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Original Article

Real-time ultrasound-guided percutaneous renal biopsy with needle guide by nephrologists decreases post-biopsy complications

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Abstract

Background. Percutaneous renal biopsy (PRB) can result in serious complications. The study is aimed to compare the biopsy yield and complications rate of the real-time ultrasonagram (USG)-guided PRB and needle tracking with and without needle guide in two different study periods.

Methods. We compared the yield and complications of 2138 kidney biopsies performed in two different periods, 1510 biopsies during the first period from April 2004–December 2010 and 628 biopsies during second period from January 2011–March 2013. All biopsies in both periods were performed by nephrologists. Radiologists provided the real-time image without needle guide during the first period while nephrologists performed both imaging and biopsy with needle guide during the second period.

Results. Of all the 2138 patients, 226 (10.5%) patients developed 118 minor and 108 major complications. Only 13 (2.1%) major complications occurred in the second period and 95 (6.7%) in the first period ($P < 0.001$). The relative risk of developing a major complication without guide was 3.04 times greater than that of the biopsies performed with use of the guide. The mean number of glomeruli per biopsy obtained during the second period (17.98 ± 6.75) was significantly greater than that of the first period (14.14 ± 6.01) ($P = 0.004$). The number of passes to acquire adequate tissue ($P = 0.001$) and percentage of cortex on biopsy ($P = 0.001$) were also significantly better in the second period. The optimal observation period post biopsy is 24 h.

Conclusions. Real-time USG imaging supported by needle guide device is associated with better biopsy yield and fewer complications.

Keywords: complications; percutaneous renal biopsy; real-time ultrasound; Ultra-pro needle guide

Introduction

Renal biopsy is an indispensable tool in the diagnosis, prognosis and management of patients with renal diseases. Renal biopsies have been performed for more than a century [1]. The first description of a biopsy technique was published by Ball in the 1930s, [2] and a more applied and efficient description was given by Iversen and Brun in 1950 [3]. With the introduction of the Franklin modified Vim-Silverman needle in 1954 [4], obtaining kidney tissue for proper histological diagnosis has been reportedly improved by 96–98% [5–7]. The advances in imaging diagnostics and biopsy procedure have evolved from indirect visualization to real-time ultrasound guidance for per cutaneous renal biopsy (PRB) [4] and yield of biopsy specimen further improved up to 99% with automated biopsy needles [8]. The safety and complications of procedures considerably improved with the automated spring-loaded biopsy device [9–11]. Nevertheless, renal biopsy can cause serious complications such as hematoma and profuse bleeding with the consequent need for blood transfusions, additional surgical procedures including nephrectomy, and rarely death [12]. Most perirenal hematomas are minor without clinical significance. Serious complications are infrequent when traditional risk factors like hypertension and bleeding diathesis are not overlooked [13, 14]. The procedure-related complications have been reported as the second most common nonsurgical medical error observed in the Harvard Medical Practice Study [15].

Presently, there is paucity of data on renal biopsy outcomes with use of the Ultra-pro needle guide in the literature. There are ongoing controversies over who should perform the PRB, radiologists or nephrologists. Complications associated with PRB should be inherently less with radiologists by virtue of expertise in imaging techniques, however equal complication rates have been reported if PRBs are performed by nephrologists [16]. Moreover, the

increasing awareness of diagnostic and therapeutic interventions amongst the nephrology fraternity, performance of ultrasound and PRB by nephrologists themselves may further improve outcomes because nephrologists have a better understanding of the renal ailments, adequate tissue required for diagnosis and complications arising from uraemia. The use of needle guide to visualize the track of the needle by nephrologists may not have an inferior yield and complications rate. We undertook this study to analyse the predictors of major complications and especially to compare the biopsy yield and complications rate of real-time ultrasonogram (USG)-guided PRB and needle tack with and without using needle guide in two different study periods.

