Adequacy and complication rates of percutaneous renal biopsy on native kidneys in Chinese with 18- vs. 16-gauge needles

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Abstract

Aim: The study aims to compare the adequacy, complication and pathological classification rates of using 18G vs. 16G needles to perform renal biopsy with ultrasound-guided on native kidneys in Chinese. Methods: We retrospectively analyzed the number of glomeruli, adequate sample rates, complication rates and pathological classification in 270 patients who were used by 18G or 16G needles separately from January, 2011 to May, 2017，and verified whether the needle gauge affect the diagnosis of the disease. Results: A total of 270 kidney biopsies were performed. Among them :72 were with 18G needles, and 198 were with16G needles. There was no difference in the number of glomeruli count under light microscope using 18G relative to 16G needles（24±11vs25±11，p=0.265）, whereas more glomeruli count were found for the 16G group using immunofluorescence microscopy(3±2 vs 5±3， p＜0.05).There was no significant difference in the adequate sample rates between 18G group and 16G group (90.28%vs93.94%, p=0.298). Minor complications including the incidence of lumbar or abdominal pain (4.17% vs 7.07%, p = 0.57), gross hematuria (4.17% vs 3.54%, p = 0.729), and perinephric hematoma without symptoms (4.17% vs1.52%, p = 0.195) were not significantly different for 18G vs 16G group. In 16G group, there was 2 cases of serious complications occurred, including severe gross hematuria requiring blood transfusion, and retroperitoneal hematoma requiring surgery. No serious complications were observed in the 18G group, even although there was no significant difference in serious complications rates between the 18G and 16G group (0% vs 1.02%，p = 1). Conclusion: There was no significant difference in the number of glomeruli, adequate sample rates, and complication rates of using the 18G and 16G needles to perform renal biopsy, and the 18G needle with smaller diameter did not affect the pathological diagnosis and classification of IgA nephropathy and lupus nephritis.

Introduction

The percutaneous renal biopsy (PRB) is a primary biopsy technique developed by Alwall in 1944 [1] and is an important technique for the diagnosis of kidney disease. Gauge of percutaneous renal biopsy needle vary from 14G to 22G [2–5]. At present, 16G needle or 18G needle is used for percutaneous renal biopsy in China, but there is still controversy about the effect and safety of 18G and 16G biopsy needles with two different diameters. Therefore, we retrospectively studied the number of glomeruli, adequate sample rates, complication rates, disease spectrum and pathological classification in renal biopsy by using 18G group and 16G group to compare the differences of using biopsy needles.

Patients And Methods

1. Patients

Patients were undergoing PRB at the Sixth Affiliated Hospital of Sun Yat-sen University，Department of Nephrology, and the Second Affiliated Hospital of Shantou University Medical College，Department of Nephrology from January 2011 to May 2017. The present study was approved by the ethics committee of

the Sixth Affiliated Hospital of Sun Yat-sen University and adhered to the tenets of the Declaration of Helsinki.

2. Instruments and methods

Apply Pajunk Delta Cut Biopsy System using 16G and 18G biopsy needles. The ultrasound, blood routine examination, liver and kidney function, and blood coagulation function were checked before the puncture. No renal biopsy contraindications were identified.

Selection of needle gauge: Prior to February 2015, renal biopsies for the patients with relative contraindications（renal insufficiency, coagulopathy, and small size kidneys （ length≤8cm）) were performed by using 18G biopsy needles, and biopsies for other patients were performed with 16G needle. After February 2015, renal biopsies were performed with 18G biopsy needle only. And we removed the 18G needle cases which used it because of relative contraindications.

Patients were asked to urinate before PRB. Under the guidance of ultrasound, the lower right renal pole was selected as the biopsy target, and the patient was prone position. First, disinfection and local anesthesia were performed, then a guide was placed, and the tip of the needle reached the renal capsule to trigger biopsy needle and kidney biopsy. Repeat these operations one more time after drawing. After the operation, the renal biopsy tissue was divided into three sections, which were placed under the light microscope, electron microscope, and fluorescent mirror tube to be preserved for pathological examination. Supine 6~8h after surgery and lying in bed 24h. At the same time, the urine color and pain were recorded and the kidney condition was examined by ultrasonography.

