Transplant International

ORIGINAL ARTICLE

What is the significance of end-stage renal disease risk estimation in living kidney donors?

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SUMMARY

Two end-stage renal disease (ESRD) risk calculators were recently developed by Grams *et al.*, and Ibrahim *et al.* to calculate ESRD risk before donation among living kidney donors. However, those calculators have never been studied among potential donors for whom donation was refused due to medical contraindications and compared to a group of donors. We compared 15-year and lifetime ESRD risk of donors and non-donors due to medical cause as estimated by those two calculators. Non-donors due to medical cause ($n = 27$) had a significantly higher 15-year ESRD risk compared to donors ($n = 288$) with both calculators (0.25 vs. 0.14, $P < 0.001$ for that developed by Grams *et al.* and 2.21 vs. 1.43, $P = 0.002$ for that developed by Ibrahim *et al.*). On the contrary, lifetime ESRD risk was not significantly different between the two groups. At both times (15 years and lifetime), we observed a significant overlap of ESRD risk between the two groups. ESRD risk calculators could be complementary to standard screening strategy but cannot be used alone to accept or decline donation.

Transplant International 2017; 30: 799–806

Key words
end-stage renal disease risk, living donors, monocentric, online calculators, renal transplantation, retrospective

Received: 3 October 2016; Revision requested: 18 November 2016; Accepted: 27 January 2017; Published online: 5 March 2017

Introduction

Kidney donation is associated with an increased risk of end-stage renal disease (ESRD) [1–6]. To maximize the safety of the procedure, living donors undergo a medical evaluation. Screening processes vary widely from one center to another, and each parameter is considered independently from the others [7–12]. The application

doi:10.1111/tri.12931

of the guidelines also varies from one center to another [13].

Recently, the Kidney Disease Improving Global Outcome (KDIGO) Group undertook the redaction of recommendations on living donor screening. These recommendations are still undergoing public review but suggest to use multiparameter ESRD risk calculators (http://kdigo.org/home/guidelines/livingdonor/). Two calculators were recently developed based on analyses of the general population [4] and a cohort of donors [14]. The first calculator provides an estimation of ESRD risk among a low-risk population (as is typical of potential living donors) at 15 years and over a lifetime in the absence of donation. The second calculator provides an estimation of outcome parameters such as proteinuria, and a composite criteria consisting of estimated glomerular filtration rate (GFR) less than 30 ml/min/1.73 m^2, or ESRD, based on analysis of a cohort of living donors with a follow-up as long as 40 years [14]. However, none of those calculators was studied in a group of potential donors for whom donation was contraindicated due to medical cause, based on current criteria. Therefore, it is not known whether the estimated ESRD risk is significantly higher when donation is contraindicated according to our current criteria.

To define the role of estimated ESRD risk calculators in living kidney donor screening, we compared estimated ESRD risk calculated using methods described by Grams *et al.* [4] and Ibrahim *et al.* [14] in subjects who had donated kidneys and those who did not due to medical contraindications.

Materials and methods

Patients

We conducted a monocentric, retrospective study on all the potential living kidney donors who underwent a complete predonation screening in our center between January 2008 and March 2016. Institutional Review Board approval was obtained (number: REF2013-11-10). High estimated ESRD risk potential donors were excluded from the analysis because ESRD risk calculators were not designed for this population. As defined by Grams *et al.* [4], high estimated ESRD risk potential donors presented at least with one or more of the following characteristics: an estimated glomerular filtration rate (eGFR) <45 ml/min/1.73 m^2; insulin-dependent diabetes mellitus; the use of four or more antihypertensive medications; a blood pressure ≥160/90 mm Hg on medication or ≥170/100 mm Hg off medication; an ACR ≥300 (in mg of albumin to g of creatinine); or a history of coronary heart disease, stroke, congestive heart failure, or peripheral arterial disease. The study was conducted in accordance with the *Declaration of Helsinki*. Research activities were also consistent with the Principles of the Declaration of Istanbul as outlined in the *Declaration of Istanbul on Organ Trafficking and Transplant Tourism*.

