

# Association of Prevalence of Benign Pathologic Findings After Partial Nephrectomy With Preoperative Imaging Patterns in the United States From 2007 to 2014

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 Supplemental content

**IMPORTANCE** Although the intent of nephron-sparing surgery is to eradicate malignant tumors found on preoperative imaging, benign masses often cannot be differentiated from malignant tumors. However, in the past there have been discrepancies in the reported percentages of benign masses removed by partial nephrectomy (PNx).

**OBJECTIVE** To investigate the annual trend of prevalence of benign pathologic findings after PNx and to investigate what potential factors are associated with this prevalence.

**DESIGN, SETTING, AND PARTICIPANTS** A total of 18 060 patients who underwent PNx between 2007 and 2014 were selected from Truven Health MarketScan Research Databases. We selected those patients who underwent PNx as an inpatient from 2007 and set the surgery date as the index date. Overall, a total of 21 445 patients with *International Classification of Diseases, Ninth Revision, Clinical Modification* code of 55.4 were identified from 2007 to 2015.

**MAIN OUTCOMES AND MEASURES** The annual trend of benign pathologic findings was described as an actual number and as a proportion. Univariate and multiple analyses were performed to investigate factors predictive of a benign final pathologic diagnosis, including type of preoperative imaging modality or performance of a renal mass biopsy.

**RESULTS** Among the 18 060 patients, mean (SD) age was 57 (12) years, and there were 10637 (58.9%) men and 7423 (41.1%) women. The overall prevalence of benign pathologic findings was 30.9% and the annual trends demonstrated a prevalence of over 30% for nearly every year of the study period. On univariate analysis, the performance of magnetic resonance imaging (MRI) and renal mass biopsy was associated with benign pathologic findings ( $P = .02$  and  $P < .001$ , respectively). On multivariable analysis, female sex (odds ratio [OR], 0.62; 95% CI, 0.58-0.66;  $P < .001$ ), older age (>65 years) (OR, 0.99; 95% CI, 0.99-0.99;  $P < .001$ ), and computed tomography (CT) only preoperative imaging (OR, 1.16; 95% CI, 1.05-1.28;  $P = .004$ ) were associated with benign pathologic findings after PNx.

**CONCLUSIONS AND RELEVANCE** We found that the overall prevalence of benign pathologic findings after PNx was higher than the literature suggests, with consistent year-over-year rates exceeding 30%. Female sex, older age (>65 years), and CT only preoperative imaging were predictive of a benign tumor. Further elucidation concerning covariates associated with a benign diagnosis should be the focus of future investigations to identify a cohort of patients who could potentially avoid unnecessary surgical intervention.

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Small, localized, incidentally discovered lesions represent the tumors that account for the largest increase in the incidence rate of renal cell carcinoma (RCC) and almost half of the new cases of RCC are localized tumors.<sup>1</sup> It is thought that increasing use of imaging modalities is responsible for the increased incidence of these incidentalomas.<sup>1</sup> Considering the increasingly well-understood disadvantages of radical nephrectomy in localized RCC, partial nephrectomy (PNx) is being used more often and the indications for its use are expanding. American and European guidelines recommend nephron-sparing surgery as the standard of care for patients with T1 masses that can feasibly undergo resection.<sup>2</sup>

The receipt of PNx is rising, while that of radical nephrectomy is declining<sup>3-5</sup> and the increasing use of PNx has yielded a variable frequency of benign pathologic findings, ranging from 8.1% to 27.5%.<sup>6,7</sup> To date, only a few studies have attempted to investigate the prevalence of benign pathologic findings after PNx and possible risk factors associated with predicting benign pathologic findings after PNx.<sup>8,9</sup> Moreover, no nationally representative study has investigated the overall prevalence of benign pathologic findings after PNx and its association with radiologic imaging patterns.

The aim of this study was to investigate the prevalence of benign pathologic findings after PNx and its association with preoperative imaging patterns using a nationally representative database.

## Methods

### Data Source

Data were derived from the nationally representative Truven Health Analytics MarketScan Commercial Claims and Encounters and Medicare Supplemental Databases (Truven Health Analytics, MarketScan Research, <https://marketscan.truvenhealth.com/marketscanportal/>). The data conformed to the Health Insurance Portability and Accountability Act of 1996 confidentiality requirements. Truven Health MarketScan Research Databases includes a database containing individual-level inpatient and outpatient insurance billing claims, which enables longitudinal tracking of patients regardless of different sites of care and multiple treatment years, as well as information regarding inpatient and outpatient treatment, demographic data, diagnoses, procedures, and costs. The use of this database without informed consent of the patients was approved by institutional review board of Stanford University because all data were deidentified.

