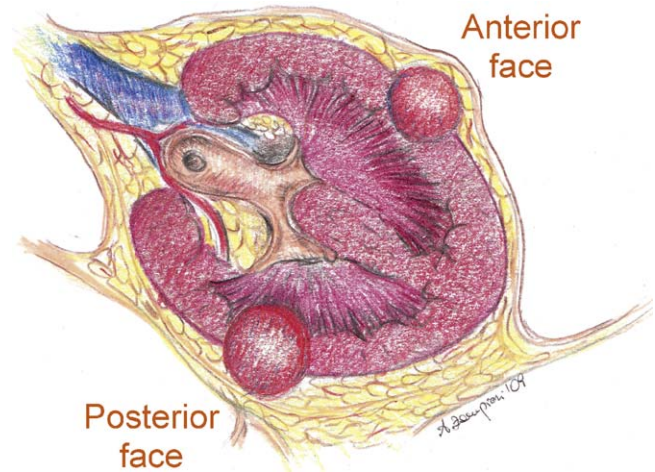


Fig. 1 – Definition of anterior and posterior face of the kidney.

The definition of previous anatomical variables was standardised according to the anatomists involved in the study. Specifically, anterior or posterior faces of the kidney were defined as those covered by the anterior or posterior layers of the renal fascia, respectively (Fig. 1). To define the longitudinal location on CT images, we used the renal sinus as a topographical landmark to subdivide the kidney into upper, middle, and lower parts (sinus line). The upper part of the kidney (upper pole) extends from the upper extremity to the first CT image in which the renal hypodense sinus appears (upper sinus line). The middle part of the kidney (middle pole) corresponds to the extent of the renal sinus. The lower part of the kidney (inferior pole) extends from the first CT image in which the renal hypodense sinus disappears (inferior sinus line) to the lower extremity (Fig. 2).

Therefore, according to longitudinal location, the tumours were classified into two different categories: (1) entirely above the upper or below the lower sinus line, or crossing the sinus line $< 50\%$; (2) crossing the sinus line $> 50\%$ or falling entirely between the sinus lines (Fig. 3a). Tumours were distinguished as being located at the lateral or at the medial rim (Fig. 3b).

The renal sinus was defined as the spacious cavity surrounded by the kidney parenchyma, lined by the renal capsule, and almost filled by the renal pelvis and vessels, with the remaining space being filled by fat [7]. On CT images the low attenuation fat outlines the collecting system and the blood vessels and differentiates the renal sinus from the parenchyma [8]. Consequently, the tumours were classified into two groups: (1) without renal sinus location, and (2) located or extended at the level of the renal sinus (Fig. 3c).

Tumours were classified into two categories with respect to the UCS: (1) absent a relationship, or (2) present a relationship (ie, involving dislocation or infiltration of the UCS) (Fig. 3d). According to the degree of tumour deepening into the parenchyma, tumours were classified into three categories: (1) $\geq 50\%$ exophytic, (2) $< 50\%$ exophytic, and (3) entirely endophytic (Fig. 3e). Finally, the tumours were categorised according to their clinical maximal diameter into two groups: (1) ≥ 4 cm, (2) 4.1–7 cm, and (3) > 7 cm (Fig. 3f).

All patients underwent an extraperitoneal NSS through a flank incision. Vessel clamping was not performed; rather, a manual or clamp compression of the parenchyma was used near the tumour. Attempts to remove the tumour with an adequate safety margin were done in all the cases. For all patients, we prospectively collected information on any intra- and postoperative complications until 30 d after surgery. All complications were graded according to an established modification of the original Clavien system [9].