Donor screening

Plasma creatinine concentrations were measured with an enzymatic method (Thermo Fisher Scientific, Waltham, Massachussets, USA) on Konelab 20i automat (Thermo Fisher Scientific). GFR was measured through a continuous ^{51}Cr-ethylene-diamine tetra acetic acid (^{51}Cr-EDTA; GE Healthcare, Little Chalfont, UK) infusion method. Estimated GFR (eGFR) was determined with the CKD-EPI formula [15]; 24-hour ambulatory blood pressure monitoring, mean nycthemeral systolic pressure was used for the estimated ESRD risk calculation.

Risk calculation

The calculator developed by Grams *et al.* [4] referred to as "calculator 1" provides an estimated ESRD risk in the absence of donation at 15 years and at lifetime and is available at http://www.transplantmodels.com/esrdrisk/. It requires the following data: age, gender, race, eGFR calculated with CKD-EPI formula, systolic blood pressure, presence or absence of hypertension medication, body mass index (BMI), presence or absence of non-insulin-dependent diabetes mellitus, ACR, smoking history.

The calculator described by Ibrahim *et al.* [14], referred to as "calculator 2," consists of a dynamic table. This calculator provides at 5, 10, 15, 20, 25, 30, 35, and 40 years after donation several probabilities: eGFR <60 or 45 ml/min/1.73 m^2, proteinuria, and a composite outcome including eGFR <30 ml/min/1.73 m^2 or ESRD. The variables used by the calculator are different for each probability calculation. For both calculators, ESRD was defined as the need for long-term dialysis or renal transplant as previously reported [4,14].

Statistical analysis

For both calculators, we focused our analysis on estimated ESRD risk probability. Data processing was carried out using EXCEL (2011, Microsoft), and statistical analyses were performed using PRISM GRAPHPAD (version

6). Potential donors were divided into two groups. The first group, referred to as "donors," consisted of those who gave a kidney. The second group, called "nondonors," consisted of potential donors who presented with a medical contraindication to donation (e.g., low measured GFR, hypertension, proteinuria, or non-insulin-dependent diabetes). Descriptive statistics are presented as medians and interquartile ranges. The nonparametric Mann–Whitney test was used to compare estimated ESRD risk between the two groups. Statistical significance was achieved when the *P*-value was lower than 0.05. For the first calculator, the ACR was input as 4 mg/g when total proteinuria was reported as negative (there was no missing data for total proteinuria).

Results

Characteristics of the population

The 15-year and lifetime estimated ESRD risk were calculated on 315 potential living kidney donors. Characteristics of these subjects separated into donors and nondonors are presented in Table 1 along with all the parameters used for the estimated ESRD risk calculation. Compared to donors, nondonors had lower eGFR (96 vs. 87 ml/min/1.73 m^2, $P = 0.007$) and mGFR (93 vs. 73 ml/min/1.73 m^2, $P < 0.0001$). Nondonors tended to be older than donors (59 vs. 49 years, $P = 0.0004$), were more likely to be black (18% vs. 10%), had a higher systolic blood pressure (128 vs. 122 mm Hg, $P = 0.008$), and were more likely to be taking antihypertensive medication (22% vs. 8%). Causes of exclusion from donation of nondonors are summarized in Table 2. The major contraindication to donation was low mGFR (67%). Noteworthy, all of them were defined as "low-risk group" according to Grams *et al.*

Calculator 1—predonation ESRD risk among donors and nondonors

Nondonors had a significantly higher estimated ESRD risk at 15 years compared to donors (0.25 vs. 0.14, $P = 0.0002$) and a comparable estimated lifetime ESRD risk (0.72 vs. 0.65, $P = 0.98$) as summarized in Table 3. There was a significant overlap of 15-year and lifetime estimated ESRD risk between donors and nondonors (Fig. 1). When mGFR was used instead of eGFR, we also obtained a significantly higher 15-year estimated ESRD risk among nondonors compared to donors (0.32

Table 1. Characteristics of potential donors.