### Study Population

All adults aged 18 years or older with a primary procedure code (using the *International Classification of Diseases, Ninth Revision, Clinical Modification* [ICD-9-CM] and *International Classification of Diseases, Ninth Revision, Current Procedural Terminology* [ICD-9-CPT] surgical codes) for elective partial nephrectomy (55.4) with a related diagnosis from January 1, 2007, through December 31, 2015, were selected. However, 2015 data were incomplete and limited to the second quarter only; hence, 1216 patients in 2015 were excluded (eFigure in

## Key Points

**Question** How high is the prevalence of benign pathologic findings after partial nephrectomy, and which radiologic modalities are associated with benign findings after partial nephrectomy?

**Findings** In this cohort study that included 18 060 patients between 2007 and 2014, overall prevalence of benign pathologic findings after partial nephrectomy was 30.9%, and it was affected by several factors including female sex, old age, and performance of computed tomographic imaging only as preoperative imaging modality.

**Meaning** The prevalence of benign pathologic findings after partial nephrectomy is high, and to avoid unnecessary surgeries for renal mass, clinicians have to focus more on possible risk factors, especially radiologic modalities.

the Supplement). We selected the any partial nephrectomy inpatient cohort starting from 2007 and set the surgery date as the index date. To determine what preoperative imaging the patient received, the following CPT codes were used: computed tomography ([CT]; 74150, 74160, 74170); magnetic resonance imaging ([MRI]; 74181, 74182, 74183); ultrasonography ([USG]; 76700, 76705, 76770, 76775); and renal mass biopsy (50200, 50205). Definition of malignant tumor group included: *International Statistical Classification of Diseases, Tenth Revision, Clinical Modification* (ICD-10-CM) codes C64.1, C64.2, and C64.9; and ICD-9-CM code 189.0. Exclusion criteria included ICD-9-CM codes 189.1, 189.2, 158, 189.8, 189.9, 198, 198.1, and 202.83. Those patients with no records of preoperative imaging within 1 year from the index date and those patients with nonrelevant diagnostic codes were also excluded. Validated codes for benign pathologic findings were ICD-9-CM codes 214.4, 223, 223.1, 233.9, 236.91, 239.5, 593.2, 593.89, 593.9, 753.1, 753.11-7, and 753.19. Considering the initiation date of ICD-10-CM or ICD-10 PCS codes that occurred late in the study period, ICD-9-CM/PCS codes were used.

### Main Outcome Measures

Our study included 2 main outcomes: overall prevalence of benign pathologic findings after PNx during the study period and the annual trend of benign pathologic findings after PNx. Prevalence was defined as the proportion of patients with a benign pathologic diagnosis among the total patients with PNx. Annual prevalence was defined by proportion of patient number of each year with a benign pathologic diagnosis among total patients with PNx in each year. Secondary outcomes were factors affecting the prediction of the benign pathologic findings after PNx including performance of each imaging modality, pattern of imaging combinations, sex, age, and geographical region. Performance of each imaging modality was defined as any CT (those patients with performance of CT regardless of any other imaging modalities), any MRI, any USG, and any biopsy. The pattern of imaging combination was categorized as CT only, CT and USG, CT and MRI, CT and MRI plus USG, and other combinations (MRI only, MRI and USG, any other combination with biopsy). The date of surgery was set as the index date and preoperative imaging up to 1 year prior to the sur-