3. Observed indicator

1. The numbers of glomeruli were recorded in the 18G and 16G groups, and statistically analyses were performed to evaluate whether the numbers of glomeruli between the two groups were statistically different. The number of glomeruli ≥ 10 as a standard of an adequate sample and then a comparison of adequate sample rates between two groups were made. Statistical data are presented as mean value ± standard deviation (SD).
2. Complications were divided into minor complications and serious complications according to Whittier et al[6, 7].The minor complications were also detected including lumbar or abdominal pain, hematuria, perirenal hematoma as well as serious complications including bleeding requiring surgical intervention or blood transfusion, decline in blood pressure, hemoglobin decline, severe infection etc.
3. The pathological diagnosis and pathological classification in group 18G and 16G were compared. Take to revalue Lee classification and Oxford classifications as the standard of IgA nephropathy classification. Take ISN/RPS2003 classification as the standard of lupus nephritis pathological classification.

4. Statistical Analysis

Statistical analysis was performed using the IBM SPSS Statistic 22. Measurement data are presented as mean value ± standard deviation, and the comparison was analyzed by Mann-Whitney U test. The enumeration data were compared with Fisher's exact test. When P-value less than 0.05, the difference is statistically significant.

Results

In this study, a total of 270 patients aged 9~85 years with an average of 40 years met the inclusion criteria and including 152 males and 118 females. In the 18G group, 72 patients including 38 males and 34 females participated, with a mean age of 41±16 years and an average of 41 years. In the 16G group,198 patients including 114 males and 84 females participated, with a mean age of 40±16 years and an average age of 40 years. There were no significant differences in age、sex or BMI between the two groups. The level of serum creatinine, hemoglobin, platelet count, PT, APTT and urinary protein also did not differ significantly from two groups before renal biopsy(Table 1).

The numbers of glomeruli were similar in 18G group relative to 16G group detected by light microscopy(24±11 vs 25± 11, p = 0.265),whereas fewer numbers of glomeruli were detected in 18G group compared with those in 16G group by for immunofluorescence examination (3±2 vs 5±3, P < 0.05)(Table 2).The adequate sample rates of the 18G group and the 16G group were not significantly different (90.28% vs 93.94%, p = 0.298) (Table 2).

The total of complications presented in this study was 12.9%(34/270 individuals) and similarly percentage of complications in the 18G and 16G patients. The incidence of lumbar or abdominal pain in the 18G and 16G patients (4.17% vs 7.07%, p = 0.572), mild gross hematuria (4.17% vs 3.03%, p = 0.729), and the incidence of small hematoma (4.17% vs 1.52%, p = 0.195) were not statistically significant different. In the 16G group, 2 cases of severe complications occurred. One case had severe gross hematuria with the blood transfusion was required, another case had retroperitoneal hematoma required renal artery embolization. Serious complications were not found in the 18G group. In the group that has the 18G needle procedure, there were no serious complications compared with 1.02% in the group with the 16-G needle procedure (0% vs 1.02% 、P = 1) (Table 3).

As for the disease spectrum、the proportion of patients with lupus nephritis in the 18G group was significantly higher than that of the 16G group (16.67% vs7.58%, p <0.05). Proportions of other diseases 、minor glomerular abnormalities、renal amyloidosis、Ischemic renal injury、immunotactoid glomerulopathy、idiopathic nodularmesangial sclerosrs、Transplant nephropathy、Thrombotic microvascular disease due to scleroderma、Alport syndrome、and Focal necrotic glomerulonephritis)in the 18G group were lower than that those of the 16G group (1.39% vs 9.6%, p <0.05)(Table 4).

