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Original Article



ORIGINAL ARTICLE

# External validation of the 2-year mortality prediction tool in hemodialysis patients developed using a Bayesian network

Maelys Granal[1], Sophie Brokhes-Le Calvez[2], Yves Dimitrov[2,3], François Chantrel[2,4], Claire Borni-Duval[2], Clotilde Muller[2,5], May Délia[2], Thierry Krummel[6], Thierry Hannedouche[2], Micher Ducher[1] and Jean-Pierre Fauvel[1]

[1]Department of Nephrology, Hospices Civils de Lyon, Hôpital Edouard Herriot, UMR 5558 CNRS Lyon, Université Lyon 1, Lyon, France, [2]Renal Research Division, AURAL Strasbourg, Strasbourg, France, [3]Department of Nephrology, CH Haguenau, Haguenau, France, [4]Department of Nephrology Groupe Hospitalier de la Région Mulhouse et Sud Alsace, Hôpital Emile Muller, Strasbourg, France, [5]Department of Nephrology Groupe Hospitalier Saint-Vincent, Clinique Ste-Anne, Service de Néphrologie, Strasbourg, France and [6]Hôpitaux Universitaires de Strasbourg, Nouvel Hôpital Civil, Service de Néphrologie et Hémodialyse, Strasbourg, France

Correspondence to: Jean-Pierre Fauvel; E-mail: jean-pierre.fauvel@chu-lyon.fr

## ABSTRACT

**Background.** In recent years, a number of predictive models have appeared to predict the risk of medium-term mortality in hemodialysis patients, but only one, limited to patients aged over 70 years, has undergone sufficiently powerful external validation. Recently, using a national learning database and an innovative approach based on Bayesian networks and 14 carefully selected predictors, we have developed a clinical prediction tool to predict all-cause mortality at 2 years in all incident hemodialysis patients. In order to generalize the results of this tool and propose its use in routine clinical practice, we carried out an external validation using an independent external validation database.
**Methods.** A regional, multicenter, observational, retrospective cohort study was conducted to externally validate the tool for predicting 2-year all-cause mortality in incident and prevalent hemodialysis patients. This study recruited a total of 142 incident and 697 prevalent adult hemodialysis patients followed up in one of the eight Association pour l'Utilisation du Rein Artificiel dans la région Lyonnaise (AURAL) Alsace dialysis centers.
**Results.** In incident patients, the 2-year all-cause mortality prediction tool had an area under the receiver curve (AUC-ROC) of 0.73, an accuracy of 65%, a sensitivity of 71% and a specificity of 63%. In prevalent patients, the performance for the external validation were similar in terms of AUC-ROC, accuracy and specificity, but was lower in term of sensitivity.
**Conclusion.** The tool for predicting all-cause mortality at 2 years, developed using a Bayesian network and 14 routinely available explanatory variables, obtained satisfactory external validation in incident patients, but sensitivity was insufficient in prevalent patients.