Table 1. Baseline Characteristics in 18 060 Participants

No. (%)	All	Benign Tumor	Kidney Cancer	P Value
Total	18 060	5588	472	
Age, mean (SD), y	56.6 (11.6)	57.5 (12.0)	56.2 (11.3)	<.001
Sex				
Male	10 637 (58.9)	2857 (51.1)	7780 (62.4)	<.001
Female	7423 (41.1)	2731 (48.9)	4692 (37.6)	
Insurance type				
Comprehensive	1705 (9.4)	634 (11.4)	1071 (8.6)	<.001
EPO	302 (1.7)	76 (1.4)	226 (1.8)	
HMO	2099 (11.6)	670 (12)	1429 (11.5)	
POS	1252 (6.9)	382 (6.8)	870 (7)	
PPO	10 568 (58.5)	3129 (56)	7439 (59.7)	
POS with capitation	93 (0.5)	31 (0.6)	62 (0.5)	
CDHP	595 (3.3)	201 (3.6)	394 (3.2)	
HDHP	348 (1.9)	104 (1.9)	244 (2)	
Missing	1098 (6.1)	361 (6.5)	737 (5.9)	
Region				
Northeast	4092 (22.7)	1206 (21.6)	2886 (23.1)	.002
North Central	4418 (24.5)	1476 (26.4)	2942 (23.6)	
South	6322 (35)	1909 (34.2)	4413 (35.4)	
West	2694 (14.9)	836 (15)	1858 (14.9)	
Unknown	527 (2.9)	158 (2.8)	369 (3)	
Missing	7 (0)	3 (0.1)	4 (0)	
Data type				
Fee for service	12 504 (69.2)	3673 (65.7)	8831 (70.8)	<.001
Encounter	1695 (9.4)	532 (9.5)	1163 (9.3)	
Medicare	3357 (18.6)	1211 (21.7)	2146 (17.2)	
Medicare encounter	497 (2.8)	169 (3)	328 (2.6)	
Missing	7 (0)	3 (0.1)	4 (0)	
PN surgery cost, median (range), \$	16 787 (0-1 038 946)	413 (0-312 151)	19 228 (0-1 038 946)	<.001
Total cost within 90 d after PN surgery, \$	19 584 (0-1 045 193)	9923 (0-640 055)	22 373 (0-1 045 193)	<.001

Abbreviations: CDHP, consumer-driven health plan; EPO, exclusive provider network; HDHP, high-deductible health plans; HMO, health maintenance organization; PN, partial nephrectomy; POS, point of service; PPO, preferred provider organization.

gery date was regarded as preoperative imaging for PNx. Additional outcomes included cost analysis regarding surgery, cost by person, and average total cost within 90 days after surgery by person. Cost estimation was as follows: total gross payment to a clinician for a specific service; ie, the amount eligible for payment after applying pricing guidelines such as fee schedules and discounts, and before applying deductibles, copayments, and coordination of benefits. Another additional analysis included prevalence of benign pathologic diagnosis and malignant disease after PNx according to age (>65 years).

### Statistical Analyses

A  $\chi^2$  test was conducted to investigate the overall and annual prevalence rate of benign pathologic diagnosis after PNx, and also to compare the difference of performance of imaging patterns during univariate analysis. Post hoc subgroup analysis was performed according to age groups. Multiple logistic regression analyses were undertaken to investigate the significant factors predicting benign pathologic findings. During mul-

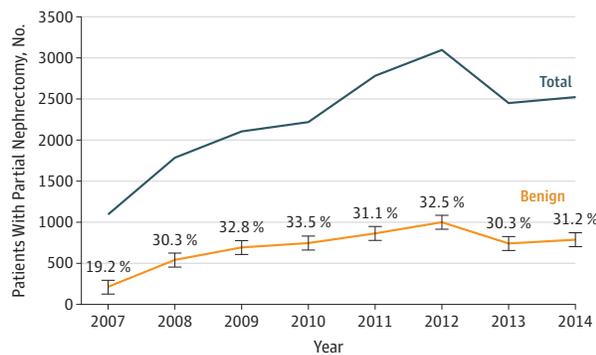
iple logistic regression analyses the variable performance of each imaging pattern was not included owing to multicollinearity. All analyses were performed with SAS statistical software (version 9.3; SAS Institute, Inc).

## Results

### Study Population

A total of 21 445 patients with ICD-9-CM code of 55.4 were identified from 2007 to 2015 using the Truven database system. Patients with no records of preoperative imaging within 1 year from index date (n = 1602) and those patients with nonrelevant diagnostic codes (exclusion criteria and patients with no diagnostic code) (n = 567) were excluded. A total of 18 060 patients were selected for final inclusion (eFigure in the Supplement). Among the 18 060 participants, 10 637 (58.9%) were men and 7423 (41.1%) were women. Basic characteristics of the study cohort are described in Table 1. Mean (SD) age of the total cohort was 56.6 (11.6) years. Female sex was prominent in the

**Figure. Annual Prevalence of Benign and Malignant Findings From 2007 to 2014**



Percentages represent the annual proportion of benign prevalence among total patients who underwent PNx.

benign pathologic findings group compared with the malignant tumor group (2731 [48.9%] vs 4692 [37.6%], respectively). Male sex was prominent in the cancer findings group compared with those in the benign findings group (7780 [62.4%] vs 2857 [51.1%], respectively). Preferred provider organization (PPO) insurance was the most prevalent type (10 568 [58.5%]).