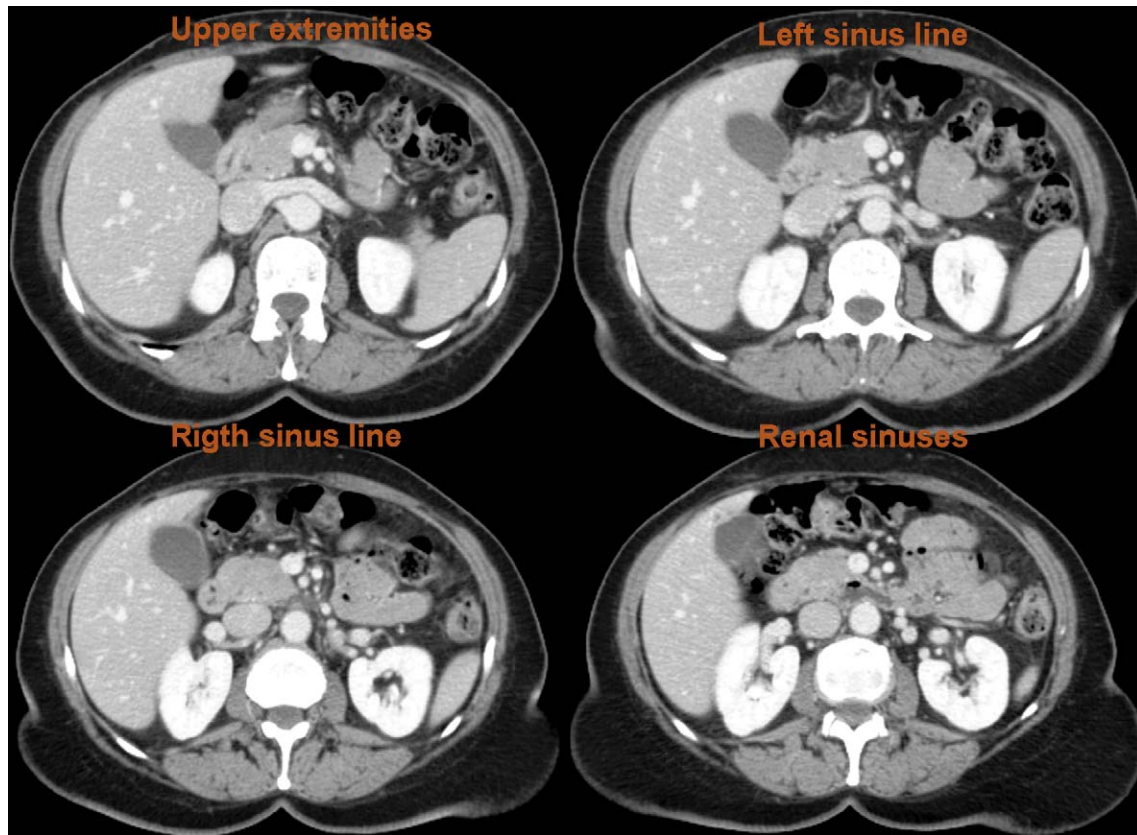


Fig. 2 – Definition of the sinus line in a normal case: (a) upper extremities; (b) left sinus line; (c) right sinus line; (d) renal sinuses.

We also included in our database the following clinical features: age, gender, body mass index (BMI), Charlson comorbidity index, symptoms at presentation according to Patard's classification [10], American Society of Anaesthesiologists (ASA) score, pathological tumour size, tumour extension according to TNM classification [11], nuclear grade according to the Fuhrman system [12], and histological subtypes according to the World Health Organisation (WHO) classification [13].

2.2. Statistical analysis

Parametric continuous variables are given as the mean plus or minus standard deviation, and nonparametric continuous variables as the median and interquartile range (IQR). The continuous variables were categorised according to the median value. The student *t* test, the Mann-Whitney *U* test, and Pearson χ^2 test were used to compare continuous and categorical variables and for the univariate analyses, as appropriate. We generated an algorithm including all the topographic variables that were significant in univariate analyses and tumour size. Then the ability of the score to predict the overall complication rates was tested in multivariate analysis using logistic regression. For all statistical analyses, a two-sided $p < 0.05$ was considered statistically significant. All data were analysed with the Statistical Package for Social Sciences software, v.16.0 (SPSS Inc., Chicago, IL, USA).