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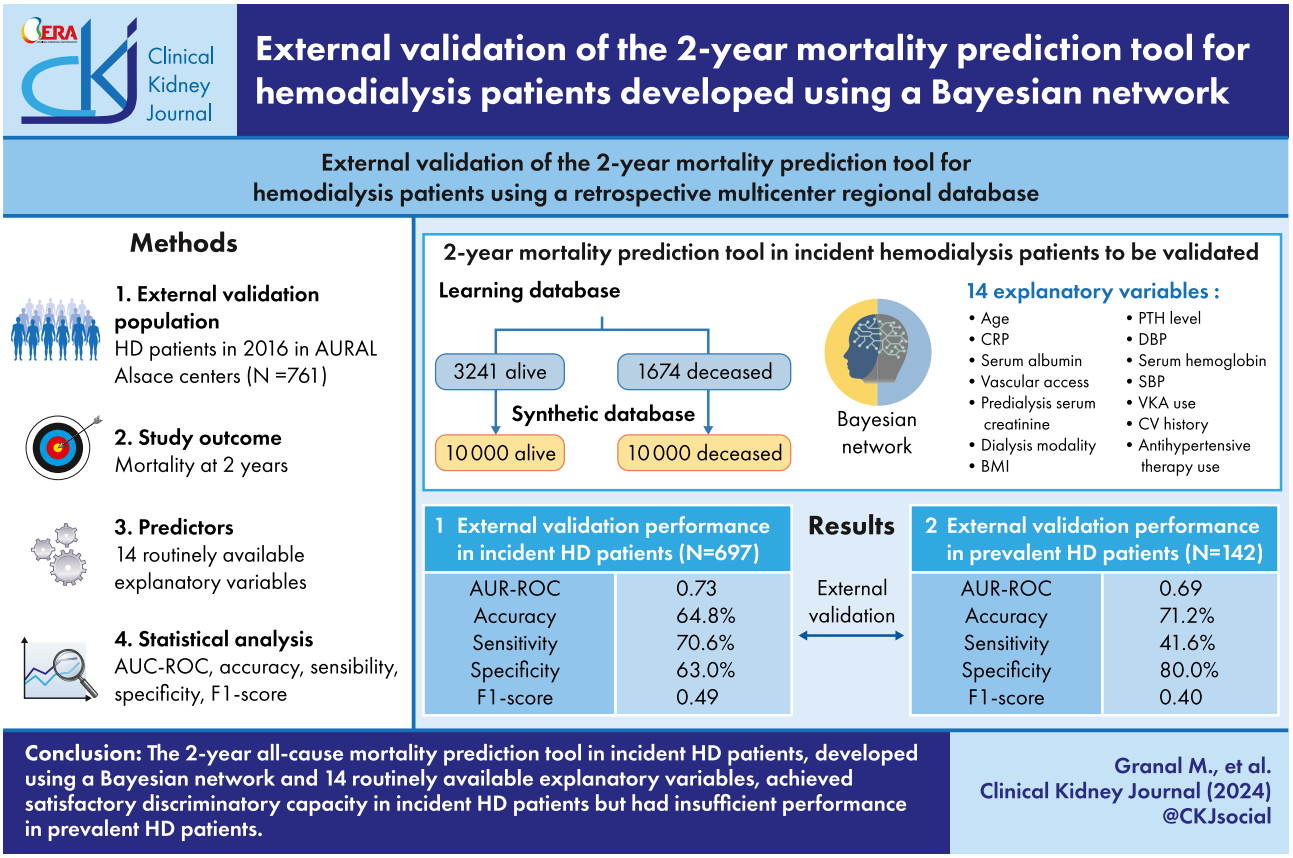
## GRAPHICAL ABSTRACT




**Keywords:** Bayesian network, external validation, hemodialysis, mortality, prediction tool

## KEY LEARNING POINTS

**What was known:**

- The annual mortality rate remains very high in hemodialysis patients, at 16.5% in France in 2021.
- Of the tools available to predict medium-term mortality, only one has been externally validated, but its application remains limited to hemodialysis patients over 70 years of age. A reliable, validated tool for predicting medium-term mortality in all hemodialysis patients is therefore needed.

**This study adds:**

- Recently, a clinical prediction tool has been developed using a Bayesian network derived from artificial intelligence (AI) to predict 2-year all-cause mortality in hemodialysis patients.
- This study provides an external validation of this predictive tool in order to generalize its use in routine clinical practice.

**Potential impact:**

- To help practitioners in proposing the most appropriate clinical decision for the management of patients who will undergo hemodialysis.
- To highlight the application of AI to improve the prevention and management of incident hemodialysis patients.
- To demonstrate the importance of using predictive tools to enhance personalized medicine and to enable individual patient care.

## INTRODUCTION

Chronic kidney disease (CKD) is a global health burden, affecting over 10% of the world's population [1, 2]. Progression of the disease to end-stage leads to the need for supportive treatment by dialysis or kidney transplantation. The number of dialysis patients worldwide exceeds 2 million, including more than 51 000 dialysis patients in France according to the latest REIN register in 2020 [3–6]. This number is constantly rising,

notably due to the ageing of the population and improvements in dialysis techniques. However, despite the many advances in hemodialysis techniques and the decrease in the rate of initiation of emergency hemodialysis, the survival of hemodialysis patients has improved only slightly, and their annual mortality rate remains very high, approaching 16.5% in France in 2021 [7]. This mortality rate is between 10 times higher, for patients over 60 years old, and 40 times higher, for patients over 90 years old, than that of the general population [8]. This rate is all the more alarming as it is higher than that of other chronic diseases, making renal failure the 10th leading cause of death worldwide [9].

