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par

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SAIGNEMENTS MAJEURS DES BIOPSIES PERCUTANEES DE GREFFONS RENAUX ET EVALUATION DE SCORES PREDICTIFS.

UNE ETUDE DE COHORTE NATIONALE FRANCAISE

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Résumé

SAIGNEMENTS MAJEURS DES BIOPSIES PERCUTANEES DE GREFFONS RENAUX ET EVALUATION DE SCORES PREDICTIFS.

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Introduction : Le risque de saignement après une biopsie percutanée de greffon est habituellement faible mais reste très variable.

Matériels et méthodes : Nous avons évalué le taux de complications hémorragiques majeures (transfusion, angiographie, néphrectomie, hémorragie/hématome) chez 28034 patients greffés rénaux ayant subi une biopsie percutanée durant la période de 2010 à 2019 en France et nous les avons comparés aux patients ayant subi une biopsie percutanée de rein natif sur la même période. Nous avons évalué la pertinence d'un score prédictif de saignement déjà valide pour les biopsies percutanées et transjugulaires de reins natifs et proposé un nouveau score spécifique pour les biopsies percutanées de greffons rénaux.

Résultats : Le risque de complications hémorragiques majeures était inférieur après une biopsie percutanée de greffon rénale par rapport aux biopsies percutanées de reins natifs (4,4% vs 5,4%) (complications hémorragiques globales : OR : 0,81 (IC95%, 0,75-0,87) ; transfusion, OR :0,50 (0,38-0,68), angiographie, OR :0,84 (0,78-0,90), néphrectomie, OR 0,42 (0,18-0,94), hémorragie/hématome, OR :0,75 (0,60-0,93)). Les centres avec un nombre élevé de biopsies rénales étaient associés à moins de saignements que les centres avec des volumes plus faibles (OR par quartile : 0,93 (0,88-0,99)).

En utilisant le score prédictif de saignement développé pour les reins natifs, le risque de complications hémorragiques varie de 0,2% (score=0-4) à 15,1% (score≥ 35 points) dans notre population de patients transplantés. Nous avons développé un nouveau score, avec de meilleures performances et moins de paramètres, spécifique aux patients transplantés rénaux (AUC : 0,672 (0,658-0,688). Le taux de décès à 30 jours après une biopsie de greffon rénal était de 0,1%.

Conclusion : Les biopsies percutanées de greffons rénaux sont peu à risques de complications hémorragiques majeures mais celles-ci restent variables selon les patients. Un taux élevé de saignement est observé chez certains patients identifiés grâce à un nouveau score prédictif de saignement.

Mots clés : percutanée, biopsie rénale écho-guidée, patient transplanté, natif, saignement, facteurs de risques, score

Abstract

MAJOR BLEEDING RISK OF PERCUTANEOUS KIDNEY TRANSPLANT BIOPSIES AND ASSEMENT OF PREDICTIVE SCORES.

A FRENCH NATIONWIDE COHORT STUDY

Background: The risk of bleeding after percutaneous kidney transplant biopsy is usually low but highly variable.

Methods: We assessed the rate of major bleeding complications (transfusion, angiographic intervention, nephrectomy, haemorrhage/hematoma) in the 28,034 kidney transplant recipients who underwent a kidney biopsy during the 2010-2019 period in France, and we compared them to patients who underwent a percutaneous native kidney biopsy in the same period. We assessed the relevance of a bleeding risk score initially validated for native kidney biopsies, and proposed a specific score for kidney transplant recipients.

Results: The risk of major bleeding was lower for kidney transplant biopsies than native kidney biopsies (4.4% vs 5.4%) (any major bleeding: OR:0.81 (95%CI, 0.75-0.87); transfusion, OR: 0.50 (0.38-0.68), angiographic intervention: OR:0.84 (0.78-0.90), nephrectomy: OR:0.42 (0.18-0.94), haemorrhage/hematoma: OR: 0.75 (0.60-0.93)). Centers with high volumes of kidney biopsies were associated with less bleeding than centers with lower volumes (OR per 1 quartile: 0.93 (0.88-0.99)). Using the bleeding risk score developed for native biopsies, the risk of bleeding varied from 0.2% (score=0-4) to 15.1% (score≥ 35 points) in our transplant population. We developed a new score with better performances and less parameters for kidney transplant recipients (AUC: 0.672 (0.658-0.688). The rate of death at day 30 after kidney transplant biopsy was 0.1%.

Conclusion: Kidney transplant biopsy is safe in most patients but varies widely. High rates of bleeding are observed in patients that are identified using a new pre-procedure bleeding risk score.

Key words: percutaneous, kidney image-guided biopsy, transplant recipient, native, bleeding, risk factors, score.

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SERMENT D'HIPPOCRATE

En présence des Maîtres de cette Faculté,
de mes chers condisciples
et selon la tradition d'Hippocrate,
je promets et je jure d'être fidèle aux lois de l'honneur
et de la probité dans l'exercice de la Médecine.

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les secrets qui me seront confiés et mon état ne servira pas
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je rendrai à leurs enfants
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INTRODUCTION

Transplant kidney biopsy is an important tool for kidney transplant management(1). It is the gold standard to identify the cause of kidney graft dysfunction in many cases (2). Protocol transplant kidney biopsies are performed in many teams even for patients with stable renal function during the first months after transplantation to identify subclinical rejections, calcineurin inhibitors toxicity and allograft nephropathy(3). Since the first biopsy in 1953(4), complication rate and diagnostic yield have been improved by technical refinement (echographic guidance(5,6), automated trocar(7), thinner needle(8), kidney transplant approach(9)) making kidney transplant biopsy as a potential outpatient procedure(10,11).

However, kidney transplant biopsy remains one of the echo-guided procedures with the highest bleeding risk according to the International Society of Radiology(12). Bleeding complications are highly variable, from 1.8% to 14%(13–19). Major bleeding complication (transfusion, surgery, interventional radiology, bladder catheterization) seems less frequent(13–19), and deaths or kidney transplant loss following biopsy are rare (from 0% to 0.3% and from 0% to 0.6% respectively)(13–19). Nevertheless, transfusion is a major risk factor for allo-sensitization, and therefore remains a concern in this population (20).

Bleeding risk factors are not clearly identified. High blood urea nitrogen (BUN), thrombocytopenia and anemia are often identified as bleeding risk factors but the role of others factors such as age and gender is more controversial(14,17,21–23).