Material and methods

In this observational study, we compared yields and complications of 2138 consecutive kidney biopsies (native/transplant kidneys) performed in two different periods, the first period from April 2004 to December 2010 and second period from January 2011 to March 2013.

All kidney biopsies were performed by percutaneous technique with real-time ultrasound on a Phillips HD 11E during the first period and Toshiba, Japan, Xario model SSA-660a, with a 3.75 MHz curvilinear probe during the second period . All biopsies were performed using spring-loaded automated devices (Bard Peripheral Vascular Inc., USA-'BARD^{R} Max-core^{R} disposable core biopsy needle') with 16/18 gauge, and 16 cm long needle with a penetration depth of 22 mm and sample notch of 18 mm. During the first period, all biopsies were performed by nephrologists with radiologists showing real-time USG image and tracking of needle *without* using the Ultra-pro needle guide; and during the second period, besides renal biopsies, real-time USG imaging and needle tracking were also performed by nephrologists themselves with needle guide (Ultra-pro II™ Needle guide, Civco, Iowa, USA), (Figure 1). Two persons are always involved in carrying out the biopsy; one nephrologist and one radiologist in first period and two nephrologists, one consultant and another trainee, in the second period. The trainee nephrologists changed every year in both periods. The needle guide provides clear visualization of the needle track making PRB easier and better than real-time USG-guided PRB without the guide. All native kidney biopsies were performed from the lower pole of left kidney and transplant kidney biopsies from the upper pole of the graft kidney. The biopsy yields, complication rates, number of passes of needle to obtain two cores of biopsy samples, percentage of cortex and medulla of each on histopathology, were compared between the two periods. The percentage of cortex and medulla was independently evaluated by two histopathologists and the mean of the two values were considered final.

Local protocols were adhered to regarding pre-biopsy screening of hematologic parameters, blood pressure, and kidney size in both periods. Briefly, pre-biopsy correction of hematologic parameters was required if platelets were $<100 \times 10^{9}$/L and or the international normalized ratio (INR) was >1.4. Anti-platelet medicines were stopped for 7 days before kidney biopsy. Immunosuppressions were not discontinued if the patients were on any immunosuppressants. Biopsies were not performed if pre-biopsy ultrasound revealed obstruction or kidney sizes less than 8 cm bilaterally and if BP exceeded 160 mmHg systolic or 90 mmHg diastolic.

Children were given general anaesthesia, while adults had an infiltration of 10 mL of 2% lignocaine as local anaesthetic. All patients were placed in a prone position with a pillow under the abdomen to obliterate the normal lumbar lordosis. All biopsies were performed with standard aseptic precautions with povidone iodine application and proper draping of the biopsy site.

Routinely, two renal tissue cores were obtained, one for histopathology and another for immunofluorescence examination (IF). The core for IF was divided into two parts if electron microscopy (EM) was indicated. The adequacy of the biopsy sample was defined by the presence of 6 glomeruli and at least 1 vessel for native kidney and 10 glomeruli and 2 vessels for transplant kidney and whether the nephropathologists deemed the material sufficient to establish the diagnosis.

