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Clinical audit; freehand renal biopsy, still a suitable method?

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ABSTRACT

Introduction: Freehand renal biopsy represents a valid alternative to the most widespread ultrasonography-guided technique, although some concerns can derive from the possible increased complication rate and lower adequacy rate.

Objectives: In the present audit study, efficacy of freehand method have been established through the analysis of 328 consecutive renal biopsies in 322 patients, instead the safety of the procedure was assessed in 196 patients.

Patients and Methods: We retrospectively reviewed hospital databases of all patients who underwent a percutaneous renal biopsy over an 18 years' period at Santa Marta and Santa Venera hospital in Acireale.

Results: The procedure led to a definitive diagnosis in the majority of cases (98.48%), being uninformative only in 5 out of 328 cases (1.52%). Comparing these results against a Proforma, resulting from analysis of best literature reports for the items studied, adverse event rates were similar.

Conclusion: Freehand renal biopsy resulted a good option to obtain renal tissue, without serious side effects. We argue about safety and we prefer to reserve this invasive procedure to selected cases, avoiding renal biopsy if biochemical and instrumental data allow a definitive diagnosis as well as in high risk patients. Our policy protects patients from the adverse effects that can result from kidney biopsy.

Implication for health policy/practice/research/medical education:

The present work investigates the usefulness and rate of minor/major complications in the execution of an invaluable ancillary diagnostic tool for the nephrology, the renal biopsy. This would shed light on the potentialities and limitations of this procedure, stressing the importance of an adequate assessment of indications and contraindications for its performance.

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Introduction

In nephrology practice, the histologic assessment of renal parenchyma can be crucial for diagnostic, prognostic and therapeutic purposes. For this reason, the performance of renal biopsy is a requirement in some cases, although this technique can be affected by complications and sometimes can lead to inadequate tissue samples. It is required a detection of the safest and efficacious procedure, case-by-case. The audits allow to the centers and individuals to monitor performance and it is a good mean to better the standard of care in nephrology units where renal biopsy is performed (1,2).

Objectives

The present clinical audit is aimed to characterize our patient population and verify the safety of bioptic procedure performed by the same operator. With this purpose we realized an audit proforma to compare our result against best literature report on these items.

Patients and Methods

A retrospectively audit of 328 renal biopsies performed in 322 patients, was undertaken at nephrology and dialysis unit of S. Marta and S. Venera hospital, ASP Catania, Acireale, between 1st November 2001 and 31st December

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2019. We extracted from our electronic database (Gepadial®, Traccia Matera, Italy) the clinical data for (detailed bioptic procedure, instrumental exams and diagnosis) in the interval of time. The same retrospective data collection was performed for the histological features on the virtual slide platform Spectrum®.

Starting from anagraphic data, diagnosis and procedure complications average values have been calculated by continuous variables and frequency in percentage, by Microsoft Excel. Minor complications were defined as: subcapsular perinephric hematoma (<5 cm diameter) and/or renal fistula (spontaneously resolved without need for further intervention). Major complications were defined as those required additional intervention (either blood transfusions or an invasive procedure such as angiography/embolization).

An audit proforma was used to assess many patients received detailed information about the procedure, the percentage of adequate samples for the diagnosis, the percentage of minor and major complication in relation to literature reports.

Biopsy procedure

Before the performance of the invasive procedure blood tests were performed by each patient to assess the coagulation status (prothrombin and partial thromboplastin time, a platelet count above 130 000 mm³ and a bleeding time below 6 minutes were required). Antiplatelet drugs are withdrawn for seven days and heparin for two days before the procedure. Blood pressure is maintained <130/80 mm Hg. All patient with a bleeding time longer than 6 minutes by Surgicutt® device are treated with vasopressin 4 µg/kg diluted in 0.9% sodium chloride solution just before the execution of the procedure (3) and bleeding time double-checked to assess the efficacy of the therapy. Since 2009 the drug was administered to all patients before bioptic procedure to obtain acceptable bleeding time.