	All	Donors	Non donors
n	315	288	27
Age years (IQR)	51 (41–59)	49 (41–58)	59 (52–62)
Female (%)	213 (63)	179 (62)	17 (61)
Black (%)	36 (11)	29 (10)	5 (18)
eGFR ml/min/1.73 m^2 (IQR)	95 (86–105)	96 (97–105)	87 (75–97)
<80 (%)	42 (12)	33 (11)	9 (33)
mGFR ml/min/1.73 m	93 (84–105)	93 (85–105)	73 (69–92)
<80 (%)	50 (15)	32 (11)	17 (63)
Systolic blood pressure mm Hg (IQR)	122 (113–130)	122 (113–130)	128 (116–148)
>140 (%)	30 (9)	21 (7)	8 (30)
Diastolic blood pressure mm Hg (IQR)	76 (72–82)	76 (71–82)	79 (72–87)
>90 (%)	29 (9)	25 (9)	4 (15)
Hypertension medication (%)	30 (9)	24 (8)	5 (22)
BMI kg/m^2 (IQR)	25 (22–28)	25 (22–28)	25 (23–29)
<24.9 (%)	160 (47)	139 (48)	11 (41)
25–29.9 (%)	137 (41)	115 (40)	10 (37)
>30 (%)	41 (12)	34 (12)	6 (22)
Non insulin dependant diabetes (%)	2 (0)	0 (0)	2 (0.3)
Alb/Creat ratio mg/g (IQR)	7 (4–11)	8 (5–11)	5 (3–10)
Smoking history (%)	108 (32)	93 (32)	10 (36)

mGFR, measured GFR; IQR, interquartile range.

Nondonors presented a medical contraindication to donation. Data are presented as medians and interquartile ranges. ACR is the urinary albumin/creatinine ratio expressed in mg of albumin per g of creatinine.

Table 2. Causes of exclusion from donation among nondonors.

	Condition	*n* = 27 (100%)
Non insulin dependant diabetes	Presence of diabetes (insulin dependant or not)	2 (7%)
Hypertension	Systolic blood pressure >160 mm Hg OR Diastolic blood pressure >100 mm Hg; without medication	4 (15%)
Proteinuria	Urinary albumin to creatinine ratio >30 mg/g	5 (19%)
Low GFR	Measured GFR <70 ml/min/1.73 m^2	18 (67%)
Obesity	BMI >35 kg/m^2	1 (4%)

Total number of medical contraindications exceeds 27 because some nondonors presented more than 1 contraindication to donation. Condition column shows our center condition to accept or decline donation.

vs. 0.14, $P < 0.001$). Estimated lifetime risk was not different between donors and nondonors (0.57 vs. 0.88) (Table 3).

Among donors, estimated 15-year ESRD risk was not different when mGFR was used instead of eGFR (0.14 vs. 0.14, $P = 0.83$) nor was estimated lifetime ESRD risk (0.59 vs. 0.57, $P = 0.46$). However among nondonors, estimated 15-year ESRD risk was higher when mGFR was used instead of eGFR (0.32 vs. 0.25, $P = 0.003$) or for estimated lifetime risk (0.88 vs. 0.72, $P = 0.002$), Table 3.

Table 3. The 15-year and lifetime probabilities of ESRD based on eGFR or mGFR in donors and nondonors.

	Donors	Non donors	*P*
n	288	27	
eGFR based			
15-year ESRD risk %			
Mean (CI95)	0.14 (0.13–0.16)	0.25 (0.16–0.35)	<0.001
Min–max	0.01–0.86	0.07–1.14	
Lifetime ESRD risk %			
Mean (CI95)	0.59 (0.52–0.66)	0.72 (0.38–1.06)	0.97
Min–max	0.03–3.72	0.09–4.13	
n	286	22	
mGFR based			
15-year ESRD risk %			
Mean (CI95)	0.14 (0.12–0.15)	0.32 (0.20–0.44)	<0.001
Min–max	0.01–0.78	0.08–1.14	
Lifetime ESRD risk %			
Mean (CI95)	0.57 (0.51–0.64)	0.88 (0.47–1.30)	0.24
Min–max	0.03–3.72	0.18–4.15	
Mann Whitney paired test between eGFR and mGFR based risk calculation			
15-year ESRD risk	0.83	0.003	
Lifetime ESRD risk	0.46	0.002	

ESRD, end-stage renal disease.

Data are presented as means and CI_{95}.

