

Endophytic Tumour Area: A New Morphometric Marker That Predicts the Outcome of Laparoscopic Partial Nephrectomy

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Abstract

Aims:

To determine morphometric and clinical variables associated with ischaemia time (IT) and complications in laparoscopic partial nephrectomy (LPN).

Material and methods:

Retrospective observational cohort study of 210 patients treated with LPN between 2006-2019.

The new morphometric variables that we proposed, were: total tumour area (TTA), line of contact (LC), endophytic tumour area (ETA), exophytic tumour area (XTA).

Central tendency and dispersion measures were calculated.

Patients were divided into two groups according to IT ($IT < 15 \text{ min}$ ($n=99$) and $IT \geq 15 \text{ min}$ ($n=111$)), for the purpose of statistical analysis. Univariate analysis was performed using the Mann-Whitney U test, and multivariate logistic regression analysis to identify variables associated with IT and complications, and COR curves and their area under curve (AUC) of ETA to predict IT and complications.

Results:

Mean age was 66.62 ± 13.33 years (28-90).

There was correlation between IT and ETA (B: 0.09; $p < 0.001$), and correlation between IT and experience (B: -0.07; $p < 0.001$).

Variables that significantly modified IT, were between others: ETA ($p < 0.001$) or LC ($p = 0.001$). ETA ($p = 0.037$) and LC ($p = 0.044$), were associated with the occurrence of complications.

The multivariate analysis to predict IT, showed that experience ($p < 0.01$) and ETA ($p = 0.001$) independently predicted IT; a second multivariate analysis to predict global complications, showed that AC ($p = 0.005$), and TTA ($p = 0.024$) independently predicted global complications. A third multivariate analysis to predict major complications (Clavien \geq III), showed that experience ($p = 0.021$), TTA ($p = 0.037$), and Charlson ($p = 0.039$), predicted major complications.

The COR AUC of ETA was 0.730 to predict IT; 0.616 to predict overall complications, and 0.678 to predict major complications.

Conclusions

ETA and surgical experience are independent variables associated with IT in LPN.

CL and TTA are independently associated with overall complications. TTA, Charlson index, and experience independently predict major complications.

Introduction

Kidney cancer is the third most frequent urological tumour, after prostate and bladder cancer.

According to data from the SEOM (1) (Spanish Medical Oncology Association), in 2018 and in terms of prevalence, kidney cancer ranked fourteenth among the most frequent neoplasias at worldwide level, with a total of 403,232 cases diagnosed (2.2%). In this same year (2018), and according to the same source, in Spain renal neoplasia was in seventh place in the national tumour ranking (with 21,584 cases (2.8%)).

According to the Spanish Cancer Registration Network (REDECAN) (2), the incidence of kidney cancer in Spain for 2020 will be 7,300 new cases (95%CI 6,569 – 8,105), of which 5,109 will appear in men (95%CI 4,464-5,817), and 2,191 new cases in women (95%CI 1,846-2,574).

As regards the death rate attributable to kidney cancer, and according to the Spanish National Institute of Statistics (INE) (3), the number of deaths in 2018 was 2,131, of which 1,414 were men.

In epidemiological terms, as established in the international consensus guide of the EUA (European Urology Association) (4), it should be noted that in terms of gender, kidney cancer is more frequent in men; it is more frequent in African-Americans, and the majority of cases are diagnosed between the fourth and sixth decade of life. The most significant risk factors are smoking, obesity, and HTA. Clinically, patients are usually asymptomatic, and incidental diagnostic involve 50% of cases. (4)

Regarding its therapeutic management, this depends on several factors, including the size of the tumour, presence of metastasis, or clinical status of the patient, etc. In this case, renal surgery with curative intention, partial nephrectomy (PN), is the treatment of choice for tumours in stage cT1 (2017 TNM classification), which strongly recommend PN (7) (8) (9)

Given the complexity of partial nephrectomy, which in most cases requires prior planning, we show through this study how certain morphometric characteristics of the renal tumour not only help to plan the intervention, but can even predict the surgical results, expressed in terms of ischaemia time and complications, two of the major concerns faced by the urologist during and after surgery.

Materials And Methods

We carried out a retrospective observational cohort study of 210 patients with renal tumours, who were treated by means of laparoscopic partial nephrectomy (LPN), performed by a single surgeon (RAA), between 2006 and 2019 in the Ferrol Healthcare Area.