A written informed consent was administered to each patient about the procedure, to understand the risk/benefit ratio. Patients underwent ultrasonography (US) with color Doppler in order to identify potential vascular abnormalities which could affect the biopsy performance. Moreover, this moment allows to establish an empathic relationship with the patient, so much to inform him further, to reassure him and to obtain collaboration during the procedure with a favorable modulation of his breathing.

The day of intervention, the patients underwent a second ultrasonography with color Doppler study to assess the position of the inferior pole of the left kidney on the lumbar plane, its depth from the skin and the best angle to approach it. The left kidney is generally preferred to the right one due to its thickness at the caudal end and

the absence of the liver hindrance (4,5). Patient is then get in prone position or on the right side, in case of supine anterolateral position (SALP) (4), if obese. After the detection of the left kidney pole, a skin mark is performed to orient the entry of the needle and after disinfection, lidocaine is used as local anesthesia and a cut of 3-4 mm by a blade is performed. Automatic biopsy gun, 16 gauge, 15-16 cm or 20 cm long, furnished with a 22 mm camera, is inserted with the same angle of previously used ultrasound probe, till reaching a safety distance calculated by ultrasound before and corresponding to the depth of renal cortex from the skin. The first specimen may contain some adipose tissue, being an indirect proof that the pararenal fat has been reached, confirming the accuracy of the previously calculated depth of the organ. This generally lead to obtain three or four specimens, for light microscopy, immunofluorescence and, in selected cases, electron microscopy study. For the assessment of adequacy, criteria used were the presence of at least 10 glomeruli or histopathologist able to make a clear diagnosis on limited number of glomeruli using all modalities. Immediately after the procedure a B-mode ultrasound and color Doppler study is performed and repeated after 3 – 6 hours and 24 hours or whenever is clinically needed.

Statistical analysis

Starting from personal data, diagnosis and procedure complications, average values (±SD) were calculated for continuous variables and frequency in percentage for binary or categorical variables. All calculations were done by Microsoft Excel for Windows.

Results

Biopsy concerned kidney tissue of 192 males (58.5%) and 136 females (41.5%), with men being biopsied at an older age than women (50.7 ± 15.7 versus 44.2 ± 16.4 years, respectively). The average number of biopsies performed per year was 17-18. The assessment of renal biopsy samples led to a definitive diagnosis in the majority of cases (98.48%), being inadequate only in 5 out of 328 cases (1.52%). Primary glomerular diseases accounted for 50.6% of all the cases, with membranous nephropathy being the most frequent (34.34%), followed by IgA nephropathy (24.7%), minimal change disease (15.7%) and focal segmental glomerulosclerosis (10.8%). Secondary glomerular diseases (n = 148; 45.1%) were mainly represented by lupus nephritis (21.6%), diabetic nephropathy (18.9%), vasculitis (12.2%) and arterio-nephrosclerosis (12.2%) (Table 1).

Renal biopsy is considered a safe procedure with low risk of serious complications (6). The assessment of post-bioptic ultrasonography in 196 patients (Table 2) demonstrated absence of procedure-related complication

