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Review

The burden of chronic kidney disease in systemic lupus erythematosus: A nationwide epidemiologic study

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ABSTRACT

Objective: To analyze the impact of chronic kidney disease (CKD) on major clinical outcome in SLE by using a nationwide database.

Patients and methods: Characteristics of all admitted SLE patients experiencing CKD (eGFR < 60 mL/min/1.73 m2) in France from 2009 to 2015 were analyzed through the French medico- administrative database. Factors associated with CKD and major clinical outcomes such as end-stage renal disease (ESRD), cardiovascular event (CVE), septic shock and death were assessed. We used a multivariate Cox proportional hazard model and subdistribution hazard models to analyze survival without major clinical events according to the presence of CKD.

Results: From 2009 to 2015, 26,320 SLE patients were hospitalized in France. Among them, 6439 (86.5% women; mean age 45.7 [16.5] years old) had a baseline stay in 2009 during which CKD was reported in 428 (6.7%) cases. Multivariate analysis showed that lupus nephritis (OR 6.6 [5.2–8.4]), high blood pressure (OR 3.5 [2.8–4.5]), septic shock (OR 3.2 [1.7–6.0]) and past cardiovascular history (OR 1.4 [1.0–2.0]) were associated with CKD status. From 2009 to 2015, ESRD, CVE, septic shock, and death occurred in 4.0%, 14.4%, 6.3% and 9.6% of the 6439 SLE patients. CKD at baseline was independently and strongly associated with the occurrence of ESRD (sdHR 15.9 [11.6–21.9]), CVE (sdHR 1.7 [1.4–2.2]), septic shock (sdHR 2.1 [1.5–2.8]) and death (HR 1.7 [1.3–2.2]) during the follow up.

Conclusion: CKD is a major risk factor for overall morbidity and mortality in SLE patients, highlighting the need for early pre-CKD lupus nephritis diagnosis and treatment.

1. Introduction

Systemic lupus erythematosus (SLE) is an autoimmune disease involving multiple organs, which affects mainly women of child-bearing age with a prevalence of 1 per 2000 [1–3]. Lupus nephritis (LN), characterized by glomerular IgM-, IgG- and IgA-containing immune complex deposits, is the hallmark of the disease and affects approximately 50% of SLE patients [4].

Clinical-epidemiological research has advanced our knowledge on the negative impact of LN on SLE outcomes. Impaired renal function at LN diagnosis and failure to normalize renal function upon aggressive immunosuppressive therapy are associated with a very poor long- term renal outcome [5–7]. Most reports on that field are however based on tertiary care data of limited sample size that impede the ability to generalize the findings. In order to measure the impact of renal function impairment on clinical outcome such as death or cardiovascular events effectively, updated comprehensive information at national level is needed.

We conducted an analysis of a French nationwide database to assess the characteristics associated with the presence of CKD (i.e. eGFR < 60 mL/min/1.73 m2) and the prognosis associated with CKD in SLE patients.

Abbreviations: CCAM, Classification Commune des Actes Médicaux (CCAM); CI, Confidence interval; CKD, Chronic kidney disease; CVE, Cardiovascular event; ESRD, End stage renal disease; HR, Hazard ratios; ICD, International Classification of Diseases; LN, Lupus nephritis; OR, Odds ratio; PMSI, Programme de Médicalisation des Systèmes d'Informations; sdHR, Sub-distributionnal hazard ratios; SLE, Systemic lupus erythematosus

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2. Methods

2.1. Study population and data source

Exhaustive data for all patients admitted in French hospitals with at least one SLE diagnosis from January 2009 to December 2015 were collected from the national medical administrative database PMSI (Programme de Médicalisation des Systèmes d'Informations, Information System Medicalization Program). PMSI database provides a summary with diagnosis and individual medical conditions at discharge of all French healthcare facilities. Information covers both medical and administrative data. Each facility produces its own anonymous standardized data, which are then compiled at the national level. Although data are anonymous, the system allows following all hospital stays for each individual patient. Routinely collected medical data includes main diagnosis, secondary diagnoses, and performed procedures. Administrative data includes age, sex, year, duration of the stay, and location of the hospital. In-hospital death is reported. Diagnoses are coded according to the International Classification of Diseases, tenth revision (ICD-10). Procedures are coded according to the "Classification Commune des Actes Médicaux" (CCAM). Regular checks are made by the social insurance authority to ensure that data are correctly imputed. The reliability and validity of PMSI data have been assessed elsewhere [8,9].