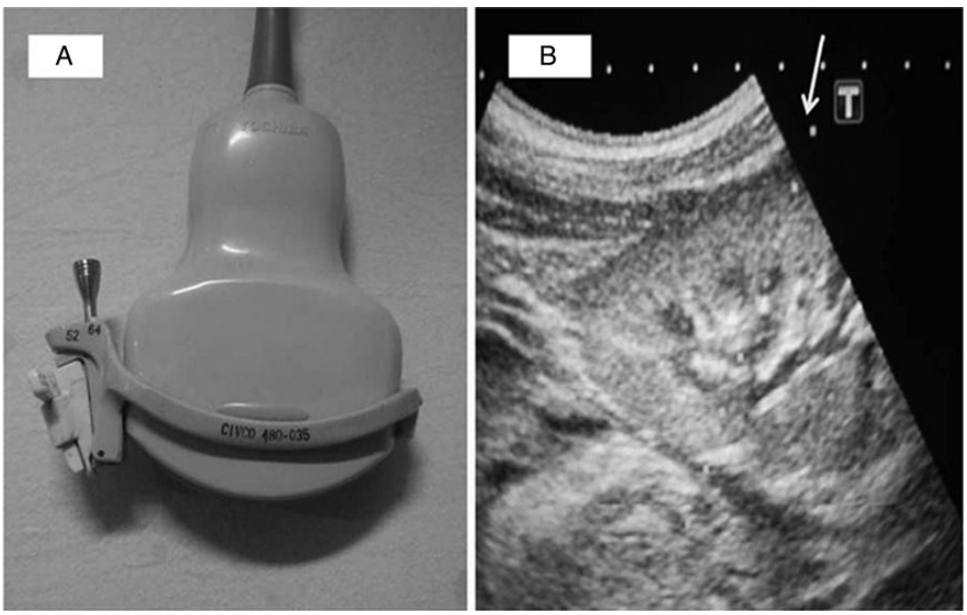

Fig. 1. (**A**) Image of Ultra-pro II needle guide, Civco, IA, USA, and (**B**) image of left kidney lower pole with dot marks of guide (arrow).

All relevant history, clinical findings, lab investigations and post-biopsy complications were noted during the hospital stay for biopsy. Safety of the procedure was evaluated on the basis of the presence or absence of major or minor complications. Complications were labelled as major if they required a blood product transfusion, invasive procedure (radiographic or surgical intervention), those resulting in acute renal obstruction, extended hospitalization, septicaemia or death; and minor complications were comprised mainly of small hematomas or transient haematuria that resolved spontaneously and did not prolong hospitalization beyond 24-h of the procedure in absence of major complications. The timing of a complication was defined by the first clinical sign or symptom or a laboratory finding (i.e. gross haematuria, severe flank pain, hypotension or decrease in haemoglobin requiring blood transfusion) suggested a clinically relevant problem. The study is approved by the ethics committee of the institute on 17 December 2013.

Statistical analysis

Data were analysed using the Statistical Package for the Social Sciences (SPSS Inc.) version 16 Chicago, IL, USA. The patients were categorized into two groups: patients biopsied during the first and second period; and subsequently, patients with and without major complications. The categorical values were compared using χ^2 test and mean values between the groups were compared using Student's *t*-test. The normality of distribution of data was tested with the Shapiro-Wilk test, and Student's *t*-test was used in the case of normal distribution of data. Median values with range have been expressed if data were not in normal distribution. Univariate and multivariate logistic regression analysis was performed to analyse the predictors of major complications with dependent variable as major complications present/absent and independent variables as age, gender, systolic and diastolic blood pressure, haemoglobin level, platelet count, serum creatinine level, eGFR, serum albumin, international normalized ration (INR) and the needle guide. The relative risk (with 95% confidence interval) of major complications with and without needle guide was also analysed. P-values of <0.05 were considered significant.

Results

The demographic profiles and biochemical characteristics of all the patients during the first and second period are shown in Table 1. Of all the 2138 biopsies, 1777 (83.1%) were native kidney and 361 (16.9%) graft kidney biopsies. The proportions of patients with different indications of biopsies were similar in two groups of patients with and without needle guide (Table 2). The clinical characteristics and coagulation parameters of the patients with and without major complications are shown in Table 3.

Yield and complications of kidney biopsies

Of all the biopsies, 1510 USG-guided biopsies were performed during the first period and 628 during the second period. Average glomeruli per kidney biopsy were 15.38 ± 6.24 and 99.6% of samples were adequate. Of the eight inadequate biopsy specimens, three had compression artefact and five had less than six glomeruli, and histopathological interpretation was difficult. The yield of the biopsy in terms of mean number of glomeruli (17.98 ± 6.75) during the second period with needle guide was significantly greater than that obtained during the first period without needle guide (14.14 ± 6.01) (P = 0.004). The percentage of cortex was significantly high during second period (96.48 ± 3.72%) when compared with that of first period (91.12 ± 4.64%), P = 0.001. The number of passes to obtain two cores of biopsy was significantly less in second period (2.14 ± 0.35) when compared with that of during the first period (2.31 ± 0.57), P = 0.001. The percentage of cortex and medulla, and number of passes of needle, was not significantly different in patients with and without major complications.