None of the patients presented any formal contraindication, neither clinical nor anaesthetic, that would impede the surgery.

All patients, sign an informed consent.

Using the application of the image viewer of our centre, we describe the following variables related to the morphology of the tumour (*proposed morphometric variables, all measured at the point of maximum diameter of the tumour*): **Endophytic Tumour Area (ETA)**, defined as the tumor area/surface within renal parenchima, and expressed in cm²; **Exophytic Tumour Area (XTA)**, defined as the area/surface of the tumour that protrudes from the renal surface/outer layer, expressed in cm²; **Total Tumour Area (TTA)**, as the total area occupied by the tumour, resulting from the sum of ETA and XTA, and expressed in cm²; and **Line of Contact (LC)**, only applicable to tumours with an exophytic component, and defined as the diameter of the tumour at the time it passes through the surface of renal parenchyma, and expressed in cm.

For the quantification of the morphometric variables that we propose, we used the application of the image viewer of our centre, which makes it possible, by tracing points and lines, to calculate areas (in mm²), as well as the distance between two points (in mm). *Figures 1 and 2*

We also analysed demographic variables (sex and age, among others), classic morphometric variables (PADUA and RENAL), clinical variables (Charlson comorbidity index and perioperative complications), and experience (as a discrete quantitative variable), referred to a single surgeon and graduated in ascending order (so that 1 (first LPN), would correspond to minimum experience, and 210 (last LPN in our series), to maximum experience).

Regarding complications, the Clavien-Dindo rating scale was used, defining as major complications those of grade \geq III.

Statistical analysis:

Central tendency and dispersion measures were calculated. The Mann-Whitney U-test was used for the analysis of differences between groups. Multivariate logistic regression analysis was performed to identify variables associated with ischaemia time (IT), and complications; the ischaemia time used as a cut-off point was 15 minutes, which corresponds to the median of the IT of the sample, thereby categorising, by statistical interest, the patients into two groups: $>15'$ and $\leq 15'$

COR curves and their area under the curve (AUC) were also performed to determine the ability of the endophytic tumour area (ETA) to predict IT and complications (global and major).

A linear regression analysis was also performed to determine the association of proposed morphometric variables with IT.

A value of $p < 0.05$ was considered statistically significant.

The Statistical Package for the Social Sciences (SPSS®), version 22 (SPSS Inc., IBM Corp., Armonk, NY, USA) was used for the analytical calculations.

Measurement of proposed morphometric variables: Using a CT image (axial view), and by using the applications of the image viewer, a dotted, curved, and/or straight line is drawn, which makes it possible to calculate areas (expressed in mm²) and/or distances between two points (expressed in mm).

Results

The data, in terms of demographic, clinical and morphometric variables, is shown in **Tables 1, 2 and 3**.

The mean follow-up of patients was 41.02±29.84 months (6.23-149.00).

The mean number of days of hospital stay was 4.17±2.72 days (2-32); with regard to tumour laterality: 51.43% were right (108), 43.81% left (92), and 4.76% bilateral (10 cases). The mean size, according to the radiological report, was 34.90±18.50 mm (7.5-120).

The mean haemoglobin before surgery was 14.08±16.1 g/dl (10.00-17.70), the mean haemoglobin after surgery was 11.88±1.64 g/dl (7.80-16.00).

From a functional point of view, mean pre-surgical creatinine level was 1.00±0.26 mgr/dl (0.60-2.29), mean immediate postoperative creatinine (first 12 hours after surgery) was 1.07±0.40 mgr/dl (0.50-3.40), at 6 months after surgery was 1.10±0.43 mgr/dl (0.51-3.30), and mean creatinine at 12 months after surgery was 1.19±0.70 mgr/dl (0.50-5.52).

No reconversion to open surgery was required in any case; 4 patients (1.90%) required re-intervention after surgery, in all cases due to hemorrhagic complications.

The most frequent complications were the need for transfusion due to anaemia (14 patients, 6.66%) and perirenal haematoma

(4 patients, 1.9%), and all of them were resolved with the use of conservative measures.

According to histological type tumour, clear cell carcinoma was the most frequent, 112 (53.33%). According to pT category, the most frequent was pT1a with 142 cases (67.3%). Tumour-free surgical margins 197 (93.80%), and affected margins 13 (6.20%).