3. Results

In this study, 119 patients (72.6%) were male and 45 patients (27.4%) were female. The median age was 62 yr (IQR: 52–69), and the median BMI was 25.4 (IQR: 23.4–28).

The Charlson score was ≤ 1 in 129 patients (78.7%) and > 1 in 35 patients (21.3%). A total of 140 patients (85.4%) were asymptomatic at diagnosis, and only 24 (14.6%) reported localised symptoms. The ASA score was 1 in 46 cases (28%), 2 in 82 cases (50%), and 3 in 36 cases (22%).

The tumours were located at the level of the right kidney in 89 cases (54.3%) and at the level of the left kidney in 75 cases (45.7%). The mean clinical tumour size was 3 ± 1.2 cm (range: 1–7). The tumours were ≤ 4 cm in 137 cases (83.5%) and 4.1–7 cm in 27 cases (16.5%).

Considering the anatomical features, 86 tumours (52.4%) were located at the level of an upper or lower pole, and 78 (47.6%) at the level of the middle pole; 117 (71.3%) were $\geq 50\%$ exophytic, 34 (20.7%) $< 50\%$ exophytic, and 13 (8%) entirely endophytic; 139 (84.8%) were located at the lateral margin and 25 (15.2%) at the medial margin of the kidney; 123 (75%) did not involve the renal sinus, and 41 (25%) did involve the renal sinus; 93 (56.7%) did not have any relationship with the UCS, and 71 (43.3%) did dislocate or involve the UCS. Tumours were located on anterior face in 90 (54.9%) cases and on posterior face of the kidney in the remaining 74 (45.1%) cases.

In particular, tumour size was significantly correlated with the involvement of both the renal sinus ($p = 0.01$) and UCS ($p < 0.002$) (Table 1).

Of the tumours, 28 (17.1%) were benign (9 angiomyolipoma, and 19 oncocytoma), 99 (60.4%) were clear cell, 23 (14%) were papillary, 11 (6.7%) were chromophobe, and 3