#### Prevalence of Benign Pathologic Findings After PNx

The crude number of benign pathologic diagnoses was 5588 among the 18 060 patients, and the overall prevalence was 30.9%. The annual prevalence of benign pathologic findings after PNx was lowest in 2007 as 19.9% and was highest in 2010 as 33.52%. The **Figure** shows the annual prevalence of benign and malignant pathologic diagnoses after PNx. With the exception of 2007, the annual rate of benign pathologic findings exceeded 30%. In additional analyses according to age, overall prevalence of benign pathologic diagnoses among patients younger than 65 and 65 years or older was 29.6% and 35.9%, respectively (**Table 2**). In both age groups, the prevalence rate showed an increasing pattern until 2012, with a slightly decreased pattern thereafter. Average annual percentage change (AAPC) was estimated to be 4.0% by methodology of NIH and approximately 4.0% to 6.85% by log-adjusted modelling.

#### Prediction of Benign or Malignant Pathologic Findings After PNx

**Table 3** summarizes the univariate analysis of imaging patterns including imaging performance and imaging combination types. Performance of MRI and biopsy was significantly associated with higher rates of malignant pathologic diagnoses ( $P = .02$  and  $P < .001$ , respectively). **Table 4** shows the findings of multiple logistic regression analyses to predict final pathologic results (benign or malignant) after PNx. Significant factors predicting benign pathologic diagnosis were sex (odds ratio [OR], 0.62; 95% CI, 0.58-0.66), older age (OR, 0.99; 95% CI, 0.99-0.99), and residence in the North Central region compared with the West region (OR, 0.88; 95% CI, 0.79-

0.98). Significant factors predicting malignant pathologic findings were all imaging combinations compared with CT imaging only (OR, 1.16; 95% CI, 1.05-1.28).

#### Cost Analysis

The cost analysis included surgery cost and total cost within 90 days after surgery by person and are summarized in **Table 1**. Median cost of PNx surgery of the benign pathologic diagnosis group by person was US \$413 (interquartile range [IQR], \$73-\$18 458). The median total cost within 90 days after PNx of the benign pathologic diagnosis group by person was US \$9923 (IQR, \$1561-\$22 478) (eTable in the **Supplement**). Total cost burden for all PNx of the benign pathologic diagnoses group was US \$90 766 792 for all observation years (2007-2014).

#### Discussion

To our knowledge, this is the first nationally representative study to report the most recent prevalence of benign pathologic diagnosis after PNx and its association with preoperative imaging patterns. The prevalence of benign pathologic findings after PNx routinely exceeded 30% and performance of MRI or biopsy before surgery could provide a better prediction of true malignant abnormalities.

As the proportion of PNx compared with radical nephrectomy continues to increase,<sup>4</sup> most of the research has focused on expansion of indications of PNx, even with clinical stage 3 lesions, with sinus fat invasion<sup>10,11</sup> and on complications including ischemia time and blood loss, and CKD.<sup>12</sup> To date, only a few reports have focused on the benign pathologic findings after PNx<sup>8,9,13,14</sup> and the prevalence of benign pathologic diagnoses has varied widely from 8% to 30%. Among the studies reporting the prevalence of benign pathologic findings, 6 studies reported a high rate (>25%), similar to our findings.

Considering the crucial problem of the socioeconomic burden of PNx and its related complications among patients with benign pathologic findings, it is clear that urologists have to focus on attempting to reduce nonmalignant final pathologic findings. Among the solutions, ascertaining the accuracy of preoperative radiologic imaging modalities is important; however, no study has thus far included the preoperative imaging modalities as a potential factor.