To select the SLE population, we first extracted from the PMSI database all the records of patients for whom at least one ICD-10 M32 ("Systemic Lupus Erythematosus") was reported. We excluded patients younger than 16 years old and patients admitted to hospital only for scheduled sessions (chronic hemodialysis, radiotherapy, chemotherapy). Hospital stays with ambiguous chaining were excluded (n = 12,190; 6%).

2.2. Ethics statement

We performed a human non-interventional study where anonymized information used in the study were collected for clinical care and epidemiological methods were used to analyze the data. According to the Public Health French Law (Law n°2012-300), approval from institutional review board and written consent are not required for human non-interventional studies. For ethical consideration, patients were however informed that data that was collected in medical records might be used for research study in accordance to privacy rule. The study protocol conforms to the ethical guidelines of the 1975 Declaration of Helsinki.

2.3. Definitions

Chronic kidney disease (CKD) was defined as having a chronic renal disease with an estimated Glomerular Filtration Rate (eGFR) < 60 mL/min/1.73 m2 (ICD code N18x) without end-stage renal disease (ESRD). ESRD was defined as having required chronic hemodialysis (GHM code 28Z04Z) or received a renal transplant (CCAM code JAEA003). Cardiovascular event was defined as having myocardial infarction (ICD codes I21x, I22x), angina pectoris (ICD code I20x), therapeutic coronary arteriography (CCAM procedure codes DDAF0010, DDAF0030, DDAF0040, DDAF0080, DDAF0070, DDAF0090, DDAF0060, DDAF0100), ischemic stroke or transient ischemic attack (ICD codes I63x, G45, G46, I64), acute limb/arm ischemia (ICD code I74x), mesenteric ischemia (ICD code K550x) and/or sudden death (ICD code I461). Septic shock was defined as the combination of at least one diagnosis of infection (ICD-10 code A00-B99 + others listed in supplementary data) with one diagnosis among the followings: R572 "septic shock", R578 "other shock", R 579 "shock without precision" or CCAM procedure code EQLF0010 and EQLF0030 which refers to the use of vasopressor agents. Specific diagnostic codes were used for lupus associated nephritis, serositis (pericarditis and/or pleural effusions), cytopenia (autoimmune hemolytic anemia, immunologic thrombocytopenic purpura, and/or Evans syndrome) and SNC disease (myelitis, encephalitis and/or cerebral vasculitis). For the exhaustive description of diagnosis and procedures codes used, see electronic supplementary materials.

2.4. Factors associated with the presence of CKD in 2009

The characteristics of patients reported at first stay in year 2009 were described. Factors associated with the presence of CKD using univariate and multivariable logistic regression procedures were analyzed. Patients with ESRD at first stay were excluded (n = 98).

2.5. Major outcomes in SLE patients with CKD from 2009 to 2015

The onset of four major outcomes - ESRD, a first cardiovascular event, a first septic shock episode and death – from first stay (2009) to 2015 were considered. Using Kaplan-Meier method, survival curves associated with any of these outcomes were plotted according to the CKD status in 2009. For death, we calculated univariate and multivariate hazard ratios (HR) associated with the presence of CKD at first stay using Cox proportional hazard models. For the other outcomes we calculated sub-distributionnal Hazard ratios (sdHR) associated with the presence of CKD at first stay using Fine and Gray's hazard model taking death as a competing event.

2.6. Statistical statement

Categorical variables are presented as number (percentage). Quantitative variables are presented as mean [standard deviation]. Odds Ratio and Hazard ratio are presented with their 95% confidence interval as OR [CI 95] and HR [CI 95]. To perform the multivariate logistic regression procedure, we used all the variables that had a level of significance < 0.05 as covariates. To perform the multivariate Cox model and subdistribution hazard models, we used age, cancer and all the significant variables of the logistic model as covariates. We used subdistribution survival hazard models to analyze factors associated with ESRD, septic shock and CVE, taking into account death as a competing event. All tests were two sided, and P values < 0.05 were considered to indicate a significant association. All analyses were performed using SAS © software version 9.4 (SAS Inc., Cary NC). Kaplan-Meïer curves were made with R software version 3.4.4, library "survival".