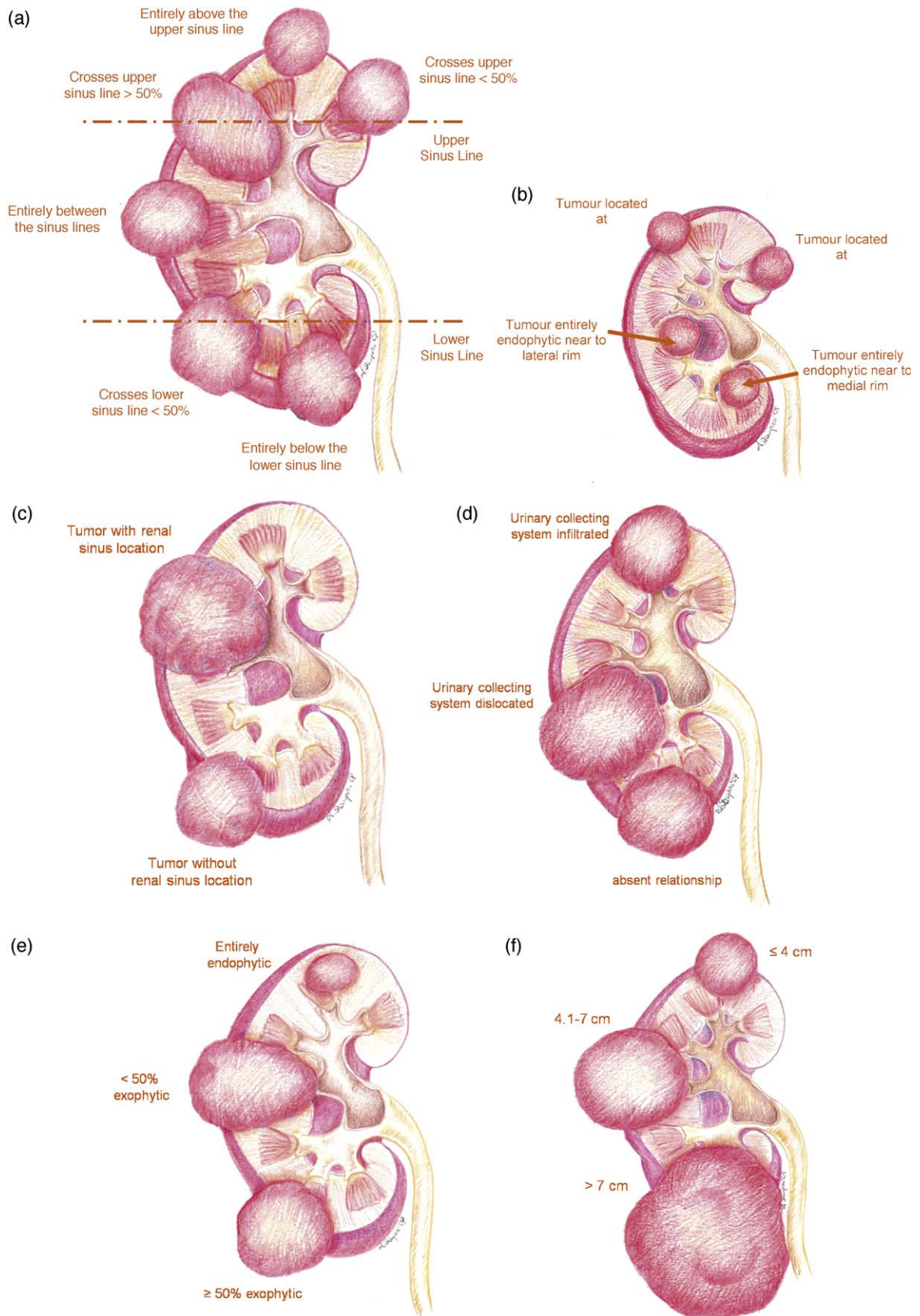


Fig. 3 - (a) Longitudinal classification of the tumours; (b) margin location of the tumours; (c) tumour relationship with renal sinus; (d) tumour relationship with urinary collecting system; (e) tumour deepening into the parenchyma; (f) tumour size classification.

Table 1 – Correlation between tumour size and other anatomical aspects included in the preoperative aspects and dimensions used for an anatomical (PADUA) classification of renal tumours

Anatomical aspects	Clinical tumour size (cm) (% of tumours)		p value
	≤4 (n = 137)	4.1–7 (n = 27)	
Longitudinal (polar) location			0.43
Superior/inferior	70 (51.1)	16 (59.3)	
Middle	67 (48.9)	11 (40.7)	
Exophytic rate			0.94
≥50%	97 (70.8)	20 (74.1)	
<50%	29 (21.2)	5 (18.5)	
Endophytic	11 (8)	2 (7.4)	
Renal rim			0.60
Lateral	117 (85.4)	22 (81.5)	
Medial	20 (14.6)	5 (18.5)	
Renal sinus			0.01
Not involved	108 (78.8)	15 (55.6)	
Involved	29 (21.2)	12 (44.4)	
Urinary collecting system			0.002
Not involved	85 (62)	8 (29.6)	
Dislocated/infiltrated	52 (38)	19 (70.4)	
Face			0.44
Anterior	77 (56.2)	13 (48.1)	
Posterior	60 (43.8)	14 (51.9)	

(1.8%) were unclassified renal cell carcinoma. The pathological stage of the primary tumour was pT1a in 109 cases (80.1%), pT1b in 16 cases (11.8%), pT2 in 2 cases (1.5%), and pT3a in 9 cases (6.6%).