Several tools for predicting 1-year or more mortality in hemodialysis patients have been developed [10–19]. Only one study has benefited from external validation [13]. While its performance is satisfactory in incident hemodialysis patients, its application remains limited to hemodialysis patients over 70 years of age. Furthermore, the mortality prediction tool cannot calculate a risk score if only 1 of the 14 predictors is missing, as is often the case in clinical practice. Recently, we have carefully developed a tool to predict 2-year all-cause mortality in hemodialysis patients [17]. This model, which was built using a Bayesian network, allows the simultaneous consideration of numerous explanatory variables, as well as the management of potentially dependent variables. Furthermore, the selection of the variables most related to the outcome is related to variance reduction without any *a priori* hypothesis. The main advantages of the prediction tool we are proposing are its development on a large, representative population and the selection of 14 predictors not only of cardiovascular (CV), but also of renal interest. In addition, the use of a model derived from artificial intelligence (AI) makes our prediction tool capable of handling missing data using Bayesian imputation. Although our prediction tool achieved satisfactory internal validation performance, it requires external validation before its generalization and use in clinical routine. Thus, the primary objective of this study was to perform an external validation of our prediction model using an external multicenter database of incident hemodialysis patients. Knowing the risk of mortality at 2 years from initiation of hemodialysis should make it possible to set up personalized management, facilitate shared decision-making between patient, relatives and clinician, and answer the question "Should hemodialysis be started?" The secondary objective was to perform an external validation using data from prevalent patients in order to extend its use to all hemodialysis patients.

## MATERIALS AND METHODS

### Database

A regional, multicenter, retrospective database was created to externally validate the tool for predicting all-cause mortality at 2 years in incident and prevalent hemodialysis patients. The inclusion and exclusion criteria chosen to create the validation database were identical to those used for the Photograph v3 learning database. The external validation database included data from all adult (≥18 years) hemodialysis patients incident or prevalent in 2016 in one of the eight Association pour l'Utilisation du Rein Artificiel dans la région Lyonnaise (AURAL) Alsace dialysis centers (Saverne, Haguenau, Strasbourg-Bergson, Saint-Anne, Strasbourg-Molière, Colmar, Mulhouse and Saint-Louis) and whose vital status at 2 years was known. Patients on hemodialysis, previously on peritoneal dialysis or returning from kidney transplantation, and persons protected by French law mentioned in articles L.1121-5 to L.1121-8 (pregnant women, minor patients, persons deprived of their liberty by a judicial or administrative decision and adults subject to a legal protection measure or unable to express their consent) were excluded from the study.

### Sample size and missing data

Currently, there is no reliable and validated statistical method for calculating the number of subjects required to externally validate a clinical prediction tool developed using a Bayesian model. As the largest number of data is recommended in statistics, an exhaustive inclusion of all AURAL Alsace hemodialysis patients over 1 year was carried out. Missing data were managed by Bayesian imputation.

### Prediction model

The development of the 2-year all-cause mortality prediction tool in incident hemodialysis patients has already been published [17]. In brief, the clinical prediction tool was developed using the Bayesian network, a model derived from AI. This model, which mimics the thinking of a clinician, is based on the conditional probability rule of Bayes' theorem. This model offers many advantages. It allows the treatment of collinear data and the management of potentially dependent variables as well as the consideration of many explanatory variables simultaneously, whatever the weight of their effect on the variable to be explained. It takes into account both the *a priori* knowledge of the experts and the experience contained in the data to model the knowledge on the subject in order to be able to reproduce the reasoning on new queries. The Bayesian network also allows for the management of missing data, which is very frequent in the medical domain.

The clinical prediction model was developed from 35 variables to cover a large panel of characteristics describing the demographic, biological and therapeutic data of nephrological interest. This prediction model was optimized, first, by increasing the number of data by creating synthetic data in order to increase the ratio of dead to alive patients, and second, by limiting the predictors to the 14 most informative variables selected according to their variance reduction. This optimization achieved a balance between ease of use and reliability for routine clinical use.

The 2-year mortality prediction tool for hemodialysis patients was developed using Netica® version 6.09 software.

### Predictors and primary outcomes

All predictors and the outcome of this external validation were defined and collected in the same terms and under the same conditions as when the prediction model was created. The 14 predictors used in the clinical prediction tool were: age, C-reactive protein (CRP), serum albumin, vascular access, predialysis serum creatinine, dialysis modality, body mass index (BMI), parathyroid hormone (PTH) level, diastolic blood pressure, serum hemoglobin, systolic blood pressure, vitamin K antagonists (VKA) use, CV history and antihypertensive therapy use. Blood pressure was defined as the average of three measurements in the sitting or supine position after a few minutes of rest according to international recommendations. Vital status (alive or dead) were collected at 2 years of follow-up.