Of all the 2138 patients, 1912 (89.4%) did not develop any complications and 226 (10.6%) patients developed

Table 1. Clinical characteristics of the patients between two different study periods, first period April 2004–December 2010 with radiologist assistance and second period from January 2011–March 2013 with needle guide

Characteristics	First period	Second period	P-value
	Without Ultra-pro guide	With Ultra-pro guide	
Number of patients	1510	628	
Median age (years)	35.5	31.0	
Range (min–max)	84 (2–85)	84 (1–85)	
Children (<16 years)	203 (13.4%)	87 (13.9%)	0.87
Male (%)	1046 (69.3%)	436 (69.4%)	0.94
Transplant kidneys (%)	242 (16.0%)	119 (18.9%)	0.76
Systolic blood pressure (mmHg)	120.7 ± 6.1	120.8 ± 6.7	0.82
Diastolic blood pressure (mmHg)	82.0 ± 4.64	81.9 ± 4.8	0.93
Haemoglobin (g/L)	111.4 ± 14.1	111.7 ± 13.8	0.55
Hb < 8 g/dL	27 (1.78%)	8 (1.27%)	0.76
Platelet count (10^9/L)	245.2 ± 63.4	253.9 ± 67.7	0.13
INR	1.1 ± 0.1	1.1 ± 0.1	0.14
INR > 1.3	9 (0.6%)	3 (0.5%)	0.78
Sr. creatinine (μmol/L)	231.6 ± 173.3	220.1 ± 160.9	0.51
Median (min–max)	167.9 (44.2–884)	335.9 (53.0–972.4)	
eGFR (mL/min/1.73 m^2)	50.40 ± 37.48	50.72 ± 35.66	0.14
eGFR < 15	255(16.9%)	95(15.1%)	0.68
Needle size (18:16)	231:1279	92:536	0.74
Kidney size (cm)	10.1 ± 0.6	9.9 ± 0.8	0.82
Sr. albumin (g/L)	29.4 ± 4.3	30.0 ± 4.9	0.008
No. of glomeruli	14.1 ± 6.0	17.9 ± 6.7	0.001
Inadequate biopsy (<6 glomeruli)	5(0.33%)	0	0.001
Cortex (%)	91.1 ± 4.6	96.5 ± 3.7	0.001
Medulla (%)	8.9 ± 4.5	3.5 ± 3.4	0.001
No. of passes	2.3 ± 0.6	2.1 ± 0.4	0.001
>2 passes (%)	498 (33.0%)	91 (14.5%)	0.02
Minor complications	101 (6.7%)	17 (2.7%)	0.001
Major complications	95 (6.3%)	13 (2.1%)	0.001

Table 2. Indications for kidney biopsies in patients with and without needle guide

Indication for biopsy	First period	Second period	P-value
	Without Ultra-pro guide (%)	With Ultra-pro guide(%)	
Acute kidney injury	118 (7.8%)	34 (5.4%)	P = 0.21
Nephrotic syndrome	678 (44.9%)	270 (43.0%)	
Acute nephritic syndrome	75 (5.0%)	42 (6.7%)	
RPGN	347 (23%)	144 (22.9%)	
Acute on CKD	24 (1.6%)	12 (1.2%)	
Multiple myeloma	19 (1.3%)	12 (1.9%)	
Acute Rejection	247 (16.4%)	114 (18.2%)	

RPGN, rapidly progressive renal failure; CKD, chronic kidney disease.