Overall complications were observed in 37 cases (22.6%). Of these, intraoperative bleeding required transfusion in 21 cases, spleen injury was seen in a single case, pleura injury was seen in a single case, postoperative transfusion was required in 10 cases, and fever or other medical complications occurred in 4 cases. According to the adopted modified Clavien system, we recorded 4 cases of grade 1 complications (2.4%), 31 cases of grade 2 complications (18.9%), and 2 cases of grade 3b complications (1.2%). The latter were the one patient with intraoperative spleen and the one with pleural injury.

Overall complication rates were significantly correlated to polar location of the tumours ($p = 0.01$); rim location ($p = 0.005$); involvement of the sinus ($p < 0.001$); involvement of the UCS ($p < 0.001$); and percentage of tumour deepening into the kidney ($p = 0.002$). In contrast, clinical tumour size did not predict the overall complication rate ($p = 0.32$), as well as anterior or posterior location of the tumour ($p = 0.62$) (Table 2). Table 3 summarises the components of the PADUA score.

The median value of the PADUA score was 7.5 (IQR: 7–9). The PADUA score was able to predict the risk of overall complications in the whole series ($p < 0.001$). Considering other clinical and pathological variables, only BMI $>25\%$ predicted the overall complication rate ($p = 0.01$) (Table 2). Stratifying by anterior or posterior tumour site, PADUA score retained a statistically significant power in both locations (Table 4).

By multivariate analysis, only PADUA score was found to be an independent predictor of the occurrence of any grade complications (Table 5). In particular, multivariate analysis

showed that a PADUA score between 8 and 9 identified a group of patients with a 14-fold higher risk of complications compared to those patients reporting scores of 6 to 7. Patients with a score ≥ 10 had a 30-fold higher risk of complications compared to those with scores of 6 or 7.

4. Discussion

This study proposed an original preoperative classification system integrating tumour size and the most important anatomical features of renal tumours suitable for NSS. This classification may represent a valid tool for improving the definition of the characteristics of tumours treated with NSS. The frequency of the different anatomical aspects considered in our classification also allowed us to demonstrate the wide variability of renal tumour locations. Moreover, this integrated anatomical system can be used to predict the risk of complications after open NSS and can be used to improve selection criteria for different surgical approaches. In particular, our data showed that in patients who underwent NSS, tumour anatomical information could be used to more accurately predict the risk of complication than could clinical tumour size. The use of these integrated anatomical classifications will represent an important tool for more correctly evaluating the forthcoming comparative studies among OPN, laparoscopic partial nephrectomy, and robotic partial nephrectomy.

The present study was designed with the purpose of translating and measuring the decision-making process of any urologist evaluating a kidney tumour suitable for NSS based on some anatomical features. All the actors in the study were urologists, excluding the possibility of an external radiological review of the CT scan images. Indeed, most of the radiologic characteristics we included in the model are usually not present in routine radiological

Table 2 – Factors predictive of the occurrence of overall any complication: univariate analysis