Table 1. Primary and secondary glomerulonephritis in the cohort of 328 biopsies

Histological diagnosis					
Primary	No.	%	Secondary	No.	%
Membranous glomerulonephritis	57	34.3	Acute Interstitial Nephritis	4	2.7
IgA nephropathy	41	24.7	Alport Syndrome	4	2.7
Minimal change disease	26	15.7	Scleroderma	2	1.35
Focal segmental glomerulosclerosis	18	10.8	Renal lymphoma	3	2.03
Non-IgA mesangioproliferative glomerulonephritis	11	6.6	Cast Nephropathy	2	1.35
Membranoproliferative glomerulonephritis	9	5.4	Light Chain Deposition Disease	2	1.35
Organized deposits (fibrillary and immunotactoid)	4	2.4	Collapsing Nephropathy	1	0.68
Total	166	100	Anti-GBM glomerulonephritis	1	0.68
Secondary	N°	%	End Stage Kidney Disease	1	0.68
Lupus nephritis	32	21.6	Chronic Allograft Nephropathy	1	0.68
Diabetic nephropathy	28	18.9	Calcineuri Inhibitory Toxicity	1	0.68
Arterionephrosclerosis	18	12.2	Postpartum acute renal failure	1	0.68
Paucimmune crescentic glomerulonephritis (ANCA)	18	12.2	Total	148	100
Renal Amyloidosis	9	6.1	Others	N°	%
Chronic interstitial nephritis	7	4.7			
IgA vasculitis	5	3.4	Unclassifiable Nephropaties	2	0.61
Obesity-related FSGS	4	2.7	Normal Kidney	7	2.13
Acute tubular necrosis	4	2.7	Inadequate sample	5	1.52
Total	125	100	Total	14	100

in 118 cases (60.2%). Minor complications were represented by spontaneously resolving hematoma (<5 cm in diameter) in 71 (36.2%) cases and spontaneously resolved asymptomatic kidney fistula in 2.04% of cases. One patient (0.51%) developed a renal abscess that has been treated with antibiotic therapy as outpatient. Major

Table 2. Number and frequency of adverse effects in the cohort subdivided by gender

Adverse events subgroup		
Total n=196, (Age)	No.	%
Men (49.5 ± 16.8)	105	33.7
Without complication	65	61.9
Hematoma <5 cm	37	35.2
Kidney fistulae	2	1.9
Hemorrhage/transfusion	2	1.9
Renal abscess	0	0.0
Women (43.4 ± 14.8)	86	27.6
Without complication	51	59.3
Hematoma <5 cm	31	36.1
Kidney fistulae	1	1.2
Hemorrhage/transfusion	4	4.7
Renal abscess	1	1.2

complications occurred in 6 patients (2.85%), all treated by blood transfusion. In the entire cohort of 328 biopsies only one patient, affected by Goodpasture syndrome treated by dialysis, required embolization procedure in addition to transfusion (0.3%). No nephrectomy was needed or lethal events occurred as a consequence of biopsy procedure.

Discussion

In this study membranous nephropathy demonstrated a higher incidence as compared to IgA nephropathy, contrasting with the prevalence of this glomerulonephritis in Asian (7) and European (8,9) series. This could be explained by the older age of patients in our cohort, as already described elsewhere (Sant'Andrea hospital) (10). Our patients were on average 45-50 years old, the age of peak incidence of membranous nephropathy (8), whereas classically IgA nephropathy has a higher incidence at younger age and among children (11).

The incidence of minimal change disease (15.7%) was comparable with the one reported in other European biopsy registries (12-14). Arterio-nephrosclerosis and diabetic nephropathy showed similar incidence of other Italian report (8), although it highly depends upon single

center biopsy policy, with some renal unit more prone to biopsy diabetic/vasculopathic patients in order to discover occult glomerulonephritis. As opposite, we prefer to reserve this invasive procedure to selected cases, avoiding renal biopsy if biochemical and instrumental data can lead to a diagnosis and in high risk patients (e.g. long bleeding time refractory to vasopressin administration). However, we performed the procedure on patients with coagulation abnormalities after plasma infusion in selected cases that could benefit from the pathological evaluation of the disease.

Here is described a freehand procedure, although the target organ is identified in advance by ultrasonography, as already reported by other nephrology units (15). This technique has been progressively abandoned during the last years, being replaced by real-time ultrasonography guidance, considered safer. This method has been introduced to supply the need of urologists to sample specific target of the kidney (eg. renal masses) and to reduce consequent bleeding complications (16,17). In the non-neoplastic kidney, however, the ultrasonography-guidance is not mandatory since the target is represented by the whole cortex and the risk of post-procedural bleeding is much lower as compared to renal mass sampling (18).