Discussion

Renal biopsy has an irreplaceable important role in the diagnosis of kidney disease, treatment options and the determination of the prognosis of the disease during the clinical work of renal medicine. At present, percutaneous renal biopsy is an essential technique in renal medicine, and the safety and success rates of PRB has been further improved after the introduction of automatic biopsy needles and real-time ultrasound guidance[9–11]. Commonly puncture needle is divided into two categories, namely negative pressure suction needle and cutting needle. However, the best needle size for the most widely used Tru-Cut needle has not yet established. In China, the most commonly used needle gauge is 16G (diameter 1.65mm, length 22mm or 15mm), and we generally believe that this size meets the requirements of renal pathological diagnosis. In addition, 18G needle diameter 1.27mm, Length 22mm or 15mm has been generally used in patients who has relative contraindications renal insufficiency, coagulopathy, and small size kidneys etc. It is controversial regarding whether the smaller diameter 18G biopsy needle is also able to meet the requirements of disease diagnosis and reduce the incidence of complications. The purpose of the retrospective analysis in this study is to clarify this issue.

The premise of accurate pathologic diagnosis is to get enough glomeruli such that the glomerular numbers of the 18G- and 16G- group can be compared. It has been reported that 16G had a significant advantage over the 18G needle in terms of the number of acquired glomeruli [12, 13], while in a prospective study of 14G and 16G biopsy needle Manno et al[14]found that there was no significant difference in the number of glomeruli obtained by two biopsies of different diameters. We conducted a retrospective analysis and found that under the light microscope, the numbers of glomeruli count between the two groups not significantly different under the same puncture method described by Manno[14].Under the immunofluorescence examination, the glomeruli count of the 16G group was slightly higher than that of the 18G group. In general, at least 10 intact glomeruli are required for a specimen assessment [15].Therefore, we set a standard for the samples to obtain accurate result such as number of glomeruli has to be more than≥ 10 and the adequate sample rates have to be compared between two group. We found that the adequate sample rates of 18G group and 16G group was not significant different. Thus, there is no obvious difference between the two groups in the number of glomeruli.

The pathological diagnosis of renal disease depends on the quality of the acquired specimen. When the number of glomeruli in pathological specimens is not enough, it may affect the diagnosis of the renal disease or classification of some diseases, resulting in misdiagnosis. For example, FSGS is characterized by focal segmental distribution and is easily missed in the presence of fewer glomeruli. Therefore, to diagnose a focal disease greater than 20 glomeruli may be needed[7]. But membranous nephropathy requires only one glomerulus to diagnose [12]. Generally, 16G needle biopsy of renal pathological diagnosis can meet the requirements. In the current study using pathological diagnosis of group 16G distribution as a standard, we did a comparative analysis of the pathological diagnosis of 18G and 16G needle proportion to assess the impact of the two different needles on the pathological diagnosis and pathological classification. We statistically analyzed the disease spectrum between the two groups and found that the incidence of lupus nephritis was 16.67% in the 18G group, which was much higher than that in the group 16G (7.58%). IgAN, MN, MCD, lupus nephritis, diabetic nephropathy, FSGS, MsPGN,

crescentic glomerulonephritis, acute tubulointerstitial injury, hypertension nephropathy, chronic sclerosing glomerulonephritis, endocapillary proliferative glomerulonephritis and anaphylatic purpura nephritis was found to be in equal proportions in the two groups whereas the proportion of other rare diseases in the 18G group was smaller than that in the 16G group (Table 4). Because lupus nephritis requires diagnosis in combination with clinical, laboratory, or pathological findings and does not rely solely on pathological diagnosis our results suggest that the size of the needle may have no significant effect on lupus diagnosis.