Five patients (2.38%) presented tumour recurrence; metastases developed during follow-up, and as a result of renal neoplasia, four patients (1.90%).

Out of our sample, 25 patients (11.8%) died from any cause, with kidney tumour (cancer-related death) being responsible in 8 cases (3.80%). Cancer-related survival at 1, 2 and 5 years was 97.4%, 97.4% and 93.9% respectively; overall survival at 1, 2 and 5 years was 95%, 92.8% and 81.4% respectively.

The Mann-Whitney U-test was used for the analysis of differences between groups. To IT (IT≥15' and <15'), the differences between groups were: TTA (p<0.001), LC (p<0.001), XTA (p<0.001), and ETA (p<0.001); and to overall complications (Yes/No), were: LC (p=0.044), and ETA (p=0.037).

Using linear regression analysis, a significant and positive correlation was found between IT and ETA (B: 0.444; $p < 0.001$), and a significant and negative correlation between IT and experience (B: -0.542; $p < 0.001$).

Multivariate logistic regression analysis was performed to identify variables associated with ischaemia time (IT), and surgical complications (overall and major). **Table 4 & 5.**

Lastly, the area under curve (AUC) COR of the endophytic tumour area was 0.730 to predict IT, 0.616 to predict overall complications, and 0.678 to predict major complications.

Discussion

Based on the different types of surgical approaches used to carry out a PN (laparoscopic, robotic, or open), numerous studies have focused on ascertaining which of them is the safest in terms of the oncological, clinical, or surgical results, without any statistically significant differences having been found between them (5) (6).

With regard to experience in laparoscopy, Porpiglia et al (10), show in their study that for the same surgeon, as the number of LPN carried out increases, and therefore their experience, there is a decrease in the number of complications, IT, and the positivity of the surgical margins. These results have been confirmed on several studies, not only in the field of urology, but also in many other fields. Once a certain minimum experience has been achieved, a laparoscopic surgery is not inferior to other types of surgical procedure in terms of oncological safety or functional results, as shown in studies by Hiroa N, et al in the field of colon-rectal cancer (11), Seiichiro Y. et al, for rectal cancer in stages 0/1 (12), Chi-Hung W. et al, in reference to paediatric surgery (13), or Stefano V. et al (14) and Piaopia Ye.at al, (15) in obstetric and gynaecological surgery.

The purpose of Porpiglia`s study was to show whether increasing experience in laparoscopic partial nephrectomy (group 1: less experience, and group 4: greater experience), resulted in lower IT, fewer complications, or a lower effect on surgical margins, amongst other factors. In the same way as our study, the experience referred to a single surgeon. The study was only capable of demonstrating that experience predicts the IT a statistically significant way ($p < 0.001$). They also conclude that the acceptable IT having become experienced is 20 minutes, and that the number of surgeries required in order to be able to achieve this is approximately 150.

Also, as regards the planning of the surgery, the anatomical and morphometric characteristics of the tumour are crucial, as revealed by numerous studies carried out on these aspects. In fact, today there are several standard classifications and international consensus in order to categorise kidney tumours according to their location, whether they affect the urinary tract or not, and whether the tumour is predominantly exophytic or endophytic, amongst other factors.

These are the classic score systems for renal tumours: PADUA, RENAL or the C-Index. All of these classification systems not only seek to unify criteria at international level with regard to their use, but also to determine the surgical difficulty of a PN and to predict complications derived from this approach, with the aim of ensuring the applicability of the surgical programming of LPN.

Continuing in this line, in 2011, Zhamshid Okhunov et al (**16**) carried out a study, founding that any of the three score systems used (PADUA, RENAL or the C-index), independently predicted the IT ($p<0.001$) and the degree to which kidney function was affected (modification of serum creatinine pre-surgery vs. post-surgery) ($p<0.001$), following an LPN.

In 2015, Darren Desantis et al (**17**), in a study whose primary aim was to determine whether there is any association between the different scoring systems used for kidney tumours with surgical complications in PN (open and laparoscopic), concluded that out of the variables used on the different scales, tumour diameter and the endophytic and exophytic tumour portions independently predicted complications in PN ($p<0.05$).

In his study, Desantis took into account variables that we consider important, such as the exophytic or endophytic tumour portion, although the variable 'experience' was not analysed as such.