Variable	Overall complications, n (%)		p value
	Absent (n = 127)	Present (n = 37)	
Longitudinal (polar) location			0.01
Superior/inferior	73 (84.9)	13 (15.1)	
Middle	54 (69.2)	24 (30.8)	
Exophytic rate			0.002
≥50%	99 (84.6)	18 (15.4)	
<50%	21 (61.8)	13 (38.2)	
Endophytic	7 (53.8)	6 (46.2)	
Renal rim			0.005
Lateral	113 (81.3)	26 (18.7)	
Medial	14 (56)	11 (44)	
Renal sinus			<0.001
Not involved	107 (87)	16 (13)	
Involved	20 (48.8)	21 (51.2)	
Urinary collecting system			<0.001
Not involved	85 (91.4)	8 (8.6)	
Dislocated/infiltrated	42 (59.2)	29 (40.8)	
Face			0.62
Anterior	71 (78.9)	19 (21.1)	
Posterior	56 (75.7)	18 (24.3)	
Tumour size (cm)			0.14
≤4	109 (79.6)	28 (20.4)	
4.1–7	18 (66.7)	9 (33.3)	
pT, 2002			0.21
Benign	18 (64.3)	10 (35.7)	
pT1a	88 (80.7)	21 (19.3)	
pT1b	14 (87.5)	2 (12.5)	
pT2	1 (50)	1 (50)	
pT3a	6 (66.7)	3 (33.3)	
Patient age (yr)			0.09
≤60	49 (71)	20 (29)	
>60	78 (82.1)	17 (17.9)	
BMI			0.01
≤25	77 (84.6)	23 (15.4)	
>25	50 (68.5)	14 (31.5)	
Charlson comorbidity index			0.68
0–1	99 (76.7)	30 (23.3)	
>1	28 (80)	7 (20)	
ASA score			0.15
1	31 (67.4)	15 (32.6)	
2	67 (81.7)	15 (18.3)	
3–4	29 (80.6)	7 (19.4)	
PADUA score			<0.001
6	34 (94.4)	2 (5.6)	
7	48 (98)	1 (2)	
8	22 (64.7)	12 (35.3)	
9	10 (62.5)	6 (37.5)	
10	8 (50)	8 (50)	
11	2 (25)	6 (75)	
12	2 (50)	2 (50)	
13	1 (100)	0	

pT = pathologic tumour stage; ASA = American Society of Anaesthesiologists; BMI = body mass index; PADUA score = preoperative aspects and dimensions used for an anatomical score.

reports. Moreover, to improve the overall quality of the analysis, all the urologists involved in the evaluation of the imaging studies were blinded to the patients' outcome.

The PADUA classification of renal tumours takes into consideration five anatomical aspects of the tumour plus its maximal diameter. This classification differs from the

RENAL nephrometry scoring system [14], with the main differences represented by the definition of the sinus lines and the evaluation of the anatomical relationship between the tumour and the UCS or renal sinus. In clinical and pathological practice, the kidney is subdivided into a superior pole, an inferior pole, and a midportion [15,16];

Table 3 – Score assigned to each anatomical feature included in the preoperative aspects and dimensions used for an anatomical (PADUA) classification

Anatomical features*	Score
Longitudinal (polar) location	
Superior/inferior	1
Middle	2
Exophytic rate	
≥50%	1
<50%	2
Endophytic	3
Renal rim	
Lateral	1
Medial	2
Renal sinus	
Not involved	1
Involved	2
Urinary collecting system	
Not involved	1
Dislocated/infiltrated	2
Tumour size (cm)	
≤4	1
4.1–7	2
>7	3

* Anterior or posterior face can be indicated with a letter ("a" or "p") following the score.

from an anatomical point of view, poles represent the extremities of the kidney [7,17,18]. In the RENAL nephrometry scoring system, two polar lines (defined as the portion of the kidney where the concentric rim of the renal parenchyma is interrupted by the renal hilar vessels, pelvis, or fat on axial imaging) were used to identify the site of the tumour. In the PADUA classification, the renal sinus is used as the topographical landmark to subdivide the kidney into upper, middle, and lower parts. The renal sinus appears in the CT images as a hypodense area in the context of the renal parenchyma. The sinus line corresponds to the passage from the oval shape of the extremity of the kidney to the appearance of a hypodense area (the adipose tissue of the renal sinus) inside the renal parenchyma. The sinus line is an easily recognisable landmark on a CT axial exam (which represents the most available preoperative diagnostic tool), but it can also be traced on coronal images on MRI examination. In our opinion, defining the sinus line on CT or MRI scans is easier than identifying the polar line described in the RENAL system, which requires coronal images in all cases.