Few studies assessed the rate of major bleeding complications after percutaneous kidney transplant biopsy comparatively to native kidney biopsy(13,24–28). Older studies reported a high rate of complications but even in recent studies the rate of bleeding in native and kidney transplant biopsies remained variable (13,24–28). Direct comparisons regarding the rate of bleeding between native and kidney transplant biopsies are uneasy. They require very large samples, to avoid publication and selection biases, and they need to take into account bleeding risk factors in kidney transplant biopsies which could be different from risks factors of

bleeding in native kidney biopsies. Finally, a better identification of the risk factors of bleeding after kidney transplant biopsy is crucial but is missing due to lack of hard data.

In the present paper, using nationwide data we assessed the rate and risk factors of major bleeding complications after percutaneous kidney transplant biopsies from 2010 to 2019 in all French patients, and we compared them to patients who underwent a percutaneous native kidney biopsy in the same period using a bleeding risk score validated for percutaneous and transjugular native kidney biopsies(29,30). In addition, we proposed a new score for kidney transplant biopsy.

PATIENTS AND METHODS

Study design

This longitudinal cohort study was built on the national hospitalization database covering hospital care from the entire French population. Data of patients admitted in hospital for a native or transplant kidney biospy in France between January 2008 and December 2019 were collected from the national medico-administrative "programme de médicalisation des systèmes d'information" (PMSI) database (i.e., medicalized information system program). Shortly, obligatory since 1991 in public and private structure this database cover more than 98% of the French population (67 million people), from birth (or immigration) to death (or emigration). Medical information, including principal and secondary diagnose, and procedure was respectively recorded anonymously according to the International Classification of Diseases, tenth revision (ICD-10) and the "Classification Commune des Actes Médicaux" (CCAM). This database was already used in various works of different medical specialities and was reliable(31–35). All data were anonymised so ethical approval was not required. The French Data Protection Authority granted access to the PMSI data. Procedures for data collection and management were approved by the Commission Nationale de l'Informatique et des Libertés (CNIL), the independent National Ethical Committee protecting human right in

France, which ensures that all information is kept confidential and anonymous, in compliance with the Declaration of Helsinki. This study requires neither information nor non-opposition of the included individuals. Access to linked anonymous file in the PMSI databases was approved by the CNIL (MR-005 registration number 0415141119).

Patient selection

For the analysis, we only included patients admitted from 2010 to 2019 letting us at least 2 years of past events to characterize patient comorbidities since 2008. We identified all patients who had a native or graft kidney biopsy during this period according to ICD-10 codes (supplemental Table 1: ICD-10 codes: JAHB001, JAHJ006, JAGH007, Z940).

Major bleeding and risk of death after biopsy

Major bleeding complication was defined by blood transfusion (ICD-10 code: FELF011), hematoma/haemorrhage (ICD-10 code: T810), angiographic intervention (ICD-10 code: EDSF003, EDSF008) or nephrectomy (ICD-10 code: JAFA002, JAFA023) occurring during the 8-days following native or graft kidney biopsy and was determined by administrative codes. For the risk of death associated with major bleeding event after biopsy, a 30-day period was considered.

Collected data

Demographic, cardiovascular and metabolic conditions

Patient information was extracted from the data collected in the hospital records. For each hospital stay, diagnoses at discharge were obtained. Each variable was identified using ICD-10 codes. We also used the Charlson Comorbidity Index(36) and the Claims-based Frailty Indicator(37) to assess patient clinical status. As the information was based on codes, there was no missing value. Cardiovascular and metabolic conditions of interest included hypertension, diabetes, obesity, heart failure, valve diseases, coronary artery disease, smoking, dyslipidemia, stroke, vascular disease, atrial fibrillation.

Kidney diagnoses known at the time of biopsy

These parameters included reported history of acute kidney failure, glomerular diseases, vascular or hypertensive kidney diseases, diabetic kidney diseases, auto-immune diseases, vasculitis, thrombotic microangiopathy, hematological-related kidney diseases, amyloidosis and other kidney diseases.

Other relevant parameters

We collected information regarding history of alcohol-related diagnoses, lung diseases, liver diseases, cancer within the years preceding the biopsy, thrombocytopenia and anemia. Medications including anti-platelet agents and anticoagulants, coagulation parameters, time between transplantation and biopsy and needle size were not available.

Pre-procedure bleeding risk score

We assessed the relevance of a bleeding risk score developed for percutaneous native kidney biopsies(29), and validated in patients with transjugular native kidney biopsies(30) (Table 1).

Statistical analyses

Data are presented as mean and standard deviations for quantitative parameters and percentages for categorical parameters. Patients who had major bleeding complications (blood transfusion, hematoma/hemorrhage, angiographic intervention or nephrectomy) in an 8-days period following the biopsy were compared to other patients using Student t test or Chi^2 as appropriate. Multivariable logistic regressions were used, and results were expressed as odd ratios (OR) and 95% confidence intervals (95%CI).

The proportion of major bleeding in patients who had a kidney transplant biopsy and in those who had a percutaneous native kidney biopsy was compared. We assessed whether our previously published major bleeding risk score initially developed in patients with percutaneous and transjugular kidney biopsies could be applied in patients with transplant kidney biopsies. The proportion of patients who had a transplant vs native percutaneous kidney biopsy as well as the proportion of major bleeding in both groups were compared

according to this score. Receiver operating characteristic (ROC) curves were constructed and areas under the curve (AUC) with 95% confidence intervals were calculated to evaluate the predictive ability of major bleeding events after kidney biopsy of the score, and were compared using the DeLong test.

RESULTS

Baseline characteristics

In this study, 28,034 patients with kidney transplant biopsy were included. We used the data of 55,026 patients who had native percutaneous kidney biopsy within the same period (Table 2). Kidney transplant recipients were significantly younger and more likely to be male. Comorbidities differed according to percutaneous biopsy type: kidney transplant patients had more elevated Charlson comorbidity and Frailty index, hypertension, diabetes mellitus, congestive heart failure, coronary artery or vascular diseases, dyslipidemia, anemia and abnormal renal function while native kidney patients had more obesity, atrial fibrillation, ischemic stroke, denutrition, alcohol related diagnoses, lung or liver diseases, history of cancer, thrombocytopenia or amyloidosis (Table 2). Kidney diagnoses known before biopsy procedure were more often acute renal failure, nephrosclerosis, diabetic nephropathy and thrombotic microangiopathy in kidney transplant recipients than in patients with native kidney biopsies (Table 2).

Bleeding complications and risk of death in transplant kidney biopsies

During the 8-day period after percutaneous biopsies, major bleeding was significantly less frequent in kidney transplant biopsies than in native kidney biopsies (1,238/28,034 (4.4%) vs 2,991/55,026 (5.4%); $p<0.0001$) (OR=0.81 (95%CI, 0.75-0.87).