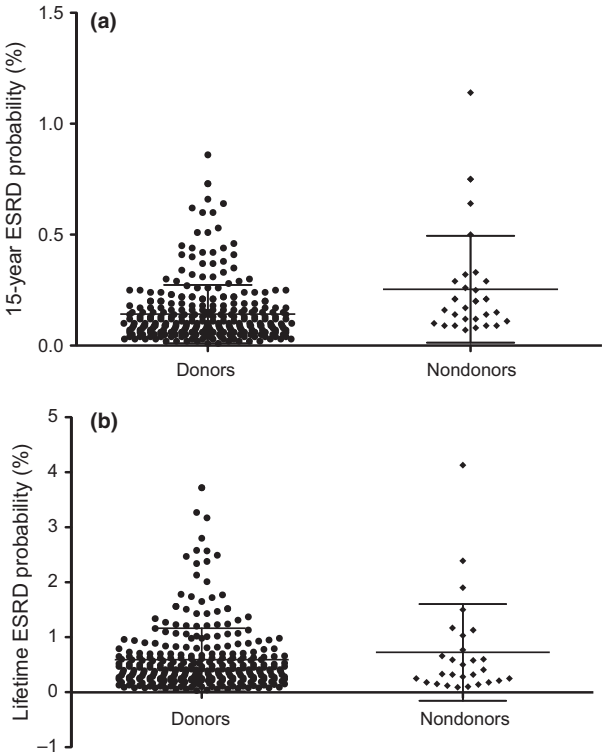

Figure 1 Plots of (a) 15-year ESRD risk and (b) lifetime ESRD risk among donors and nondonors due to medical cause. Data are presented as means and 95% confidence intervals (CI_{95}). ESRD, end-stage renal disease.

Calculator 2—ESRD risk among donors and nondonors

At all time points after donation (except for 40 years), nondonors due to medical cause had a significantly higher estimated ESRD risk compared to donors (Table 4). Fifteen years after donation, estimated ESRD risk was 2.21 among nondonors compared to 1.43 among donors ($P = 0.002$). Estimated ESRD risk 40 years after donation was not significantly different

between nondonors and donors (26.4 vs. 22.6, $P = 0.32$). As shown on Fig. 2, there was a significant overlap of estimated ESRD risk probability between the two groups at 15 years and 40 years after donation, meaning that no clear cutoff of estimated ESRD risk was identified.

Discussion

Even though estimated ESRD risk is increased among donors compared to healthy nondonors, this risk remains very low and significantly lower than general population ESRD risk. Clinicians caring for potential kidney donors can explain that point to potential living kidney donors by stating that they have been carefully screened and selected to have the lowest ESRD risk as possible. However, in accordance with the "primum non nocere" principle, a new screening strategy was proposed by Grams *et al.* and Ibrahim *et al.* This strategy is based on calculating predonation or postdonation estimated ESRD risk. However, the place of ESRD risk calculators remains to be established in living kidney donors. Grams *et al.* [4], Ibrahim *et al.* [14], but also the new KDIGO guidelines currently suggest using a multiparameter-based calculation to estimate ESRD risk prior to donation. This calculation could be used to help clinicians better evaluate "cumulative" (e.g., addition of high blood pressure, mild proteinuria, age, smoking ....) ESRD risk and to better inform potential donors. The major finding of our study is that even though the 15-year estimated ESRD risk was statistically different between donors and nondonors, it did not differ for longest follow-up times and neither calculator identified a clear estimated ESRD risk cutoff between the two groups.

First of all, the two calculators do not provide the same 15-year and lifetime risks. The main difference between the two calculators is the population in which they were developed. Calculator 1 was developed by analysis of general population and therefore does not take into account the donation-associated risk. Calculator 2 was developed in a cohort of white kidney donors and therefore takes into account the donation-associated ESRD risk.

Table 4. Probability of the composite outcome eGFR lower than 30 ml/min/1.73 m^2 or ESRD among donors and nondonors due to medical cause calculated using calculator 2.

	Donors	Non donors	*P*
n	288	27	
5 year			
Mean (CI95)	0.49 (0.43–0.57)	0.70 (0.47–0.93)	0.03
Min–max	0–1.90	0–1.90	
10 year			
Mean (CI95)	0.99 (0.87–1.12)	1.73 (1.37–2.08)	0.002
Min–max	0–2.60	0–2.60	
15 year			
Mean (CI95)	1.43 (1.29–1.57)	2.21 (1.77–2.64)	0.002
Min–Max	0–3.9	0–5.5	
20 year			
Mean (CI95)	3.11 (2.81–3.41)	4.43 (3.57–5.28)	0.005
Min–Max	0–8.70	0.70–8.70	
25 year			
Mean (CI95)	5.74 (5.28–6.19)	8.33 (6.22–10.44)	0.02
Min–Max	0–12.70	0.70–30.30	
30 year			
Mean (CI95)	11.11 (10.2–12.0)	16.60 (13.9–19.3)	0.0006
Min–Max	0–18.80	0.70–30.30	
35 year			
Mean (CI95)	16.8 (15.7–17.9)	20.9 (17.9–23.9)	0.02
Min–Max	0–37.0	3.60–37.0	
40 year*			
Mean (CI95)	22.6 (21.1–24.0)	26.4 (19.7–33.0)	0.32
Min–Max	0–38.9	3.60–38.9	

*The number of donors was 225; the number of nondonors was 17.