The role of pre-PNx imaging modalities is well established with good accuracy in predicting RCC.<sup>15-18</sup> However, to date, no studies have addressed the trends of preoperative imaging or in its efficacy in predicting for malignant histologic findings. We found that the combination of MRI and biopsy were associated with a higher rate of malignant pathologic diagnoses, which implies that a multimodality approach may be more accurate. Furthermore, multiple logistic regression analysis showed that imaging combinations were superior to the performance of CT alone to accurately predict malignant pathologic findings.

Although CT is still the standard modality to predict a renal mass and still displays a high accuracy rate,<sup>16</sup> for the past decade, other studies have demonstrated that MRI and renal

mass biopsy can be highly predictive.<sup>15,17-19</sup> However, current imaging modalities are still limited in differentiating benign from malignant lesions, especially in the case of distinguishing oncocytoma or lipid-poor angiomyolipoma from RCC.<sup>20,21</sup>

**Table 2. Prevalence of Benign and Malignant Pathologic Findings After Partial Nephrectomy by Age**

Year	Age at Partial Nephrectomy, No. (%) <sup>a</sup>			
	≤64 y		≥65 y	
	Benign Pathologic Findings	Malignant Findings	Benign Pathologic Findings	Malignant Findings
2007	174 (19.61)	713 (80.38)	36 (17.39)	171 (82.60)
2008	408 (28.87)	1005 (71.12)	133 (35.84)	238 (64.15)
2009	522 (30.40)	1195 (69.59)	170 (43.14)	224 (56.85)
2010	572 (32.81)	1171 (67.18)	173 (36.11)	306 (63.88)
2011	647 (29.88)	1518 (70.11)	217 (35.51)	394 (64.48)
2012	748 (30.87)	1675 (69.12)	258 (38.27)	416 (61.72)
2013	551 (29.65)	1307 (70.34)	192 (32.37)	401 (67.62)
2014	555 (28.86)	1368 (71.13)	232 (38.53)	370 (61.46)
Total	4177 (29.6)	9952 (70.4)	1411 (35.9)	2520 (64.1)

<sup>a</sup> Percentage reflected the annual benign or malignant prevalence of findings among total patients according to years.

**Table 3. Univariate Analysis of Imaging Patterns to Predict Benign Tumor or Malignant Abnormality After Partial Nephrectomy**

Imaging Pattern	Benign Pathologic Findings	Malignant Pathologic Findings	P Value
<b>No (%)</b>			
Imaging			
Any CT	5109 (91.4)	11 386 (91.3)	.76
Any MRI	1774 (31.8)	4176 (33.5)	.02
Any USG	2950 (52.8)	6413 (51.4)	.09
Any biopsy	345 (6.2)	1022 (8.2)	<.001
Imaging combinations			
CT + MRI	596 (10.7)	1421 (11.4)	.002
CT+MRI+USG	701 (12.5)	1629 (13.1)	
CT+USG	1760 (31.5)	3579 (28.7)	
CT only	1742 (31.2)	3838 (30.8)	
All other combinations	789 (14.1)	2005 (16.1)	
Total	5588	12 472	

Abbreviations: CT, computed tomography; MRI, magnetic resonance imaging; USG, ultrasonography.

**Table 4. Multiple Logistic Analysis to Predict Benign Pathologic Findings After Partial Nephrectomy**

Variable	OR (95% CI) <sup>a</sup>	P Value <sup>a</sup>	OR (95% CI) <sup>b</sup>	P Value <sup>b</sup>
Sex, female vs male	0.62 (0.58-0.66)	<.001	0.62 (0.58-0.66)	<.001
Age	0.989 (0.986-0.991)	<.001	0.989 (0.986-0.991)	<.001
Imaging pattern				
Any CT	NA		1.01 (0.90-1.14)	.87
Any MRI			1.07 (0.99-1.15)	.08
Any USG			0.94 (0.89-1.01)	.07
Any Biopsy			1.38 (1.21-1.57)	<.001
Imaging combination pattern				
All other combinations vs CT only	1.16 (1.05-1.28)	.004	NA	NA
CT + MRI vs CT only	1.07 (0.96-1.20)	.25		
CT + MRI + USG vs CT only	1.03 (0.93-1.15)	.54		
CT + USG vs CT only	0.93 (0.86-1.01)	.08		
Geographic region				
North Central vs West	0.88 (0.79-0.98)	.02	0.88 (0.79-0.97)	.01
Northeast vs West	1.05 (0.94-1.17)	.37	1.06 (0.95-1.18)	.30
South vs West	1.03 (0.93-1.14)	.57	1.03 (0.93-1.14)	.56
Unknown vs West	1.02 (0.83-1.25)	.85	1.02 (0.83-1.25)	.85

Abbreviations: CT, computed tomography; MRI, magnetic resonance imaging; NA, not applicable; OR, odds ratio; USG, ultrasonography.