Specifically, angiographic intervention (56/28,034 (0.20%) vs 214/55,026 (0.39%); $p<0.0001$), blood transfusion (1,118/28,034 (4%) vs 2,614/55,026 (4.8%); $p<0.0001$), nephrectomy (7/28,034 (0.02%) vs 33/55,026 (0.05%); $p=0.03$) or hemorrhage/hematoma

(104/28,034 (0.37%) vs 273/55,026 (0.50%); p=0.01) were also less frequent in kidney transplant biopsies (Table 3). Respective ORs were 0.50 (0.68-0.38), 0.84 (0.90-0.78), 0.42 (0.94-0.18) and 0.75 (0.93-0.60).

The rate of death at day 30 was 0.11% (32/28.034) in kidney transplant biopsy. This rate was lower than the one observed for native kidney biopsy (32/28,034 (0.11%) vs 543/55,026 (0.99%) (Table 3).

Bleeding risk: center effect

We assessed the effect of percutaneous biopsy procedure frequency using quartile of volume on bleeding events for centers with more than 10 biopsies over 2010 to 2019. A center effect was found for percutaneous kidney transplant biopsies (OR per 1 quartile 0.93 (95%CI, 0.88-0.99) (Table 4).

Risk factors of major bleeding

When all patients (native and transplant kidney biopsies) were considered as a whole, parameters associated with major bleeding included older age, Charlson and Frailty index, female gender hypertension, diabetes mellitus, congestive heart failure, valve disease, coronary artery disease, vascular disease, atrial fibrillation, ischemic stroke, smoking, denutrition, alcohol related diagnoses, lung and liver diseases, anemia, thrombocytopenia, history of previous cancer, acute and chronic renal failure, auto-immune renal disease, vasculitis, hematological related kidney disease and thrombotic microangiopathy in univariate analysis (Table 5). Only Charlson and Frailty index, female gender, congestive heart failure, valve disease, anemia, thrombocytopenia, history of cancer, acute and chronic renal failure, auto-immune renal disease, vasculitis, hematological related kidney disease and thrombotic microangiopathy remained significant in multivariate analysis (Table 5).

Of note, using multivariable analysis, percutaneous kidney transplant biopsies was associated with a significantly lower risk of major bleeding (OR 0.53 (95%CI, 0.48-0.57); p<0.0001) (Table 5).

Use of pre-procedure major bleeding risk score in transplant kidney biopsy

The pre-procedure bleeding risk score developed for percutaneous and transjugular native kidney biopsy was used (Figure 1)(29,30). This score was less efficient to predict bleeding events after percutaneous kidney transplant biopsy with an AUC at 0.668 (95%CI, 0.654-0.683) with the continuous score and at 0.661 (95%CI, 0.648-0.676) with the simplified score. However, there was a 75-fold difference between the highest (13/86 (15.1%) for score ≥ 35 points) and the lowest risk (1/495 (0.2%) for score 0 to 4 points) groups (Figure 2). Patients with a pre-procedure score ≥ 20 represented 44% of kidney transplant recipients versus 23.7% of the native kidney population. Though, the risk of bleeding was significantly lower after percutaneous kidney transplant biopsies compared to native kidney biopsies when the score was ≥ 20 respectively 826/12,330 (6.7%) versus 2,031/13,056 (15.6%) (p<0.0001). Of note, the risk of bleeding was higher after percutaneous kidney transplant biopsies versus native kidney biopsies when the score was ≤ 20, 107/15,704 (2.6%) versus 960/41,970 (2.3%) (p=0.043), respectively.

New bleeding risk score for transplant kidney biopsy

Parameters associated with the risk of major bleeding are indicated in Table 6. Younger age, Charlson comorbidity index, Frailty index, female gender, congestive heart failure, anemia, acute and chronic renal failure, glomerular disease, hematological related kidney disease, vasculitis and thrombotic microangiopathy were significant risk factors of major bleeding (Table 6). Using these parameters, we were able to build a specific kidney transplant kidney risk score. Of note, this score did not use the same parameters as the one used for native kidney biopsies (Table 7). The area under the ROC curve was 0.672 (95%CI, 0.658-0.688) for kidney transplant biopsies.

DISCUSSION

The present study assessed the risk of major bleeding after transplant kidney biopsies in 28,034 in kidney transplant recipients. Percutaneous kidney transplant biopsies are associated with less major bleeding than percutaneous native kidney biopsies, particularly when the pre-procedure risk score is high (≥ 20). The pre-procedure risk score developed for percutaneous and transjugular native kidney biopsy is helpful to predict major bleeding. Finally, we propose a new pre-procedure bleeding risk score adapted for kidney transplant biopsy.

First, percutaneous kidney transplant biopsy is a relatively safe procedure with an overall risk of major bleeding complications in a 8-days period of 4.4%. The most frequent complication was the need of blood transfusion (4%), followed by hemorrhage/hematoma (0.4%), the need of angiographic intervention to stop bleeding (0.2%) and nephrectomy (0.02%). A higher rate of major bleeding complications than most of works in the literature was found (from 0% to 2.8% for protocol biopsies(15–17,38,39)from 0% to 3.4% for cause biopsies(13,16,17,39)). This difference could be explained by higher rate of blood transfusion in our work. Indeed, the rate of angiographic procedure and of nephrectomy was similar (from 0 to 0.3% and from 0% to 0.6% respectively), whereas transfusion rate was lower (from 0% to 3.3% in the literature)(13–17,22,23,27,39,40). These reports were small and usually monocentric and selection bias may occur. As our results were based on real life data, there was no publication bias in our work. Some of these reports also assessed outpatient kidney transplant biopsies or protocol kidney transplant biopsies. These patients could present less comorbidities compared to the patients assessed in our works explaining the difference in the rate of major bleeding complications. Of note, in a recent large nationwide sample of 14,268 percutaneous kidney transplant biopsies, *Charu and al*(26) showed a higher rate of transfusion (4.9%) and of angiographic intervention (0.4%) within the 2 days after an inpatient percutaneous kidney transplant biopsy.

Second, our results confirm that percutaneous kidney transplant biopsies were safer regarding bleeding events compared to native kidney especially when the pre-procedure risk score is ≥

20. The risk of overall major bleeding associated with percutaneous kidney transplant biopsy is 4.4% versus 5.4% with the percutaneous native kidney biopsy and is significantly lower for each category of major bleeding complications (angiographic intervention, nephrectomy, transfusion and hemorrhage/hematoma. Various studies showed similar results but with variable rate of bleeding complications. Older studies showed very high rate of overall bleeding (major and minor) complications (16.2-19.6% in native vs 8.7-12.6% in transplant percutaneous kidney biopsies) whereas more recent ones showed similar or lower rate of overall bleeding complications (6,3-6,5% in native vs 3,9-5,3% in transplant percutaneous kidney biopsies)(13,24,26,27). Regarding only major bleeding complications, percutaneous kidney transplant biopsies were safer than in native kidney in several works (2-5,7% in native vs 0-4,9% in transplant percutaneous kidney biopsies for transfusion and 0,6-0,8% in native vs 0-0,4% in transplant percutaneous kidney biopsies for angiographic intervention)(25–28).