It is most frequent biopsy finding in the China is IgA nephropathy, marking up 36.3% of all primary glomerulopathies[23]. However, the number of glomeruli may affect classification of IgA nephropathy including Lee and Oxford classifications. Therefore, the difference in the proportion of different classification of IgA nephropathy is most likely related to the small sample size, which may be related to the size of the needle. In order to further analyze the influence of needle size on diagnosis of pathological classification, we comparatively analyzed the pathological classification in the 18G and 16G group (Table 5,6). The proportion of IgA nephropathy Lee grade IV was higher in the 18G group than that in the 16G group (48.00%vs24.19%, $P < 0.05$),whereas there was no significant difference in the proportion of other IgA nephropathy pathological classification between two groups. Similarly, we have chosen the new Oxford classification(MEST-C) which was published in 2017 that added to cellular/fibrocellular crescents score, compared with the older Oxford classification(MEST) which was published in 2009. The results reveal that the proportion of Oxford classifications(MEST-C)of IgA nephropathy of segmental glomerulosclerosis was higher in the 18G group than that in the 16G group 52%vs24.59%, P 0.05), whereas there was no significant difference in the proportion of other IgA nephropathy pathological index between two groups. Furthermore, we evaluate the size of the needle whether effect lupus nephritis classification and the result show that there was no significant difference in the ratio of lupus nephritis classification between two group. Considering the glomerular count and adequate sample rates of the 18G group and the 16G group, we suggest that the change in needle gauge is not a major cause of change in the proportion of IgA nephropathy in the two groups. In conclusion, through statistical analysis, our results strongly suggest that 18G needle with smaller diameter has no significant impact on the diagnosis and pathological classification of renal diseases.

Complications of renal needle biopsy include gross hematuria, lumbar abdominal pain, perirenal hematoma, arteriovenous fistula, infection etc[16],with bleeding the most common complication[17]. Most of these complications are not intervened, but severe complications requiring surgical intervention is rare. The incidence of serious complications is about 1 to 7%[6, 14, 18, 19], and 0.1% of patients died of renal biopsy[20]. A question that needs to be addressed in the field is whether it is possible to use a needle with smaller diameter for PRB to reduce postoperative complications. The correlation between the diameter of needle and the incidence of postoperative complications remains controversial. Corapi et al[21]found that the greater the risk of puncture needle bleeding was higher than that of small diameter puncture needle. Peters et al[13] concluded that 16G needle was superior to 18G in the quality of sampling and postoperative complications. Roth and Mai J et al[17, 22] pointed out that the incidence of postoperative

complications was similar in 16G group and 18G group. In our study, abdominal pain, gross hematuria, and perirenal hematoma were common complications of renal biopsy. Notably, there were two case of severe complications in the 16G group. Because the complication rate is relatively rare, the research between the two groups of mild complications and the incidence of serious complications did not show statistically significant difference.

Taken together, 16G biopsy needle has no obvious advantage over 18G needle by comparing the number of glomeruli and the adequate sample rate, and the smaller diameter 18G needle do not affect the diagnosis of the disease. Therefore, 18G needle has the same application value as 16G needle.

Declarations

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Conflict of interest The authors declared that they have no conflicts of interest to this work.

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Tables

TABLE 1 Baseline demographic and laboratory features in the 18G and 16G groups

	18G	16G	p
Male	38（53%）	114（58%）	
Female	34（47%）	84（42%）	0.482
Age	41±16	40±16	0.756
Creatinine(μmol/L)	255±242	216±316	0.11
Hemoglobin(g/L)	116±28	118±26	0.394
Platelets number(*10E9/L)	231±82	248±88	0.084
PT	12±1.8	13±1.2	0.279
APTT	28±5.5	29±4.7	0.466
Proteinuria (g/24 hr)	3.3±4.3	3.2±4.2	0.821
BMI(kg/m^2)	4.73±5.19	23.71±4.29	0.991

PT, prothrombin time; APTT, Activated Partial Thromboplastin Time

TABLE 2 Adequacy of renal biopsy

	18G	16G	P
LM	24±11	25±11	0.265
IF	3±2	5±3	0.003
LM ≥10	65（90.28%）	186（93.94%）	0.298

LM: Light microscopy glomeruli count; IF: Immunofluorescence microscopy glomeruli count