Table 3. The demographic profiles, clinical and biochemical parameters of patients with and without major complications

Characteristics	Total patients (mean ± SD)	With major complication	Without major complication	P-value
Number of patients	2138	108	2030	
Age (years)	35.65 ± 15.56	31.97 ± 15.92	35.84 ± 15.52	0.012
Gender (M:F)	1482:656	74:34	1408:622	0.854
Systolic blood pressure (mmHg)	120.71 ± 6.25	125.78 ± 7.22	120.45 ± 6.08	<0.001
Diastolic blood pressure (mmHg)	82 ± 4.65	84.35 ± 3.86	81.88 ± 4.63	<0.001
Haemoglobin (g/L)	111.4 ± 14.0	101.1 ± 17.7	112.0 ± 13.5	<0.001
Platelet count (10^9/L)	247.12 ± 65.43	213.71 ± 85.19	248.89 ± 63.75	<0.001
INR	1.05 ± 0.13	1.11 ± 0.12	1.05 ± 0.12	<0.001
Sr. creatinine (μmol/L)	228.07 ± 169.73	356.25 ± 199.78	221.88 ± 165.31	<0.001
eGFR (per 10 mL/min)	0.84 ± 0.62	0.54 ± 0.52	0.86 ± 0.62	<0.001
Sr. albumin (g/L)	29.6 ± 4.5	28.8 ± 7.1	29.7 ± 4.3	0.064
USG (with:without needle guide)	628:1510	13:95	615:1425	0.001
Native: transplant	1777:361	99:9	1678:352	0.012
No. of glomeruli	15.38 ± 6.24	14.25 ± 5.44	15.44 ± 6.28	0.053
Cortex (%)	92.61 ± 4.65	91.12 ± 4.53	92.94 ± 4.66	0.259
Medulla (%)	7.39 ± 4.66	8.88 ± 4.49	7.06 ± 4.46	0.263
No. of passes	2.26 ± 0.52	2.34 ± 0.63	2.26 ± 0.51	0.093

Sr, serum; eGFR, estimated glomerular filtration rate; USG, ultrasonogram; INR, international normalized ratio.

Table 4. Univariate and multivariate logistic regression analysis predicting Post biopsy major complications

Univariate analysis	Odds ratio	95%CI	P-value
Age (per year)	0.98	0.97–0.99	0.12
Gender (male/female)	1.04	0.68–1.58	0.85
Systolic BP (per 10 mmHg)	1.14	1.11–1.18	<0.001
Diastolic BP (per 10 mmHg)	1.13	1.08–1.18	<0.001
eGFR (per 884 mL/s/m^2)	0.98	0.97–0.99	<0.001
Sr. creatinine (per μmol/L)	1.38	1.27–1.50	<0.001
<123.76 (*n* = 618)			
123.76–265.2 (*n* = 840)	1.24	1.06–1.84	0.004
>265.2 (*n* = 680)	2.11	1.04–4.54	0.001
Hemoglobin (per g/L)	0.56	0.48–0.65	<0.001
Platelet count(per 10^9/L)	0.99	0.98–1.00	<0.001
Albumin (per g/L)	0.67	0.44–1.02	0.064
INR (per 0.1 increase)	14.33	2.71–75.67	0.002
Ultra-pro needle guide (versus no needle guide)	0.32	0.17–0.57	<0.001
Cortex (%)	0.97	0.93–1.02	0.26
No. of passes	1.32	0.95–1.84	0.09
Needle size (18G versus 16G)	0.52	0.21–1.29	0.16
Multivariate analysis			
Systolic BP (per 10 mmHg)	1.10	1.07–1.15	<0.001
Diastolic BP (per 10 mmHg)	1.09	1.04–1.15	<0.001
eGFR (per 10 mL/min)	0.98	0.97–1.00	0.02
Sr. creatinine (per μmol/L)	1.42	1.20–1.69	<0.001
Haemoglobin (per g/L)	0.73	0.55–0.96	0.02
Platelet count (per 10^9/L)	0.99	0.99–1.00	0.09
INR (per 0.1 increase)	1.87	0.32–10.78	0.48
Ultra-pro needle guide (versus no guide)	0.26	0.13–0.49	<0.001