However, in our work, bleeding risk factors identified in overall population are more frequently encountered in patients who had a percutaneous kidney transplant biopsy making these populations not very comparable. We assess if the use of our bleeding risk score initially developed for percutaneous and transjugular native kidney biopsy could help us to predict bleeding complication in transplant recipients(29,30). The area under the ROC curve is 0.668 showing a predictive link between the pre-procedure score and the risk of bleeding after percutaneous kidney transplant biopsy. This pre-procedure risk score is significantly less reliable than in native kidney biopsy (AUC=0.800) but there is a 75-fold difference in the bleeding rate between the highest (13/86 (15.1%) for score ≥ 35 points) and the lowest risk (1/495 (0.2%) for score 0-4 points) groups.

Focusing only on percutaneous kidney transplant biopsies, we identify younger age, Charlson comorbidity index, Frailty index, female gender, congestive heart failure, anemia, acute and chronic renal dysfunction, glomerular disease, hematological related kidney disease, vasculitis and thrombotic microangiopathy as specific risk factor of bleeding. Studies assessing bleeding risk factors after percutaneous kidney transplant biopsies showed contradictories results.

Female gender was identified as a risk factor in *Peter et al*(23) and *Charu et al*(26) works but not in *Morgan et al*(17) and *Refield et al*(14) works. Older age was identified by 2 large series as a risk factor of bleeding contrary to our work(17,26). Renal dysfunction is more often identified as a risk factor but not in the large serie of *Redfield et al*(14,17,26,40). These might be explained by some heterogeneities in complication definitions, post biopsy monitoring, operator specialty (nephrologist, surgeon, radiologist), needle gauge and type (14 to 18 gauge, automated, Tru-cut) and procedure (ultrasound-guided, blind).

Based on the identified risk factors of our work, a new pre-procedure score is propose. The area under the ROC curve tends to be better than the previous score (AUC=0.672). These pre-procedure risk scores could be helpful in daily practice with kidney transplant patients. Indeed, some scores widely used had similar AUCs (CHA_2DS_2-VASC score to predict ischemic strokes in patients with atrial fibrillation (AUC=0.672) or the Geneva revised score to predict pulmonary embolism (AUC=0.693))(41,42).

Finally, our study highlight a center volume effect on major bleeding complications frequency and particularly in percutaneous kidney transplant biopsy. *Tøndel et al*(43) also found an increase of the bleeding risk with a cut-off of thirty biopsies per years by center (native and transplant kidney included) in a nationwide study in Norway.

Our work has some limits. As our analysis was based on administrative code (ICD-10), we missed several parameters potentially involved in bleeding complications occurrence including biological coagulation parameters, presence of antiplatelet agents or anticoagulants and their withdrawal before biopsy, size of gauge and number of passes, resistive index or specialty of operators (radiologist or nephrologist). Also, transfusion indication were not available. It is possible that patients with lower level of hemoglobin before the procedure were more often transfused after biopsy even without active bleeding complication.

The strengths of our work reside in his size and design. At our knowledge, it represent the largest analysis focusing on the issue of major bleeding complication after percutaneous kidney transplant biopsy. Our datas were also agreed with other nationwide work(26).

Choosing a 8-day period after percutaneous biopsy permit to truly estimate all complications(14,17,18,25). Therefore, our findings were based from real life data and could be integrated in clinical practice.

CONCLUSION

In conclusion, percutaneous kidney transplanted biopsy is a safe procedure regarding bleeding complications and is safer compared to native kidney biopsies especially when pre-procedure risk score is high. Multivariable analysis identified younger age, Charlson comorbidity index, Frailty index, female gender, congestive heart failure, anemia, acute and chronic renal dysfunction, glomerular disease, hematological related kidney disease, vasculitis and thrombotic microangiopathy as specific risk factor of bleeding. Our different pre-procedure scores can help us to assess the risk of major bleeding after percutaneous kidney transplant biopsy.

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Table 1 : Major bleeding risk score

Components of the score*	Points
	5
Age	
45-60	**1**
61-71	**2**
>71	**3**
Charlson comorbidity index	
2 - 4	**1**
5 - 6	**2**
> 6	**3**
Frailty index	
1.5 - 4.4	**1**
4.5-9.5	**2**
>9.5	**3**
Gender (male)	**-1**
Dyslipidemia	**-1**
Obesity	**-1**
Anaemia	**8**
Thrombocytopenia	**2**
Cancer within preceding years	**2**
Abnormal renal function	**2**
Acute renal failure	**4**
Glomerular disease	**-1**
Vascular or hypertensive renal disease	**-1**
Diabetic kidney disease	**-1**
Auto-immune disease	**2**
Vasculitis	**5**
Hematological-related renal disease	**2**
Thrombotic microangiopathy	**4**
Amyloidosis	**-2**
Other renal presentation	**-1**

* = sum of the points + 5
Score: from 0 (minimal score) to 41 (maximal score) points