The involvement of the renal sinus is another parameter of the PADUA classification. Frank et al classified tumours

Table 5 – Multivariate models predicting overall complications

Variable	HR	95% CI	p value
Padua score			
6–7	Reference		
8–9	14.535	3.984–53.031	<0.001
≥10	30.641	7.753–120.948	<0.001
BMI (≤25 vs >25)	0.513	0.217–1.211	0.12

HR = hazard ratio; CI = confidence interval; BMI = body mass index.

based on a central extension into the kidney in direct contact with or invading the pelvicaliceal system and/or renal sinus based on preoperative three-dimensional CT [19]. The renal sinus is easily identifiable on both CT and MRI scans, allowing evaluation of the anatomical relationships between tumour and UCS or renal sinus. The RENAL scoring system included in a single category (N) the relationship between tumour and both UCS and renal sinus [14]. We believe that measuring the distance between the tumour and the previous anatomical structures is more complex than our simple evaluation of the anatomical relation. All the other parameters are similar in the two classifications.

With regard to tumour size, we preferred to use the maximum diameter rather than tumour volume; it is more commonly adopted and easier to understand than volume.

One potential limitation of this prospective study is the lack of evaluation of warm ischaemia time, which is an important indirect parameter of the difficulty of conservative treatments. In our experience we did not clamp the renal arteries but rather performed a compression of the parenchyma in the area surrounding the tumour, which resulted in higher risks of both bleeding and transfusions. However, the overall complication rate in our series overlapped those recorded in other recently published studies [20]. Other authors should test the ability of our classification to predict the warm ischaemia time duration as well as the occurrence of complications after partial nephrectomy performed with vessel clamping.

In our series, all the patients were treated by open partial nephrectomy; thus, the generalisability of our findings in patients treated by laparoscopic or robotic partial nephrectomy should be tested. Another potential drawback of the study is the limited external validity of these results in patients with T1b tumours potentially suitable for NSS. Few patients with these characteristics were included in the present study, according to our current indications for elective NSS. However, we believe that this classification

Table 4 – Preoperative aspects and dimensions used for an anatomical (PADUA) score according to anterior or posterior tumour location

Face	PADUA score	No complications, n (%)	Complications, n (%)	p value
Anterior	6–7	48 (98)	1 (2)	<0.001
	8–9	15 (60)	10 (40)	–
	≥10	8 (50)	8 (50)	–
Posterior	6–7	34 (94.4)	2 (5.6)	<0.001
	8–9	17 (68)	8 (32)	–
	≥10	5 (38.5)	8 (61.5)	–

might have a significant role in the accurate selection of those patients with T1b tumours suitable for partial nephrectomy.

Another interesting application of this anatomical and dimensional renal tumour classification could be the potential relationship with oncological outcomes, such as local recurrence or progression-free survival. Data from this prospective study are too immature to answer to this question.

5. Conclusions

The PADUA score of renal tumour candidates for NSS is a simple anatomical system integrating the most important features defining location of renal tumours and their relationship with the most important anatomical structures of the kidney. Our study demonstrated that the PADUA score is able to predict the risk of surgical and medical perioperative complications in patients who underwent OPN. The use of an appropriate score can help clinicians stratify patients suitable for NSS into subgroups with different complication risks. Moreover, this classification could be used as a standardised tool to test the comparability between groups of patients undergoing partial nephrectomy with those undergoing different surgical approaches. Further experiences are needed to validate this scoring system in patients who undergo pure laparoscopic or robotic partial nephrectomy.

Author contributions: Vincenzo Ficarra had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Ficarra, Artibani.

Acquisition of data: Secco, Novara, Macchi, Porzionato, De Caro.

Analysis and interpretation of data: Ficarra.

Drafting of the manuscript: Ficarra.

Critical revision of the manuscript for important intellectual content: Novara, Macchi, Porzionato, De Caro, Artibani.

Statistical analysis: Ficarra, Novara.

Obtaining funding: None.

Administrative, technical, or material support: Artibani, De Caro.

Supervision: Artibani.

Other (specify): None.

Financial disclosures: None.

Funding/Support and role of the sponsor: No funding or other financial support was received.

Acknowledgment statement: The authors thank Antonietta Zampieri for her valuable collaboration with pictures.

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