Other authors such as Jason C. Sea et al (**18**), Linhui Wang. et al (**19**), or Luke T. Lavallée et al (**20**), present similar results to those of Okhunov et al (**16**) in LPN, although using a robotic approach (**18**) (**19**), or open PN (**20**).

One interesting study published in 2018 by Sachin Yallappa et al (**21**), analysed both the classic PADUA and RENAL systems globally and individually for each of their items, in relation to the prediction of results following PN. They demonstrated that IT is independently associated with the PADUA score ($p=0.016$), the RENAL score ($p=0.032$), and with some of the variables included in the RENAL system, such as tumour radius (R) ($p=0.004$), the exophytic/endophytic component (E) ($p=0.022$), or the polar lines (L) ($p=0.01$). It also studied the relationship between the different variables included on the scales with surgical complications, demonstrating that the location of the tumour in the renal sinus ($p=0.008$), medial/lateral localisation ($p=0.029$), and affectation of the renal collecting system ($p=0.006$), are independently associated with renal complications.

With the aim of refining the classic scoring systems for kidney tumours, new classifications have appeared, which are mainly based on the classic scales (PADUA, RENAL), such as the study published in 2019 by Vincenzo Ficarra et al (**22**), in which the SPARE system was presented (Simplified PADUA RENAL), as a novel classification system for kidney tumours, in which the number of variables of the classic PADUA system are reduced from six to four (affectation of the renal sinus, exophytic tumour portion, tumour size, and renal border affected). The authors demonstrated that SPARE independently predicts both the overall post-surgical complications ($p<0.001$), as well as the major post-surgical complications ($p=0.001$), and concluded that their grading system could replace the classic PADUA system to evaluate the complications of tumours suitable to PN.

The study of Ficarra et al (22), was performed on a large sample of 531 patients, treated through to PN with different approach modalities (open=237, laparoscopic=152, and robotic=142). Through their analysis, they demonstrated how SPARE predicts global complications in both open ($p=0.004$), laparoscopic (<0.001) and robotic nephrectomy ($p=0.009$), or through multivariate analysis, age and SPARE also predict global complications. They also analysed each of the variables that make up SPARE, showing through univariate analysis how all of the components of SPARE predict global complications. We find the results of this analysis interesting, as it breaks down the capacity of the new scale to predict complications in the different modalities of approach of a PN.

In 2014, Scott Leslie et al (23) defined a new variable of great interest: the Tumor Contact Area (TCA), which they describe as the portion of the tumour in intimate contact with the renal parenchyma. This new concept has raised, per se, numerous new studies in order to determine its relation with surgical complexity, postoperative complications or its relation with loss of renal function after PN. Leslie et al. in their study showed that there was a statistically significant association between $TCA \geq 20\text{cm}^2$ and, surgical time $\geq 4\text{h}$ ($p=0.012$), hospital stay ($p=0.0007$), and complications ($p=0.037$); no significant association with IT was found ($p=0.820$).

The new concept of TCA they introduced, whose calculation was made using the formula $4\pi r^2$ (where r =radius of the tumour), and required software that shows renal images in 3D. The TCA could be equivalent to the morphometric variable "endophytic tumour area" that we propose in our study, and for whose calculation the use of mathematical formula or specific complementary software was not necessary, so we think that the estimate is simpler.

In terms of results, and in contrast to the study by Leslie et al, we were not able to demonstrate any association of our variable ETA with complications, but we found a statistically significant association between ETA and IT.

In this same line, and in reference to TCA, in 2019, Vincenzo Ficarra et al (24), attempted to demonstrate the association of TCA both with post-surgical complications and with renal function impairment (expressed as glomerular filtrate), and showing that TCA independently predicts changes in renal function after PN ($p=0.005$), but without finding any statistically significant differences with respect to complications.

They did observe, however, that TCA ($\geq 20\text{ cm}^2$ vs $<20\text{ cm}^2$) predicts IT ($p<0.001$). As for the repercussion on renal function after PN, we did not take this variable into account in our work.

TCA continued to be the subject of numerous studies. In 2016, Po-Fan (25), established a mathematical formula to more precisely calculate the TCA of renal tumours on imaging techniques (CT), proving at the same time how TCA is a better predictor of loss of renal function than the classic RENAL grading scale, COR AUC of TCA: 0,86 vs COR AUC of RENAL: 0,69. The formula devised was: $TCA= 2\pi r d$ (where r is the radius of the tumour, and d its depth in the renal parenchyma).