95% CI, 95% confidence interval; BP, blood pressure; eGFR, estimated glomerular filtration rate by MDRD formula; Sr., serum; *n*, number; INR, international normalized ratio; G, gauge.

complications. Of the 226 patients with complications, 118 (5.4%) patients had only minor complications while 108 (5.1%) patients had 128 major complications. Of the minor complications, 76 (3.5%) had gross haematuria, 38 (1.7%) small haematoma formation and 4 (0.2%) patients had transient hypotension mostly because of vaso-vagal reflex. These complications were managed conservatively and did not require any intervention or overstay in the hospital.

Of all the 128 major complications, gross haematuria was observed in 63 (2.94%), large haematoma in 24 (1.12%), hypotension requiring intravenous fluid administration and close vital monitoring in 15 (0.7%), blood transfusion in 13 (0.6%), radiological interventions like digital subtraction angiography and embolization in 11 (0.5%) and bladder outlet obstruction due to clot formation in bladder in 2 (0.1%) which also required clot evacuation and per urethral Foleys catheterization. There were no nephrectomy or death directly attributed to the biopsy complications. Eighty-four (77.77%) complications were observed in the first 6 h, 14 (12.96%) between ≥6–12 h, 8 (7.40%) between ≥12–24 h and only 2 (1.85%) after 24 h.

Only 13 (2.1%) major complications were observed out of 628 biopsies performed by nephrologists with needle guide during the second period while 95 (6.3%) major complications were observed out of 1510 biopsies performed without guide during the first period ($P < 0.001$). The relative risk of developing major complications without Ultra-pro needle guide was 3.04 (95% confidence interval 1.74–6.19, $P = 0.001$) times greater than that with the use of needle guide.

Predictors of percutaneous renal biopsy complication

The factors predicting major complications on univariate and multivariate logistic regression analysis are shown in Table 4. On univariate analysis, systolic and diastolic blood pressure, serum creatinine, eGFR, haemoglobin, platelet count, coagulation profile, use of needle guide were significant predictors of major complications. The systolic and diastolic blood pressure, serum creatinine, eGFR, haemoglobin and needle guide remained as significant predictors of major complications on multivariate analysis, while platelet count and INR lost the significance.

Discussion

To the best of our knowledge, this is one of the largest single-centre studies which compared the post-biopsy major complications with and without use of Ultra-pro needle guide. Various other larger studies published to date either consisted of national registry data or meta-analyses which had [17, 18] their own kind of limitations and heterogeneity of biopsy populations with varying

approaches for biopsy at different centres. In this study, we observed that the post-biopsy major complications were three times higher with USG imaging and needle tracking without needle guide. Not only the yield and adequacy with a larger number of glomeruli and proportionately lower number of inadequate biopsies was observed with needle guide, but the number of passes and complications was also significantly less with the use of needle guide. The reason for the higher rate of complications during the first period may be the difficult needle coordination between radiologist and nephrologists without needle guide; needle guide reduces sliding of the ultrasound transducer on slippery gel which makes the complex task of coordination and alignment of transducer plane and biopsy needle plane easier to perform. A better yield of cortex was reported with caudal angulations when compared with cephalad angulations of the needle in a study on porcine kidney biopsies [19]. All native kidney biopsies were performed from the lower pole with caudal angulations and transplant kidney biopsies from the upper pole with cephalad angulations. This is the first study on human kidney biopsy which compared the yield in terms of percentage of cortex with and without needle guide.