Table 2 : Baseline characteristics according to the type of percutaneous biopsy

	Percutaneous native kidney biopsy (n=55026)	Percutaneous biopsy in kidney transplant (n=28034)	p	Total (n=83060)
Age, years	58.0±17.4	51.6±14.7	<0.0001	55.8±16.8
Sex (male)	33523 (60.9)	17706 (63.2)	<0.0001	51229 (61.7)
Charlson comorbidity index	4.6±2.8	4.8±2.7	<0.0001	4.6±2.8
Frailty index	7.1±7.7	8.6±7.6	<0.0001	7.6±7.7
Hypertension	29392 (53.4)	20971 (74.8)	<0.0001	50363 (60.6)
Diabetes mellitus	12376 (22.5)	7476 (26.7)	<0.0001	19852 (23.9)
Obesity	8626 (15.7)	3863 (13.8)	<0.0001	12489 (15.0)
Heart failure with congestion	5827 (10.6)	3825 (13.6)	<0.0001	9652 (11.6)
Valve disease	2454 (4.5)	1189 (4.2)	0.15	3643 (4.4)
Coronary artery disease	5486 (10.0)	4404 (15.7)	<0.0001	9890 (11.9)
Vascular disease	5889 (10.7)	4081 (14.6)	<0.0001	9970 (12.0)
Atrial fibrillation	4839 (8.8)	2090 (7.5)	<0.0001	6929 (8.3)
Ischemic stroke	1006 (1.8)	362 (1.3)	<0.0001	1368 (1.6)
Smoker	5565 (10.1)	2726 (9.7)	0.08	8291 (10.0)
Dyslipidemia	10257 (18.6)	6440 (23.0)	<0.0001	16697 (20.1)
Poor nutrition	4865 (8.8)	2077 (7.4)	<0.0001	6942 (8.4)
Alcohol related diagnoses	3689 (6.7)	939 (3.3)	<0.0001	4628 (5.6)
Lung disease	5749 (10.4)	2070 (7.4)	<0.0001	7819 (9.4)
Liver disease	3345 (6.1)	1493 (5.3)	<0.0001	4838 (5.8)
Anaemia	13382 (24.3)	14484 (51.7)	<0.0001	27866 (33.6)
Thrombocytopenia	3854 (7.0)	1733 (6.2)	<0.0001	5587 (6.7)
Previous cancer	13264 (24.1)	2562 (9.1)	<0.0001	15826 (19.1)
Abnormal renal function	17566 (31.9)	23791 (84.9)	<0.0001	41357 (49.8)
Acute renal failure	16671 (30.3)	13656 (48.7)	<0.0001	30327 (36.5)
Glomerular disease	18018 (32.7)	4493 (16.0)	<0.0001	22511 (27.1)
Nephrosclerosis	4751 (8.6)	3624 (12.9)	<0.0001	8375 (10.1)
Diabetic nephropathy	3974 (7.2)	2639 (9.4)	<0.0001	6613 (8.0)
Auto-immune renal disease	3307 (6.0)	592 (2.1)	<0.0001	3899 (4.7)
Vasculitis	2335 (4.2)	488 (1.7)	<0.0001	2823 (3.4)
Hematological diseases associated with renal disease	1716 (3.1)	246 (0.9)	<0.0001	1962 (2.4)
Thrombotic microangiopathy	969 (1.8)	705 (2.5)	<0.0001	1674 (2.0)
Amyloidosis	204 (0.4)	68 (0.2)	0.002	272 (0.3)
Other	688 (1.3)	361 (1.3)	0.65	1049 (1.3)

Table 3 : Proportion of bleeding in native versus transplant percutaneous kidney biopsy

	Percutaneous native kidney biopsy	Percutaneous biopsy in kidney transplant	p	Total
	(n=55026)	(n=28034)		(n=83060)
Bleeding events from day 0 to day 8:				
Angiographic intervention	216 (0.39)	56 (0.20)	<0.0001	272 (0.33)
Nephrectomy	33 (0.05)	7 (0.02)	0.03	40 (0.05)
Blood transfusion	2614 (4.75)	1118 (3.99)	<0.0001	3732 (4.49)
Hemorrhage/hematoma	273 (0.50)	104 (0.37)	0.01	377 (0.45)
Any of the bleeding events	2991 (5.43)	1238 (4.42)	<0.0001	4229 (5.09)
Angiographic intervention or nephrectomy or transfusion	2778 (5.05)	1160 (4.14)	<0.0001	3938 (4.74)
Death at day 30	543 (0.99)	32 (0.11)	<0.0001	575 (0.69)

Table 4: Major bleeding events in patients with percutaneous transplant kidney biopsy by quartile of center volume

Quartile of center volume	Mean number of biopsies by center, 2010-1019	Number of patients with percutaneous biopsies, n	Number pf patients with native biopsy / transplant	Major bleeding among patients with percutaneous biopsy, n (%)	Major bleeding among patients with native percutaneous biopsy, n (%)	Major bleeding among patients with transplant percutaneous biopsy, n (%)
1	159±86	20,827	17,936 / 2,891	1,081 (5.2)	949 (5.3)	132 (4.6)
2	524±121	21,661	15,835 / 5,826	1,268 (5.9)	956 (6.0)	312 (5.4)
3	1035±235	22,778	12,425 / 10,353	1,063 (4.7)	653 (5.3)	410 (4.0)
4	4473±1121	17,794	8,830 / 8,964	817 (4.6)	433 (4.9)	384 (4.3)

Volume was evaluated for centers with more than 10 biopsies over 2010-2019.

Odds ratio for the risk of major bleeding based on center volume in patients with native percutaneous biopsy = 0.97 (95% CI 0.94-1.01), p=0.11.

Odds ratio for the risk of major bleeding based on center volume in patients with transplant percutaneous biopsy = 0.93 (95% CI 0.88-0.99), p=0.02.

Table 5 : Risk factors of major bleeding after percutaneous biopsy : univariate and multivariable analysis

	Univariate analysis		Multivariable analysis	
	OR, 95%CI	p	OR, 95%CI	p
Age (quartile)	1.242 (1.207-1.277)	<0.0001	1.015 (0.980-1.052)	0.41
Charlson comorbidity index	1.438 (1.398-1.479)	<0.0001	1.157 (1.110-1.205)	<0.0001
Frailty index	1.588 (1.542-1.635)	<0.0001	1.219 (1.177-1.263)	<0.0001
Sex (male)	0.768 (0.722-0.817)	<0.0001	0.846 (0.791-0.905)	<0.0001
Hypertension	1.202 (1.127-1.282)	<0.0001	0.880 (0.814-0.951)	0.001
Diabetes mellitus	1.129 (1.052-1.212)	0.001	0.883 (0.807-0.966)	0.007
Heart failure with congestion	2.105 (1.948-2.275)	<0.0001	1.115 (1.018-1.222)	0.02
Valve disease	1.992 (1.773-2.238)	<0.0001	1.144 (1.006-1.302)	0.04
Coronary artery disease	1.284 (1.176-1.402)	<0.0001	1.004 (0.904-1.115)	0.94
Vascular disease	1.231 (1.126-1.345)	<0.0001	0.850 (0.767-0.944)	0.002
Atrial fibrillation	1.934 (1.769-2.115)	<0.0001	1.102 (0.993-1.222)	0.07
Ischemic stroke	1.304 (1.049-1.620)	0.02	0.814 (0.648-1.022)	0.08
Smoker	1.184 (1.075-1.305)	0.001	0.993 (0.890-1.107)	0.90
Dyslipidemia	1.026 (0.951-1.108)	0.51	0.921 (0.843-1.006)	0.07
Obesity	0.977 (0.895-1.066)	0.60	0.850 (0.773-0.936)	0.001
Poor nutrition	2.276 (2.090-2.479)	<0.0001	1.039 (0.947-1.141)	0.42
Alcohol related diagnoses	1.515 (1.350-1.699)	<0.0001	0.975 (0.851-1.117)	0.72
Abnormal renal function	1.650 (1.549-1.758)	<0.0001	1.303 (1.205-1.410)	<0.0001
Lung disease	1.485 (1.354-1.629)	<0.0001	0.892 (0.806-0.987)	0.03
Liver disease	1.601 (1.433-1.788)	<0.0001	0.924 (0.813-1.050)	0.23
Anaemia	4.245 (3.976-4.533)	<0.0001	2.875 (2.665-3.100)	<0.0001
Thrombocytopenia	2.422 (2.211-2.653)	<0.0001	1.208 (1.092-1.337)	<0.0001
Previous cancer	1.616 (1.506-1.734)	<0.0001	1.158 (1.063-1.262)	0.001
Acute renal failure	3.648 (3.417-3.894)	<0.0001	2.034 (1.889-2.191)	<0.0001
Glomerular disease	0.854 (0.794-0.918)	<0.0001	0.840 (0.776-0.909)	<0.0001
Nephrosclerosis	0.885 (0.795-0.986)	0.03	0.825 (0.735-0.925)	0.001
Diabetic nephropathy	0.854 (0.756-0.964)	0.01	0.729 (0.632-0.840)	<0.0001
Auto-immune renal disease	1.553 (1.373-1.757)	<0.0001	1.279 (1.115-1.466)	<0.0001
Vasculitis	4.052 (3.651-4.498)	<0.0001	2.630 (2.342-2.954)	<0.0001
Hematological diseases associated with renal disease	2.748 (2.394-3.154)	<0.0001	1.437 (1.236-1.670)	<0.0001
Thrombotic microangiopathy	4.342 (3.818-4.938)	<0.0001	2.172 (1.886-2.501)	<0.0001
Amyloidosis	1.012 (0.590-1.734)	0.97	0.719 (0.412-1.253)	0.24
Other	1.153 (0.889-1.496)	0.28	0.729 (0.558-0.953)	0.02
Kidney transplant	**0.863 (0.759-0.982)**	**0.03**	**0.526 (0.483-0.574)**	**<0.0001**