Major iatrogenic effects of renal biopsy in our survey occurred in very few cases (6 out of 196, 2.85%), consistent with the reported range in literature for this kind of complications (1-7%) (6,15,19-22). While complications treated by blood transfusions had stricter criteria in recent update on best practice (0.4-1.5%) (23). In a study comparing freehand and real time techniques, there is no difference in the rates of major or minor complications using 16G needles (15), whereas a higher risk of minor complications in the freehand as compared to the real-time technique has been reported with 14G needles (15-19). Biopsy related complications rate were similar using the ultrasound-marked blind or real time ultrasound techniques, whether it was practiced by a nephrologist or an interventional radiologist (24).

Of note, in our cases series a complicated hemorrhage occurred in 6 patients, four women and two man, although the higher prevalence of male gender in the cohort. This result was already reported in literature by Manno et al, that postulated a role for female sex in predicting post-biopsy bleeding (21).

Minor complications are possible issues during a procedure aimed to diagnose a renal medical disease to prevent uremia, being present in a wide range of cases as reported in literature; 11 to 91% (6,15,19-21,24-27). This discrepancy can be explained by the timing of post-biopic ultrasonography examination to detect hematoma, leading to <15% of complication detection soon after the procedure, with incidence increasing after 1 or 24 hours

(6). CT scan has been proposed as a better method and could provide more frequency of hematoma detection (26). Renal arteriovenous Fistula was found less frequently than in literature reports: 2.04% against 5% (28).

In our practice, ultrasonography is performed before and just after the procedure, with eventual second-check after some hours in presence of pain or other symptoms. A further ultrasonography study is performed around 24 hours after the procedure and before the patient is discharged. With this protocol, we detected hematoma in 71 of 196 patients (36.2%) and uncomplicated fistula in 4 cases (2.04%). These results demonstrate a higher incidence of minor complications as compared to another survey (6). However, this can be explained by an increased detection rate due to the higher number of ultrasonography studies performed with our protocol.

This is a retrospective study may be affected by an information bias. We did not compare patients for differences in biochemistry results due to the absence of systematically recorded data. Some minor symptoms, as pain or colic, were not available. We only could take into account the incidence of minor and major complications of renal biopsy and its utility as diagnostic tool. Further studies with prospective design are required to better characterize the diagnostic role of renal biopsy and its impact on therapeutic choices, to evaluate the impact of all the possible complications of this procedure and the potential role of the preventive assessment of patients' risk factors (e.g. age, gender, systolic blood pressure, baseline serum creatinine, hemoglobin, prothrombin and partial thromboplastin time, platelet count, bleeding time, needle gauge and number of needle passes).

As for our audit proforma, all patients in the study received understandable information and were able to give their consent. Procedure led to a diagnosis in the majority of patients, being inadequate only in a few cases (1.52%). Minor complication was comparable to literature reports (6,15,19,20,21). Arteriovenous non complicated renal fistula was reported in percentage less than reported from literature (28), while for major complication only need for transfusion was slightly more frequent, as recommended: 2.85% against 0.4-1.5% (23). No serious complications were reported in our survey, as nephrectomy or death. Our audit proforma reached satisfying results (Table 3), even compared with results reported by other authors (6, 15,19-22, 24,30) (Table 4). In conclusion we demonstrated that our procedure is safe as requested on the basis of literature reports.

Conclusion

This study showed that freehand technique is a safe procedure that leads to collect adequate samples for histological examination. Ultrasonography-guided biopsy