3. Results

3.1. Characteristics of SLE patients

Between 2009 and 2015, 26,320 SLE patients were hospitalized in France. Among them 6439 (5567 (86.5%) women; mean age 45.7 [16.5] years old) had a stay in 2009 and could be followed over the entire 2009 to 2015 period (Fig. S1 – flow chart). As expected, SLE patients in France are mostly followed in tertiary academic hospitals (51% versus 36% in community hospitals and 13% in for-profit hospitals). The 2009 distribution of the SLE stays by French administrative districts and by age and sex groups are presented in Figs. S2 and S3.

3.2. Factors associated with the presence of CKD in 2009: cross-sectional study

Among the 6439 SLE admitted in 2009, 428 (6.7%) had CKD (Fig. S1). In the univariate analysis, we found that CKD status in SLE was associated with male gender (OR 1.7 [1.3–2.1] p = 0.0002), lupus nephritis (6.1 [4.8–7.6], p < 0.0001), high blood pressure (OR 3.4 [2.7–4.2], p < 0.0001), septic shock (OR 4.1 [2.3–7.3]) and cardiovascular past history (OR 3.4 [2.7–4.2]). In the multivariate analysis, all these

Table 1
ESRD onset associated with CKD status in SLE patients.

	SLE patients at first stay n = 6439	Univariate sdHR [CI 95]	p	Multivariate sdHR [CI 95]	p
> 50 y.o (%)	2418 (37.6)	0.6 [0.4–0.7]	< 0.0001	0.5 [0.3–0.6]	< 0.0001
Male gender. n (%)	872 (13.5)	1.2 [0.9–1.7]	0.2	1.2 [0.8–0.1.7]	0.44
Chronic Kidney Disease. n (%)	428 (6.7)	21.5 [16.7–27.6]	< 0.0001	15.9 [11.6–21.9]	< 0.0001
Associated SLE manifestations. n (%)					
Lupus nephritis	570 (8.9)	6.2 [4.8–8.0]	< 0.0001	2.1 [1.5–3.0]	< 0.0001
Serositis	185 (2.9)	1.3 [0.7–2.6]	0.4	–	–
Cytopenia	123 (1.9)	0.6 [0.2–2.0]	0.4	–	–
CNS disease	29 (0.5)	1.0 [0.1–7.1]	1.0	–	–
Associated SLE conditions. n (%)					
High blood pressure	771 (12.0)	2.6 [2.0–3.4]	< 0.0001	1.7 [1.3–2.4]	0.0009
Diabetes mellitus	256 (4.0)	0.9 [0.4–1.7]	0.6	–	–
Septic shock	68 (1.1)	0.4 [0.1–2.5]	0.3	0.1 [0.01–1.0]	0.05
Cardiovascular past history	440 (6.8)	1.7 [1.2–2.5]	0.007	1.7 [1.1–2.5]	0.02
Cancer	207 (3.2)	0.6 [0.2–1.4]	0.2	0.6 [0.2–1.6]	0.3

CI, confidence interval; CKD, chronic kidney disease; CNS, central nervous system; ESRD, end stage renal disease; sdHR, sub-distributionnal hazard ratios; SLE, systemic lupus erythematosus.
Univariate and multivariate hazard ratios (HR) of ESRD occurrence during follow up according to baseline status calculated by using Cox proportional hazard model.

parameters remained significantly associated with CKD except for male gender (Table S1). From 2009 to 2015, 10.1% of the 6011 patients who had no CKD at baseline eventually developed CKD (Fig. S4) and 33.15% of the 428 patients who had CKD at baseline eventually developed ESRD.

3.3. Major outcome in SLE patients with CKD

Among the 6439 SLE patients identified at baseline in 2009, 250 (4.0%), 927 (14.4%) and 411 (6.3%) experienced ESRD, cardiovascular event (CVE) and septic shock during the overall 2009–2015 period, respectively. Furthermore, 9.6% (n = 618) of SLE patients admitted in 2009 were dead in 2015. Interestingly, univariate and multivariate hazard ratios determined by using Cox proportional hazard model for death and subdistribution hazard models for the other outcomes demonstrated that the presence of CKD at baseline was strongly and independently associated with the occurrence of ESRD (sdHR 15.9 [11.6–21.9], $p < 0.0001$), but also CVE (sdHR 1.7 [1.4–2.2], $p < 0.0001$), septic shock (sdHR 2.1 [1.5–2.8], $p < 0.0017$) and death (HR 1.7 [1.3–2.2], $p < 0.0001$) during follow up (Tables 1, 2, 3 and 4). Of note, the association between CKD and each of these 4 major outcomes remained statistically significant after adjustment on factors (i.e. lupus nephritis, high blood pressure, septic shock and cardiovascular past history) shown to be associated with CKD status at baseline. Kaplan- Meïer survival analyses for each of these 4 major outcomes according to the CKD status at first stay are shown Fig. 1.