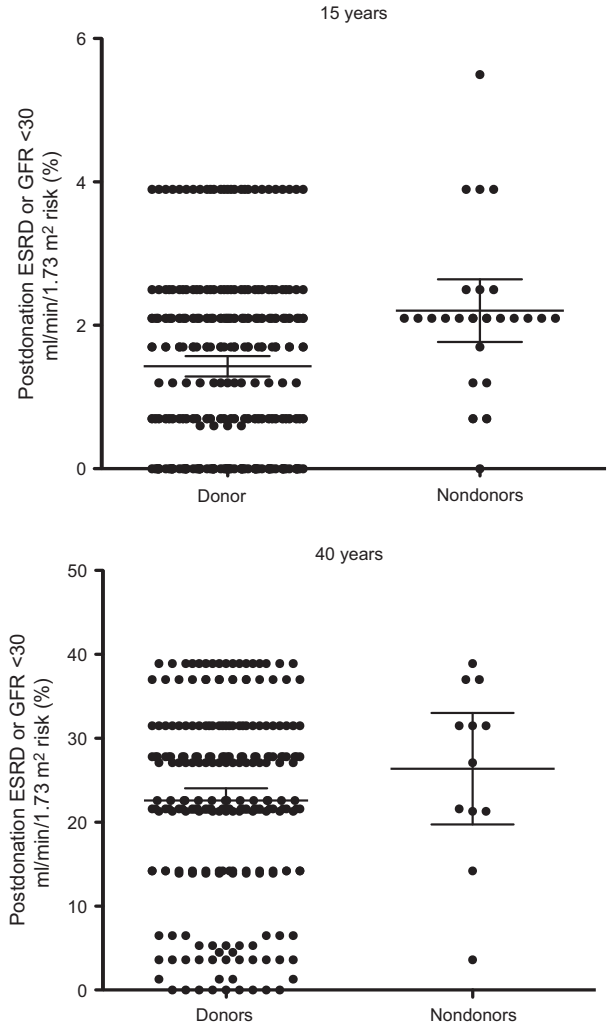

Figure 2 Plots of the composite outcome "ESRD or GFR lower than 30 ml/min/1.73 m^2" risk among donors and nondonors due to medical cause with calculator 2. Data are presented as means and 95% confidence intervals (CI_{95}). ESRD, end-stage renal disease; GFR, glomerular filtration rate.

Contrarily to 15-year estimated ESRD risk, lifetime estimated risk did not differ between donors and nondonors. This could be due to the fact that donors were significantly younger than nondonors leading to a longer exposure time to the ESRD risk. Lifetime risk estimation was suggested to be less precise than the 15-year ESRD risk estimation as it was based on cohorts with short follow-up time [4], but has a stronger clinical relevance than 15-year evaluation term. In fact, in our cohort, median age of donors was 49 years. With a life expectancy of 82 years in France in 2014, it means that donors have nearly 33 years to live after donation. This highlights the need for long-term evaluation of renal function.

With calculator 1, all our donors had an estimated 15-year ESRD risk lower than 1%, which is lower than what was reported in the Organ Procurement and Transplantation Network (OPTN) registry [4]. Both calculators were developed in the USA where ESRD incidence rate is twice higher to the one observed in France (370 vs. 163 new cases per year per million inhabitants) [16,17]. Therefore, the real ESRD risk in our population may be lower than the one obtained with the calculators. However, our goal was to compare estimated ESRD risk prediction between donors and nondonors. We assumed that estimated ESRD risk overestimation in our population would be the same in the two subgroups of our study.