TABLE 3 Comparative analysis of biopsy complications N(%)

	18G	16G	p
Minor complications			
lumbar or abdominal pain	3（4.17%）	14（7.07%）	0.572
gross hematuria	3（4.17%）	6（3.03%）	0.704
perinephric hematoma without symptoms	3（4.17%）	3（1.52%）	0.195
serious complications	0(0%)	2（1.02%）	1
Total complications	9(12.5%)	25(12.63%)	1
Total number	72	198	

TABLE 4 Comparative analysis of disease spectrum N(%)

	18G	16G	p
IgA nephropathy	25（34.72%）	62（31.31%）	0.659
Membranous nephropathy	12（16.67%）	42（21.21%）	0.493
Minimal change disease	3（4.17%）	20（10.10%）	0.145
Lupus Nephritis	10（16.67%）	15（7.58%）	0.038
Diabetic nephropathy	5（6.94%）	10（5.05%）	0.554
FSGS	2（2.78%）	8（4.04%）	1
Mesangial proliferative glomerulonephritis	1（1.39%）	6（3.03%）	0.679
Crescentic glomerulonephritis	4（5.56%）	3（1.52%）	0.084
Acute tubulointerstitial injury	2（2.78%）	7（3.54%）	1
Hypertension nephropathy	2（2.78%）	1（0.51%）	0.174
Chronic sclerosing glomerulonephritis	3（4.17%）	2（1.01%）	0.12
Endocapillary proliferative glomerulonephritis	1（1.39%）	2（1.01%）	1
Anaphylatic purpura nephritis	1（1.39%）	1（0.51%）	0.463
Others*	1（1.39%）	19（9.6%）	0.019

*Others：minor glomerular abnormalities；renal amyloidosis；Ischemic renal injury；immunotactoid glomerulopathy；idiopathic nodularmesangial sclerosrs；Transplant nephropathy；Thrombotic microvascular disease due to scleroderma；Alport syndrome；Focal necrotic glomerulonephritis.

TABLE 5 Comparative analysis of IgAN classification（SMK Lee Classifications） N(%)

	18G	16G	p
Grade Ⅰ	0	0	
Grade Ⅱ	0	7（11.29%）	0.185
Grade Ⅲ	8（32%）	26（41.94%）	0.471
Grade Ⅳ	12（48%）	15（24.19%）	0.041
Grade Ⅴ	5（20%）	14（22.58%）	1

TABLE 6 Comparative analysis of IgAN classification（Oxford classifications*,2017） N(%)

	18G	16G	p
M1	25(100%)	61(100%)	1
E1	7(28%)	25（40.98%）	0.329
S1	13（52%）	15（24.59%）	0.022
T1	7（28%）	9（14.75%）	0.221
T2	4（16%）	12（19.67%）	0.77
C1	4(16%)	8(13.11%)	0.739
C2	3(12%)	10(16.39%)	0.748

*The Oxford classification consisted of mesangial hypercellularity (M0, mesangial score ≤ 0.5; M1, mesangial score > 0.5), endocapillary hypercellularity (E0, absent; E1,present), segmental glomerulosclerosis (S0, absent; S1, present), tubular atrophy/interstitial fibrosis (T0, ≤25%; T1, 26%-50%; T2, >50%), and cellular/fibrocellular crescents(C0,absent; C1,<25%; C2,≥25%)

TABLE 7 Comparative analysis of Lupus Nephritis classification（The ISN/RPS classification,2003） N（%）

	18G	16G	p
Class I	0(0%)	0(0%)	
Class II	0(0%)	3（20%）	0.25
Class III	0(0%)	0(0%)	
Class IV	2（20%）	3（20%）	1
Class V	0(0%)	2（13.33%）	0.5
Class VI	0(0%)	0(0%)	
Class III+V	3（30%）	1（6.67%）	0.267
Class IV+V	5（50%）	6（40%）	0.697