4. Discussion

The health care system in France offers a large-scale opportunity to study long-term outcome in SLE among an entire population across multiple study centers. Our analysis of the French medical administrative database showed that CKD is strongly associated with a worsened morbidity and mortality in SLE.

We analyzed all SLE patients admitted into French hospitals over a 7-year period. SLE patients with CKD were approximately 17 times more likely to require chronic dialysis and/or renal transplantation, as compared with those without CKD. Moreover, SLE patients with CKD were approximately twice more likely to suffer CVE, septic shock or death.

Renal failure stands as a major predictor of mortality and morbidity in patients with SLE [10–13]. Previous studies highlighted that decreased eGFR level at baseline and no early renal response to therapy are both associated with poor prognosis in severe nephritis [5,6,14]. Other features - such as ethnicity, urine protein output and pathologic findings on kidney biopsy at baseline - known to be predictive of the renal outcome [5–7,15,16] were unfortunately not available in our nationwide database.

Progression to ESRD within the 15 years after diagnosis is expected in 10 to 30% of SLE nephritis adult patients [17,18]. The increased mortality observed in ESRD patients underlines the need for early diagnosis and optimized treatment of lupus nephritis [19].

Table 2
CVE onset associated with CKD status in SLE patients.

	SL patients at first stay n = 6439	Univariate sdHR [CI 95]	p	Multivariate sdHR [CI 95]	p
> 50 y.o (%)	2418 (37.6)	2.3 [2.0–2.6]	< 0.0001	1.8 [1.5–2.0]	< 0.0001
Male gender. n (%)	872 (13.5)	1.8 [1.5–2.1]	< 0.0001	1.3 [1.1–1.6]	< 0.0013
Chronic Kidney Disease. n (%)	428 (6.7)	1.9 [1.5–2.3]	< 0.0001	1.7 [1.4–2.2]	< 0.0001
Associated SLE manifestations. n (%)					
Lupus nephritis	570 (8.9)	0.7 [0.6–0.9]	0.01	0.7 [0.5–0.9]	0.007
Serositis	185 (2.9)	1.1 [0.7–1.6]	0.7	–	–
Cytopenia	123 (1.9)	0.9 [0.5–1.4]	0.5	–	–
CNS disease	29 (0.5)	3.1 [1.7–5.6]	0.0003	–	–
Associated SLE conditions. n (%)					
High blood pressure	771 (12.0)	2.2 [1.9–2.6]	< 0.0001	1.4 [1.2–1.7]	< 0.0001
Diabetes mellitus	256 (4.0)	2.4 [1.9–3.0]	< 0.0001	–	–
Septic shock	68 (1.1)	1.3 [0.7–2.3]	0.4	0.7 [0.3–1.4]	1.0
Cardiovascular past history	440 (6.8)	5.0 [4.2–5.9]	< 0.0001	3.7 [3.1–4.4]	< 0.0001
Cancer	207 (3.2)	1.1 [0.8–1.5]	0.6	0.7 [0.5–1.1]	0.12

CI, confidence interval; CKD, chronic kidney disease; CNS, central nervous system; CVE, cardiovascular event; sdHR, sub-distributionnal hazard ratios; SLE, systemic lupus erythematosus.