Various larger studies have reported minor complication rates varying from 7.5 to 58.6% and major complications from 0.3 to 4.3% [19–22]. We have observed minor complications in 5.4% and major complication in 5.1% of patients. The large variation in complication rate may be because of varying definitions for major and minor complications, different biopsy populations [20–22] and management strategies applied in these studies [23–25]. Gulcu *et al*. [26] showed minor complication in 22.9% cases on routine post-biopsy Doppler USG in all patients when insignificant small haematomas were also easily picked up. Our study clearly demonstrated the lower complication rate and safety of biopsy with the use of needle guide. The higher major complications rate in our patients could be because of higher serum creatinine values at the time of biopsy in our cohort of patients compared with other studies reported in the literature (Supplementary Table 5). We have also observed that the relative risks of complications increases with increasing serum creatinine values. Advanced renal dysfunction may cause platelet dysfunction not only quantitatively but also qualitatively [27–29].The post-biopsy observation period is another important issue in the present scenario as many centres do PRB as day care procedure and patients are discharged after 12 h of observation [30, 31]. The advantage of this approach is that it prevents inpatient admission and is cost-effective. However, we observed that if a patient is discharged within 12 h of observations, at least 10% of cases will develop complications after discharge from day care which may be catastrophic for these patients particularly if patients live in remote places and emergency care facilities are lacking. Our study indicates that it is advisable to discharge the patient at least after 24 h of observation. Similarly, Whittier *et al*. [12] have also suggested an optimal observation period of 24 h as less than 12 h observation risks missing more than 15% of complications in their study. One of the important risk factors in assessing the invasive procedures is always the skills and experience of physicians performing the procedures. Being a tertiary care teaching institute, biopsies are performed by resident doctors under the supervision of consultant nephrologists at our institute. Therefore, the potential learning curve effect associated with the safety and efficacy of the procedure, remains a concern in any teaching institute and the use of new devices minimizes the procedure-related complications making it safer and easier [29].

In 2012, Korbet [32], in his editorial on a publication of 22 years experience of Norwegian PRB [17], showed a concern of declining trend of kidney biopsy by nephrologists across the world. He addressed that PRB, a part and parcel of nephrology practice, is in jeopardy of being lost along the way. He raised the concerns that radiologists performed a biopsy in 54% cases and nephrologists in only 33% in a Norwegian study [17]; gradually an increasing number of radiologists are performing PRB in the USA [33] and furthermore, only 55% of nephrologists are performing renal biopsies in Australia [34]. The unfortunate reasons that fewer nephrologists are performing PRB have been attributed to a number of issues including reimbursement, liability, inconvenience and increasing workload [16, 35]. Our study clearly showed better yields and fewer complications when the biopsy procedure and radiological imaging were both performed by nephrologists *per se*. This approach is beneficial as it saves the time of shifting from nephrology ward to radiology centre, prevents unmonitored shifting from one place to another in the immediate post-biopsy period and is cost-effective in terms of saving extra fees for radiologists. Our study does not demonstrate the superiority of either nephrologists or radiologists over each other as nephrologists have performed biopsies in both periods. However, the nephrology-performed biopsy has the advantage of more comprehensive patient information and consent on the day of biopsy when patients often have additional questions; moreover, radiologists can explain the procedure but not the indication and clinical implications. It is possible that the needle guides are already in practice in some of the countries; however, evidence in the literature is lacking. The declining trend of PRB by nephrologists is a wake-up call for all of us as nephrologists, and every attempt should be made to prevent it. The minimal complications and better yield with needle guide devices reported in our study, may be one small step in preventing such decline.

This study is an observational and single-centre study, therefore the potential bias of observational studies cannot be ignored and the results of a single-centre study cannot be generalized. A randomized, multicentre, controlled study would be required to prove the definitive superiority of one over the other, however, even in a randomized controlled trial, blinding for the needle guide would be a difficult issue.

Conclusion

For nephrologists carrying out renal biopsies, the use of real-time ultrasound supported by a needle guide device is associated with fewer complications and better biopsy yield.

Supplementary data

Supplementary data are available online at http://ndt.oxfordjournals.org.

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Conflict of interest statement. Authors declare none.

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