Table 3. Audit proforma

Criteria	Expected	Obtained
Assess information	100%	100%
Adequate tissue	95-99%	98.5%
Minor complications		
Gross hematuria	3,5% (0.3 to 14.5)	Not reported
Hematoma	11-91%	36.2%
Renal AV fistula	5%	2.04%
Major complications		
Transfusion	0.9% (0.4 to 1.5)	2.85%
Intervention	0.6% (0.4 to 0.8)	0.3%
Nephrectomy	0.01	0%
Bladder obstruction	0.3%	0%
Death	0.02%	0%

method is a safe method too. In our opinion different factors can lead to major complications, both by freehand and ultrasonography guided methods. We excluded from this diagnostic procedure some high risk patients, preventing some serious complications. Preliminary study of the patient, with appropriate clinical, laboratory and ultrasonography with color Doppler assessment have a major role in preventing complications (24,28,29). Although the clinicians are generally comfortable with the technology that is part of their routine expertise and

ultrasonography -guided Doppler ultrasound procedure is commonly considered the gold-standard, this can represent a conundrum in case of judicial proceedings. In this setting the employment of safer or literature-suggested technologies doesn't protect the clinician from the verdict if the misconduct is consequence of negligence or inexperience.

Limitations of the study

The retrospective design is one of the major limitations of this study that included only patients who underwent freehand biopsy. Although we did not observe a significant difference in minor and major complications between ultrasonography-guided and freehand biopsy, a higher probability of repeated needle insertions in freehand biopsy should be evaluated. In addition, the freehand biopsy needs a better patient cooperation and a well-trained operator.

Authors' contribution

Conceptualization: MG, VL. Methodology: MG, VL, FP. Validation: FP, GB. Formal Analysis: MG. Investigation: MG. Resources: MG, VL. Data Curation: MG, VL. Writing original draft: MG, VL, FP, GB. Preparation: MG, VL, FP, GB. Writing Review and Editing: MG, VL. Visualization: MG, VL.

Table 4. Some of the most important studies concerning complications related to kidney biopsy intervention

Criteria	Whittier (6)	Ali (15)	Korbet (19)	Preda (20)	Manno (21)	Lees (22)	Corapi (24)	Whittier (30)	Our survey
N° Patients		527	1.055	170 (native kidney)	162	2.563	7.487-9.456	767 (native kidney)	196
Adequate tissue		77.3%-86.4%	99%	96.47%	100%	93.6%		99%	98.5%
US guided/ hand free	Hand Free/ US guided	Hand Free/ US guided	US guided	US guided	US guided	US guided	Hand Free/ US guided	US guided	Hand Free
Biopsy gun gauge	14 G-16 G	14 G-16 G	14 G	14 G	16 G	16 G	14-16-18 G	14 G-16 G	16 G
Minor complications									
Gross hematuria	3%-18%	0%-1.8%	4.5%	1.76%	0.4%		3.5%	0.52%	Not reported
Hematoma	3%-10%	0%-0.9%		15.88%	33.3%		17%	4.56%	36.2%
Renal AV fistula	0.4%-18%	Not detected		1.17%	0.4%				2.04%
Major complications									
Transfusion	1%-6%	0%-1.29%	5.3%	2.35%	0.42%	1.8%	0.9%	5.2%	2.85%
Intervention	0.1%-0.4%	0%-1.7%		2 patients	0.64%	0.4%	0.6%	5.9%	0.3%
Nephrectomy	0.1%-0.4%			2 patients	0.21%	0	0.01%	0%	0%
Bladder obstruction	0.3%			0%	0%	0	0.3%	1 patient	0%
Death	0.02%-0.1%		0.09%	1 patient	0%	1 patient	0.02%	1 patient	0%

Not all physicians provides serial Doppler ultrasound of the kidney after the interventions, some performed ultrasound studies only if patients complain symptoms (15-19-20-22-24-30). The study of Ali has reported less adverse event, but biopsy adequacy is quite low (15).

Conflicts of interest

The authors declare that they have no competing interests.

Ethical issues

The research followed the tenets of the Declaration of Helsinki. This research is not an interventional study and need no approval for local Ethical Committee. Accordingly, all patients going to have a renal biopsy are requested to express their informed consent to perform the examination and to submit their consent to use personal and clinical data, with the aim to participate to scientific purposes studies. Ethical issues (including plagiarism, data fabrication, double publication) have been completely observed by the authors.

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