This mathematical formula proposed by Hshieh et al, to calculate TCA undoubtedly provides accuracy in its measurement, but its application is laborious, and it considers that all renal tumours are spherical, which entails a certain degree of imprecision; our way of measuring morphometric variables does not require any mathematical formula, something that many entail a certain degree of imprecision, but it is applicable to all renal tumours, regardless of their geometric shape. This feature makes it a tool that is both easy to apply and reproducible.

Finally, and based on the study presented by Po-Fan Hshieh et al, in 2018 Chalairat Suk-Ouichai et al (26), presented a study in which they showed that, using the formula $TCA = 2\pi r^2 d$, TCA is associated with loss of renal function independently, only in the case of exophytic masses ($p=0.01$), but not in the case of endophytic masses ($p=0.27$). Neither complications nor IT were taken into account.

We believe that experience is a variable to be considered in every complex surgical procedure. Moreover, it is difficult to compare studies on complex surgical techniques if experience is not taken into account. Also, as regards the pre-surgical planning of an LPN, either using graduation scales for tumour lesions, such as the classic PADUA or RENAL, or complex mathematical formulas that require associated software to calculate the tumour contact area, these make the planning of an LPN into an additional laborious process, far from the intended purpose, which is to facilitate a fast, comfortable, simple pre-surgical management, and something that we consider to be of great importance: that it is reproducible at any hospital. These are precisely the objectives we intend to achieve when we propose the set of morphometric variables presented in this paper, together with the method of measuring them. This method loses precision if we compare it with the mathematical formulas presented, and which we consider to be one of the weak points of our work; however, our method is sufficiently precise to predict important variables such as IT and complications.

Conclusions

In the light of the results obtained in our study, we can conclude that:

ETA and surgical experience are independently associated with IT in LPN.

TTA and LC independently predict overall complications. TTA, experience, and the Charlson index are independently associated with major complications.

The integration of the morphometric variables we propose for the pre-operative analysis of an LPN could help with its planning and appropriate surgical programming, based on the surgeon's experience.

Declarations

This article does not contain any experimental studies with human participants or animals performed by any of the authors

All authors confirmed that all methods were carried out in accordance with relevant guidelines and regulations

Conflict of interest: all authors declare that they have no competing interests.

All authors declare that ethical approval and consent have been waived through the approval of the Galician ethics committee, by virtue of the current legal standard: Resolution of January 15, 2020 of the General Technical Secretariat of the Ministry of Health of Spain, which publishes Instruction 7/2019, relative to the protocol for the treatment of complementary data to medical history records.

Authors' contributions: All authors read and approved the final version of the manuscript.

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Tables

Table 1. Demographic variables.

| AGE | MEAN + DT | MEDIAN | MINIMUM-MAXIMUM |
|-----|-------------------|----------|-----------------|
| | 66.62±13.33 years | 68 years | 28-90 years |
| SEX | MALE, n (%) | | FEMALE, n (%) |
| | 137 (65.4%) | | 73 (34.6%) |

Table 2. Classic and proposed morphometric variables.

| | MEAN + DT | MEDIAN | MINIMUM-MAXIMUM |
|-------------------------------|-------------------------------|----------------------|-----------------------------|
| Total tumour area | 10.87 ± 14.07 cm ² | 6.97 cm ² | 1.10-106.78 cm ² |
| Line of contact | 2.94 ± 1.44 cm | 2.63 cm | 0.18-12.3 cm |
| Endophytic tumour area | 3.72 ± 4.25 cm ² | 2.44 cm ² | 0.00-33.04 cm ² |
| Exophytic tumour area | 7.15 ± 13.21 cm ² | 3.02 cm ² | 0.00-106.78 cm ² |
| R.E.N.A.L. | 6.30 ± 2.13 | 6.00 | 4-11 |
| PADUA | 8.40 ± 2.20 | 8.00 | 5-14 |

Table 3. Clinical variables.

| | MEAN + DT | MEDIAN | MINIMUM-MAXIMUM |
|----------------|-----------------|-----------|------------------------------|
| Charlson index | 4.94 ±2.43 | 4.20 | 00-14 |
| Ischaemia time | 16.74 ±8.38 min | 15.00 min | 3.00-40.00 min |
| Complications | Global, n (%) | | Major (Clavien ≥ III), n (%) |
| | 39 (18.5%) | | 9 (4.3%) |