Current screening strategy evaluates separately clinical, morphological, and biological parameters, and contraindicates donation if a single parameter, such as GFR or hypertension, is out of the recommendation range [7–12]. To compare those two strategies, we included nondonors at low risk of ESRD. In fact, those nondonors reflect potential donors who could benefit most from ESRD risk evaluation. We found a significantly higher 15-year estimated ESRD risk in this group than in the group of donors. Estimated lifetime risk was not different. This observation leads to two conclusions: Either the parameters we used to contraindicate donation were not relevant and the donation could have been authorized safely using only the ESRD risk estimation or the single clinical parameters are relevant and the ESRD risk estimation cannot be used alone for the living donor screening.

Regarding ESRD risk only, nondonors mainly consisted of potential donors with low mGFR. It was previously shown that kidney donation increased ESRD risk between threefold and eightfold compared to healthy matched nondonors in the United States [2]. In Norway, the donation-associated ESRD risk was 11-fold higher than that of healthy nondonors [1]. Donation-associated ESRD risk may not be similar for all the donors, and evidence suggests that this risk depends on ethnicity and age [2]. Data regarding prediction of ESRD by baseline eGFR are contradictory. Whereas an eGFR at donation lower than 90 ml/min/1.73 m^2 was found to be significantly associated with ESRD by Grams *et al.* [4], it was not by Ibrahim *et al.* [14]. The latter found that baseline eGFR was associated with the probability of an eGFR lower than 60 or 45 ml/min/1.73 m^2 but, surprisingly, not with the probability of developing ESRD. The lack of data regarding donation-associated risk stratified according to predonation mGFR may explain the significant overlap of ESRD risk between nondonors due to medical cause and donors. Beyond the donor ESRD risk,

low GFR can also be a contraindication due to concerns regarding the quality of the kidney. This concern could be responsible for some of the contraindications to donation, especially for older potential donors.

Our study has its own limits. Due to the relatively short follow-up time (8 years) and the relatively low number of included donors and nondonors, we could not measure ESRD rates in our cohort because none of the included potential donors or real donors has developed ESRD. Therefore, we could not compare the estimated ESRD risk with an observed ESRD rate. However, our study also has several strengths: We compared the estimated ESRD risk obtained with eGFR or mGFR for the calculator 1 developed by Grams *et al.* [4] even though this calculator was not developed for mGFR use (the calculator developed by Ibrahim *et al.* [14] does not require baseline GFR to calculate ESRD risk). This comparison addressed the recent concerns raised by Spital *et al.* [18] regarding the limitation of eGFR to predict the risk of ESRD after kidney donation with this calculator: We showed that use of estimated or measured GFR did not change our results regarding calculator 1. However, among nondonors, use of mGFR instead of eGFR gave significantly higher 15-year and lifetime ESRD risks. This was due to the fact that nondonors had a measured GFR significantly lower than estimated GFR, which was not the case for donors. This observation is in accordance with what was reported regarding the relationship between eGFR and mGFR among potential donors [19]. Moreover, we recently published two studies showing that mGFR (and not eGFR) divided by the volume of the remaining kidney could be used to predict functional gain of the remaining kidney following donation [20] and that measured GFR could not be predicted precisely by calculators or equations for nearly 60% of donors [19]. For these reasons, we think that eGFR cannot replace mGFR in living donor screening. Despite the relatively low number of potential donors who had at least one medical contraindication to donation ($n = 27$) included in our study, this is, to our best knowledge, the first time that such potential donors are taken into account in a predonation screening study.

In conclusion, both calculators found a significantly different 15-year estimated ESRD risk between donors and nondonors but no clear cutoff between these two groups. Consequently, at the individual level, the clinical, biological, and radiological screening, systematically performed prior to a potential kidney donation, cannot be replaced by ESRD risk calculators developed in broad populations. Grams *et al.* [18] in a recent letter to the editor of the New England Journal of Medicine suggested that multiparameter calculator-based strategies could be complementary to current single parameter-based screening. Our results are in accordance with such conclusions.

Authorship

FG: designed study, performed study, analyzed data and wrote the paper. MC: designed study and wrote the paper. CL: designed study, collected data and wrote the paper. SB: wrote the paper. CF: collected data and designed study. AM, CPB, DE, GF, JPB, LL and MOT: collected data.

Funding

The authors have declared no funding.

Conflict of interest

The authors have declared no conflicts of interest.

Acknowledgements

François Gaillard thanks Ecole de l'INSERM-Liliane Bettencourt.

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