Table 6: Risk factors of major bleeding after percutaneous biopsy in patient with kidney transplant: univariate and multivariable analysis

	Univariate analysis		Multivariable analysis	
	OR, 95%CI	p	OR, 95%CI	p
Age (quartile)	0.980 (0.925-1.039)	0.49	0.907 (0.848-0.970)	0.004
Charlson comorbidity index	1.272 (1.206-1.341)	<0.0001	1.240 (1.155-1.333)	<0.0001
Frailty index	1.288 (1.219-1.361)	<0.0001	1.139 (1.072-1.211)	<0.0001
Sex (male)	0.797 (0.710-0.895)	<0.0001	0.853 (0.756-0.962)	0.01
Hypertension	1.138 (0.994-1.302)	0.06	0.844 (0.725-0.984)	0.03
Diabetes mellitus	1.088 (0.959-1.235)	0.19	0.848 (0.720-0.999)	0.05
Heart failure with congestion	1.750 (1.520-2.015)	<0.0001	1.194 (1.018-1.401)	0.03
Valve disease	1.397 (1.092-1.789)	0.008	1.048 (0.807-1.362)	0.72
Coronary artery disease	1.182 (1.018-1.371)	0.03	1.035 (0.868-1.235)	0.70
Vascular disease	1.074 (0.917-1.258)	0.37	0.805 (0.671-0.965)	0.02
Atrial fibrillation	1.473 (1.221-1.778)	<0.0001	1.170 (0.951-1.438)	0.14
Ischemic stroke	1.339 (0.858-2.088)	0.20	0.937 (0.594-1.478)	0.78
Smoker	1.194 (0.997-1.430)	0.06	0.993 (0.818-1.206)	0.95
Dyslipidemia	1.032 (0.902-1.180)	0.65	0.940 (0.807-1.096)	0.43
Obesity	1.164 (0.994-1.362)	0.06	1.035 (0.874-1.226)	0.69
Poor nutrition	1.470 (1.217-1.775)	<0.0001	0.958 (0.785-1.169)	0.67
Alcohol related diagnoses	1.335 (1.008-1.768)	0.04	1.000 (0.739-1.352)	1.00
Abnormal renal function	1.889 (1.548-2.306)	<0.0001	1.328 (1.070-1.648)	0.01
Lung disease	1.275 (1.045-1.555)	0.02	0.894 (0.725-1.103)	0.30
Liver disease	1.510 (1.217-1.874)	<0.0001	1.016 (0.804-1.285)	0.89
Anaemia	2.262 (1.998-2.560)	<0.0001	1.710 (1.490-1.963)	<0.0001
Thrombocytopenia	1.709 (1.408-2.074)	<0.0001	1.081 (0.879-1.329)	0.46
Previous cancer	1.091 (0.901-1.322)	0.37	0.855 (0.697-1.049)	0.13
Acute renal failure	2.499 (2.209-2.827)	<0.0001	1.870 (1.640-2.132)	<0.0001
Glomerular disease	1.381 (1.198-1.591)	<0.0001	1.214 (1.044-1.412)	0.01
Nephrosclerosis	1.007 (0.850-1.193)	0.93	0.866 (0.725-1.036)	0.12
Diabetic nephropathy	1.054 (0.871-1.277)	0.59	0.874 (0.693-1.102)	0.25
Auto-immune renal disease	1.371 (0.969-1.938)	0.08	0.898 (0.624-1.292)	0.56
Vasculitis	4.327 (3.373-5.552)	<0.0001	3.149 (2.418-4.102)	<0.0001
Hematological diseases associated with renal disease	2.478 (1.632-3.763)	<0.0001	1.654 (1.064-2.569)	0.03
Thrombotic microangiopathy	3.521 (2.812-4.410)	<0.0001	2.172 (1.708-2.763)	<0.0001
Amyloidosis	1.721 (0.691-4.285)	0.24	1.318 (0.522-3.328)	0.56
Other	1.274 (0.809-2.007)	0.30	0.992 (0.624-1.576)	0.97

Table 7 : Specific kidney transplant biopsy major bleeding score

Components of the score	Points
	4
Age	
18-44	-1
45-58	-2
59-69	-3
>69	-4
Charlson comorbidity index	
0-2	1
3 4	2
5 6	3
>6	4
Frailty index	
0-2.2	1
2.3-5.2	2
5.3-10.8	3
>10.8	4
Anemia	2
Acute renal failure	2
Vasculitis	3
Thrombotic microangiopathy	2

score from 0 (minimal score) to 20 (maximal score) points

Figure legends

Figure 1: Major bleeding pre-procedure risk score ROC curve

ROC curves are presented using the continuous score (figure 1A) and the simplified (8-level) score (figure 1B). Area under the ROC curve (AUC) for percutaneous transplant biopsies (red curve) was quite good but was significantly lower than in patients with percutaneous native kidney biopsies (blue curve). The AUC for percutaneous native kidney and transplant kidney biopsies was respectively 0.800 (95%CI, 0.793-0.808) vs 0.668 (95%CI, 0.654-0.683) ($p<0.001$) for the continuous score, and 0.793 (95%CI, 0.786-0.801) vs 0.661 (95%CI, 0.648-0.676) ($p<0.001$) for the 8-level score.