<sup>a</sup> Multiple logistic regression analysis was done without adjustment of imaging pattern.

<sup>b</sup> Multiple logistic regression analysis was done without adjustment of imaging combination pattern.

However, the present results are still notable because of the superiority of all other complex combinations including MRI only, MRI and USG, any other combinations with biopsy when compared with performance of CT alone.

To date, there is no consensus on the utility of pre-PNx imaging other than for CT. Most reports on the accuracy of MRI to predict RCC in small renal masses are based on retrospective studies.<sup>15,18,19</sup> The retrospective interpretation of MRI is different from the real-time interpretation in clinical practice. The ultimate interpretation technologies of CT or MRI that could be helpful to predict RCC in small renal masses is a time-intensive undertaking that is not feasible in clinical practice. Kim et al<sup>19</sup> reported a poor diagnostic accuracy of CT and MRI to predict RCC in small renal mass, with a sensitivity of 79.7% and 88.1%, respectively, and specificity of 44.4% and 33.3%, respectively, using subjective radiologic interpretation in real clinical practice.

There are several studies worth mentioning that investigate other nonradiologic factors that might affect the histologic prediction.<sup>7,22-26</sup> Although most recently Bauman et al reported no relationship with sex and age,<sup>8</sup> several studies have focused on sex and age, in which female sex and younger age predominantly predicted benign pathologic findings. Female predominance in benign pathologic diagnoses could be explained by association between AML and women.<sup>27</sup> Our study also showed female predominance in benign pathologic findings after PNx. However, with regard to age, the older age group showed higher predominance in benign pathologic findings after PNx.

Reducing the benign pathologic findings after PNx is an important issue considering the inherent surgical risk and surgery-related costs. Given our findings, it may be helpful for urologists to focus more on the extended role of MRI and the performance of biopsy to reduce benign pathologic findings after PNx. Recently, more high-quality evidence of the performance of biopsy in patients with suspicious small renal malignant tumors has been published,<sup>28-30</sup> which provide further information about the possible final diagnosis in situations with equivocal clinical and radiographic findings.

### Limitations

Although this study is the first nationally representative cohort study about the prevalence of benign pathologic find-

ings after PNx, several limitations exist. First, as this is an administrative data set, there is no information about tumor size and pathologic stage. Although this study used diagnosis codes for identification of the cohort and outcomes, there is a possibility of misclassification bias. We could not surmise a reason why there were patients in the database who were excluded because they had no records of pre-PNx imaging. Second, we could not classify the types of surgical approaches including open, laparoscopic, or robotic surgery. Increasing availability of robotic surgery could be an important factor for benign pathologic diagnoses after PNx as well as increased imaging modalities. Moreover, there is a marked difference of the prevalence between 2007 and other years, which could be explained by fast dissemination of robotic assisted PNx. Third, the cost data we used were total payments, which is directly associated with consumers' total expense. However, it is possible that this may not be reflective of the total charge cost, which is related to a variety of charges including the direct and indirect cost of the hospital stay. Although there was a marked difference in the total payment costs between the benign and malignant diagnoses groups, this difference could not be fully explained. It is possible that fixed cost may account for the difference, which is associated with surgical equipment costs and increased operation times. Moreover, there are 2 types of fee paying: fee-for-service and encounter. In addition, immunohistochemical staining cost, oncotyping, additional radiologic imaging before or during the operation after admission could be possible factors for the difference.

### Conclusions

Prevalence of benign pathologic findings after PNx is not low, and exceeds 30% on an ongoing annual basis. Each imaging modality including MRI and biopsy, and combinations of modalities affect the prediction of benign pathologic findings. Urologists have to focus more on high prevalence of benign pathologic findings after PNx and consider other imaging modalities including MRI and biopsy. Avoiding unnecessary surgery is more than an issue of cost-effectiveness in patients' view. Clinicians have to focus more to make every effort to reduce the likeleyhood of benign pathologic findings after PNx.

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**Acquisition, analysis, or interpretation of data:** Li, K. Chung, B. Chung.

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