Table 4

| - | ISCHAEMIA TIME (≥15 MINUTES VS < 15 MINUTES) | | |
|------------------------|--|-------------|------------------|
| | OR | 95%CI | p |
| Sex | 1.026 | 0.386-2.730 | 0.958 |
| Total tumour area | 1.000 | 1.000-1.000 | 0.559 |
| Endophytic tumour area | 1.005 | 1.003-1.007 | <0.001 |
| R.E.N.A.L. | 1.259 | 0.992-1.597 | 0.058 |
| Charlson index | 1.111 | 0.899-1.372 | 0.330 |
| Experience | 0.970 | 0.960-0.979 | <0.001 |

Table 5

| - | GLOBAL COMPLICATIONS | | | MAJOR COMPLICATIONS (CLAVIEN \geq III) | | |
|------------------------|----------------------|--------------|--------------|--|-------------|--------------|
| | OR | 95%IC | p | OR | 95%IC | p |
| Experience | 0.994 | 0.987-1.002 | 0.124 | 0.966 | 0.939-0.995 | 0.021 |
| Endophytic tumour area | 1.000 | 0.999-1.002 | 0.606 | 1.004 | 0.998-1.009 | 0.197 |
| Contact line | 1.120 | 1.036-1.212 | 0.005 | 1.192 | 0.962-1.478 | 0.108 |
| Total tumour area | 0.999 | 0.0997-1.000 | 0.024 | 0.995 | 0.991-1.000 | 0.037 |
| Charlson index | 1.097 | 0.873-1.379 | 0.428 | 1.603 | 1.024-2.509 | 0.039 |
| PADUA | 1.510 | 0.940-2.428 | 0.089 | 2.357 | 0.673-8.261 | 0.180 |
| RENAL | 0.694 | 0.401-1.202 | 0.192 | 1.095 | 0.289-4.146 | 0.893 |
| Age | 0.994 | 0.957-1.032 | 0.738 | 0.982 | 0.911-1.060 | 0.648 |

Figures



Figure 1

the total tumour area is 8.34 cm², line of contact 3.25 cm, and the exophytic tumour area would be 4.93 cm².

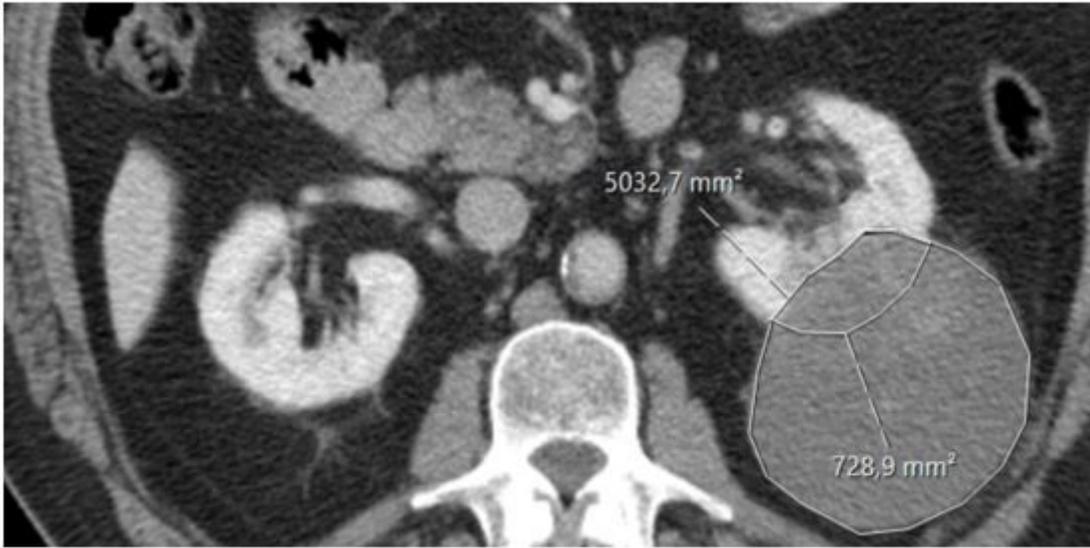


Figure 2

the total tumour area is 50.33 cm², and the endophytic tumour area is 7.29 cm².