Figure 2: Risk of major bleeding according to the continuous pre-procedure risk score

Risk of major bleeding (angiographic intervention, nephrectomy, blood transfusion, haemorrhage/hematoma) at day 8 in relation to the number of points of the continuous pre-procedure risk score (from 0-4 to 35-41) in patients with percutaneous native and kidney transplant biopsies. Proportion of major bleeding according to the score in native and kidney transplant biopsies are 27/5,550 (0.49%) and 1/495 (0.20%) with score from 0 to 4, 176/15,053 (1.16%) and 56/3,547 (1.58%) with score from 5 to 9, 291/11,622 (2.44%) and 107/5,394 (1.98%) with score from 10 to 14, 466/9,278 (5.02%) and 248/6,268 (3.96%) with score from 15 to 19, 746/6,256 (11.92%) and 339/6,520 (5.20%) with score from 20 to 24, 768/4,649 (16.52%) and 255/4,602 (7.71%) with score from 25 to 29, 445/1,917 (23.21%) and 119/1,122 (10.61%) with score from 30 to 34, 72/234 (30.77%) and 13/86 (15.12%) with score ≥ 35, respectively.

Figure 3: Major bleeding pre-procedure risk score created for percutaneous ROC curve

ROC curve is presented using the new score created for percutaneous kidney transplant biopsies after identified specific risk factors. Area under the ROC curve (AUC) for percutaneous transplant biopsies (red curve) was still quite good but was significantly lower than in patients with percutaneous native kidney biopsies (blue curve). The AUC for percutaneous native kidney and transplant kidney biopsies was respectively 0.766 (95%CI, 0.759-0.775) vs 0.672 (95%CI, 0.658-0.688), $p<0.001$.

Figure 1: Major bleeding pre-procedure risk score ROC curve

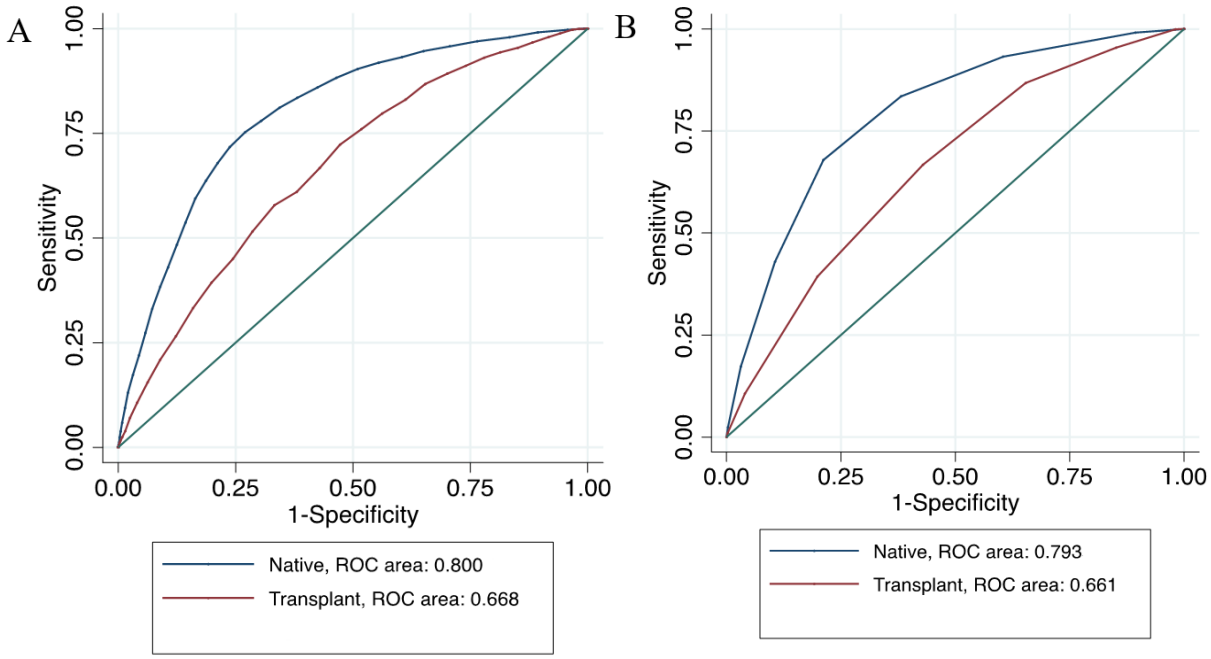


Figure 2: Risk of major bleeding according to the continuous pre-procedure risk score