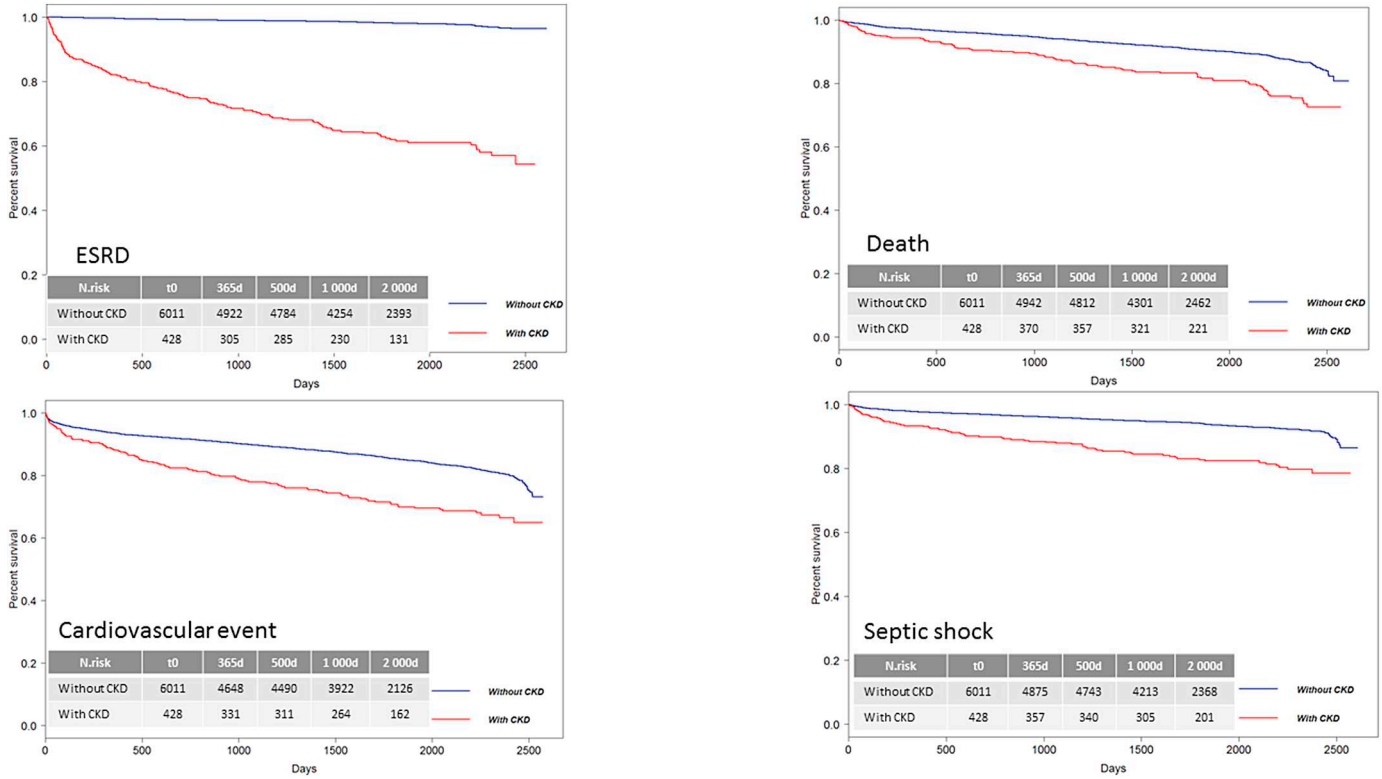

Fig. 1. Survival without major outcomes in SLE population according to CKD status at first stay.
Kaplan-Meier curves represent the survival without each of the 4 major outcomes (end-stage renal disease –ESRD, cardiovascular event, septic shock and death) considered according to the CKD status at first stay. Time 0 is the first day of the first SLE stay in 2009. Follow up ended up at December 31st, 2015. Blue lines represent the outcome in patients without CKD at first stay. Red lines represent the outcomes in patients with CKD at first stay.

Cardiovascular events due to accelerated atherosclerosis are the leading cause of death in SLE [20]. Probably because they do not incorporate important risk factors such chronic kidney disease, models for predicting CVD established in the general population (such as Framingham model) underestimate the cardiovascular risk in SLE [21]. The subclinical atherosclerosis associated with SLE affects mostly patients with lupus nephritis [22]. Our study highlights the strong association of CKD and CVE in SLE and supports a drastic primary prevention of CVD in SLE patients with CKD.

Severe infection is of major concern in SLE patients, with both short- and long-term morbidity and mortality [23]. In our series, CKD status in SLE increased the risk for septic shock by 2. Such finding is consistent with a previous study showing that SLE patients with LN were at increased risk for pneumococcal infection [24]. Of note, around 10% of septic shock in SLE were caused by vaccine-preventable pathogens [23]. Hence, our study also points to the need for an optimal vaccination coverage in SLE with CKD.

Our study has some limitations. Because it is a hospital database, we had no access to the out- of-the-hospital healthcare use and mortality. Our analysis might therefore have misestimated the true prevalence of SLE and mortality rates. However, the selected population had SLE characteristics (i.e., prevalence, sex ratio, age) consistent with previously published large SLE epidemiologic studies in France [1]. PMSI is based on coding diagnosis and procedures that might not be always sufficiently accurate. Importantly, as highlighted by others, the sensitivity, specificity and accuracy of ICD-10 codes from French

Table 3
Septic Shock onset associated with CKD status in SLE patients.

	SLE patients at first stay n = 6439	Univariate sdHR [CI 95]	p	Multivariate sdHR [CI 95]	p
> 50 y.o (%)	2418 (37.6)	2.0 [1.6–2.4]	< 0.0001	1.8 [1.4–2.2]	< 0.0001
Male gender. n (%)	872 (13.5)	2.1 [1.7–2.6]	< 0.0001	1.7 [1.3–2.1]	< 0.0001
Chronic Kidney Disease. n (%)	428 (6.7)	2.7 [2.1–3.5]	< 0.0001	2.1 [1.5–2.8]	0.0017
Associated SLE manifestations. n (%)					
Lupus nephritis	570 (8.9)	1.8 [1.4–2.4]	< 0.0001	1.7 [1.2–2.3]	0.0017
Serositis	185 (2.9)	2.1 [1.3–3.2]	0.0014	–	–
Cytopenia	123 (1.9)	1.0 [0.5–2.1]	0.9	–	–
CNS disease	29 (0.5)	4.0 [1.8–9]	0.0007	–	–
Associated SLE conditions. n (%)					
High blood pressure	771 (12.0)	1.8 [1.5–2.3]	< 0.0001	1.3 [1.0–1.7]	0.048
Diabetes mellitus	256 (4.0)	1.5 [1.0–2.2]	0.07	–	–
Septic shock	68 (1.1)	–	–	–	–
Cardiovascular past history	440 (6.8)	2.3 [1.8–3.1]	< 0.0001	1.7 [1.3–2.2]	0.0004
Cancer	207 (3.2)	1.7 [1.1–2.6]	0.02	1.3 [0.8–2.0]	0.32

CI, confidence interval; CKD, chronic kidney disease; CNS, central nervous system; sdHR, sub-distributionnal hazard ratios; SLE, systemic lupus erythematosus.

Table 4
Death onset associated with CKD status in SLE patients.

	SLE patients at first stay n = 6439	Univariate HR [CI 95]	p	Multivariate HR [CI 95]	p
> 50 y.o (%)	2418 (37.6)	4.9 [4.0–5.8]	< 0.0001	3.9 [3.2–4.7]	< 0.0001
Male gender. n (%)	872 (13.5)	2.4 [2.0–2.9]	< 0.0001	1.6 [1.3–1.9]	< 0.0001
Chronic Kidney Disease. n (%)	428 (6.7)	2.0 [1.6–2.5]	< 0.0001	1.7 [1.3–2.2]	< 0.0001
Associated SLE manifestations. n (%)					
Lupus nephritis	570 (8.9)	0.9 [0.7–1.2]	0.7	1.1 [0.8–1.4]	0.6
Serositis	185 (2.9)	2.1 [1.5–3.0]	< 0.0001	–	–
Cytopenia	123 (1.9)	1.6 [1.0–2.5]	0.07	–	–
CNS disease	29 (0.5)	1.7 [0.6–4.5]	0.3	–	–
Associated SLE conditions. n (%)					
High blood pressure	771 (12.0)	2.3 [1.9–2.7]	< 0.0001	1.3 [1.1–1.6]	0.007
Diabetes mellitus	256 (4.0)	2.3 [1.7–3.2]	< 0.0001	–	–
Septic shock	68 (1.1)	5.3 [3.5–8.0]	< 0.0001	3.1 [2.1–4.7]	< 0.0001
Cardiovascular past history	440 (6.8)	2.8 [2.3–3.5]	< 0.0001	1.6 [1.3–2.0]	< 0.0001
Cancer	207 (3.2)	5.4 [4.3–6.8]	< 0.0001	3.5 [2.7–4.4]	< 0.0001

CI, confidence interval; CKD, chronic kidney disease; CNS, central nervous system; HR, hazard ratios; SLE, systemic lupus erythematosus.

administrative data used for SLE case definition remain unknown [1]. On the other hand, because of the French Health Insurance System, PMSI gather exhaustive data from French hospitals, meaning that our data include all patients with at least one diagnosis of SLE hospitalized in France over a protracted period of seven years.

5. Conclusion

In SLE, CKD is strongly associated with septic shock, cardiovascular events and death. Our results illustrate the critical importance of early detection (i.e. before the onset of renal function impairment) and treatment of lupus nephritis.

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Appendix A. Supplementary data

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