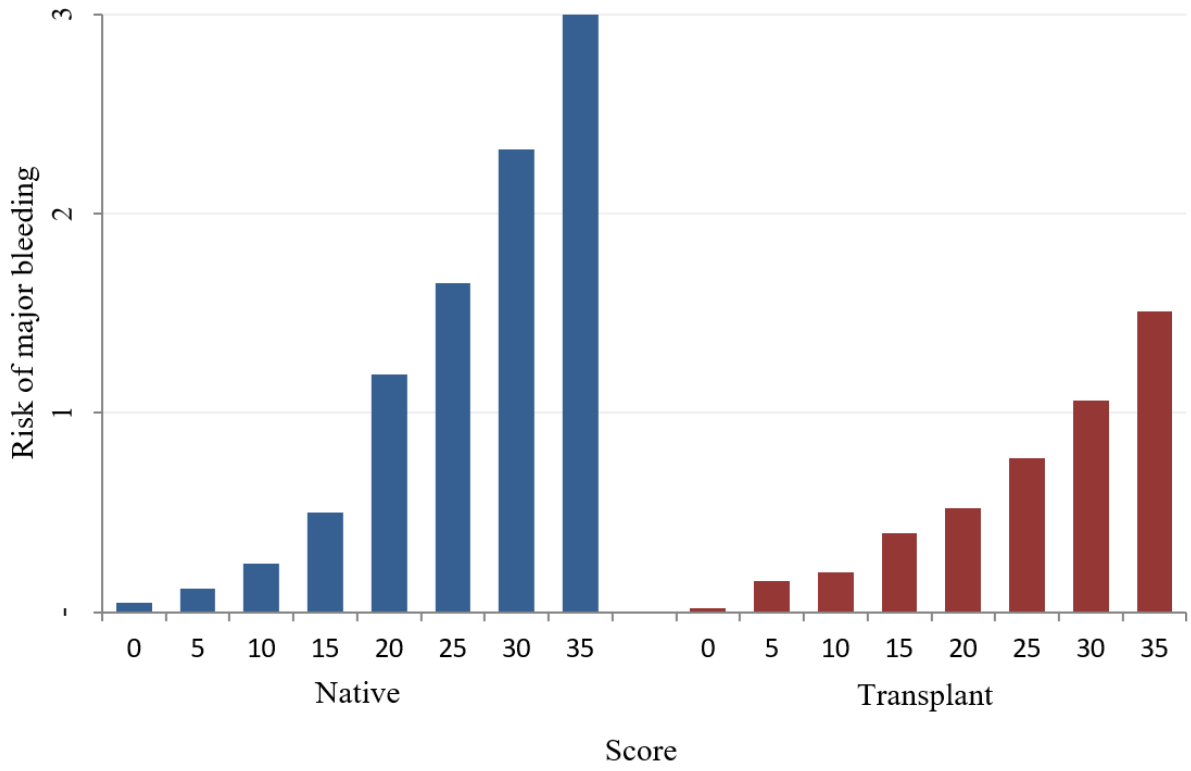
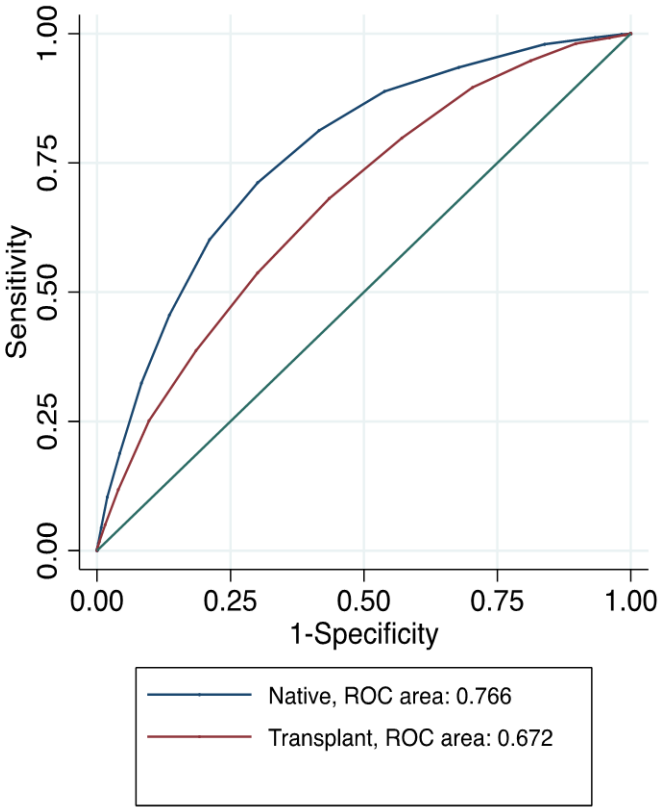


Figure 3: Major bleeding pre-procedure risk score created for percutaneous kidney transplant biopsy ROC curve



Supplemental Table 1: International Classification of Diseases Tenth Revision Code (ICD-10)

JAHB001	Biopsie du rein, par voie transcutanée sans guidage
JAHJ006	Biopsie du rein sur une cible, par voie transcutanée avec guidage échographique
JAGH007	Biopsie du rein sur plusieurs cibles, par voie transcutanée avec guidage échographique
Z940	Greffe de rein
FELF011	Transfusion de concentrés de globules rouges d'un volume inférieur à une demi masse sanguine
T810	Hémorragie et hématome compliquant un acte à visée diagnostique et thérapeutique, non classés ailleurs
EDSF003	Embolisation sélective ou hypersélective de l'artère rénale, par voie artérielle transcutanée
EDSF008	Embolisation suprasélective de l'artère rénale, par voie artérielle transcutanée
JAFA002	Néphrectomie totale, par lombotomie
JAFA023	Néphrectomie totale unilatérale, par laparotomie

Vu, le Directeur de Thèse

Vu, le Doyen
De la Faculté de Médecine de Tours
Tours, le

SAIGNEMENTS MAJEURS DES BIOPSIES PERCUTANEES DE GREFFONS RENAUX ET EVALUATION DE SCORES PREDICTIFS.

UNE ETUDE DE COHORTE NATIONALE FRANCAISE

Introduction : Le risque de saignement après une biopsie percutanée de greffon est habituellement faible mais reste très variable.

Matériels et méthodes : Nous avons évalué le taux de complications hémorragiques majeures (transfusion, angiographie, néphrectomie, hémorragie/hématome) chez 28034 patients greffés rénaux ayant subi une biopsie percutanée durant la période de 2010 à 2019 en France et nous les avons comparés aux patients ayant subi une biopsie percutanée de rein natif sur la même période. Nous avons évalué la pertinence d'un score prédictif de saignement déjà valide pour les biopsies percutanées et transjugulaires de reins natifs et proposé un nouveau score spécifique pour les biopsies percutanées de greffons rénaux.

Résultats : Le risque de complications hémorragiques majeures était inférieur après une biopsie percutanée de greffon rénale par rapport aux biopsies percutanées de reins natifs (4,4% vs 5,4%) (complications hémorragiques globales : OR : 0,81 (IC95%, 0,75-0,87) ; transfusion, OR : 0,50 (0,38-0,68), angiographie, OR : 0,84 (0,78-0,90), néphrectomie, OR : 0,42 (0,18-0,94), hémorragie/hématome, OR : 0,75 (0,60-0,93)). Les centres avec un nombre élevé de biopsies rénales étaient associés à moins de saignements que les centres avec des volumes plus faibles (OR par quartile : 0,93 (0,88-0,99)). En utilisant le score prédictif de saignement développé pour les reins natifs, le risque de complications hémorragiques varie de 0,2% (score=0-4) à 15,1% (score≥ 35 points) dans notre population de patients transplantés. Nous avons développé un nouveau score avec de meilleures performances et moins de paramètres spécifique aux patients transplantés rénaux (AUC : 0,672 (0,658-0,688). Le taux de décès à 30 jours après une biopsie de greffon rénal était de 0,1%.

Conclusion : Les biopsies percutanées de greffons rénaux sont peu à risques de complications hémorragiques majeures mais celles-ci restent variables selon les patients. Un taux élevé de saignement est observé chez certains patients identifiés grâce à un nouveau score prédictif de saignement.

Mots clés : percutanée, biopsie rénale écho-guidé, patient transplanté, natif, saignement, facteurs de risques, score

Mathieu KACZMAREK

42 pages – 7 tableaux – 3 figures – 1 table supplémentaire

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Date de soutenance : 13 octobre 2021.