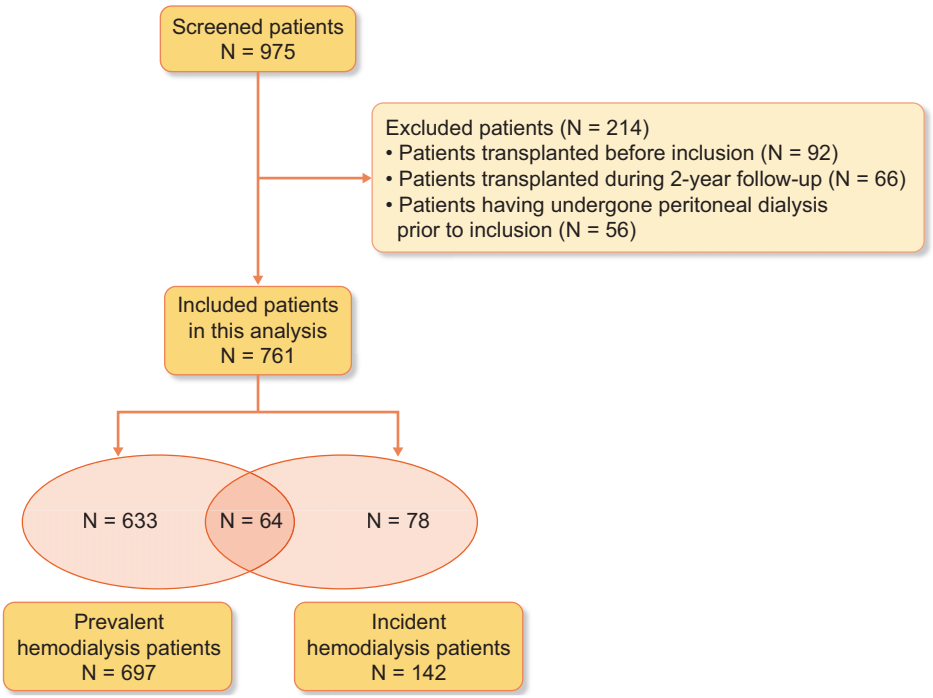



**Figure 1:** Flowchart of validation population.

### Statistical analysis

The validation database was described in terms of median and interquartile range (IQR) for all quantitative variables and percentages for categorical variables as well as for discretized quantitative variables. The statistical software used for data analysis was MedCalc®. Statistical Software version 20.114 (MedCalc Software bvba, Ostend, Belgium).

The median (IQR) and distribution of the training database variables were compared with the median (IQR) and distribution of the validation database variables. Quantitative variables were compared using the Mann–Whitney test because none of the distributions followed a normal distribution. Discretized quantitative variables and categorical variables were compared using the Chi-squared test. A difference was considered significant if $P < .05$.

The performance of the external validation of the clinical prediction tool for 2-year mortality of hemodialysis patients was evaluated using area under the curve of the receiver operating characteristics (AUC-ROC), sensitivity, specificity, accuracy and F1-Score. Sensitivity represents the percentage of patients predicted to have died out of all patients who died (i.e. true positives out of the sum of true positives and false negatives). Specificity represents the percentage of living patients in relation to all living patients (i.e. true negatives in relation to the sum of true positives and false negatives). The ROC curve represents sensitivity as a function of 1 – specificity. It is used to assess a model's overall performance. It is equal to 100% for a perfect model (perfectly discriminating between positive and negative individuals) and 50% for a non-informative model (corresponding to hazard). F1-Score assesses the ability of a classification model to effectively predict positive individuals, by making a trade-off between precision and recall, themselves based on the rates of true positives, false positives and false negatives. The idea behind the F1-Score is to ensure that a classifier makes good predictions of the relevant class (good precision) in sufficiently large numbers (good recall) on a target dataset. Like precision and recall, the F-measure ranges from 0 (the worst possible value) to 1 (the best possible value). Accuracy represents the precision of the model, i.e. the percentage of correctly classified individuals. AUC-ROC, sensitivity, specificity, F1-Score and precision can be expressed as percentages.

The external validation presented herein was also carried out using Netica® software version 6.09.

## RESULTS

### Study population

A total of 975 hemodialysis incident patients in 2016 or prevalent in 2016 in one of the eight dialysis centers of AURAL Alsace (France) were selected. Of these 975 patients, 214 were excluded for various reasons (patients transplanted before inclusion or during the 2-year follow-up, patients who started dialysis by peritoneal dialysis). The study therefore included a total of 761 patients for external validation of the 2-year mortality prediction tool, including 142 incident and 697 prevalent hemodialysis patients. The complete flow chart is detailed in Fig. 1.

The main characteristics of the 142 incident hemodialysis patients were: 62.7% male, median age 72.9 years (IQR 63.7–79.5), median systolic and diastolic blood pressures 141 (IQR 128–162) mmHg and 65 (IQR 54–76) mmHg, respectively, and 55.6% had a history of CV disease. The vast majority were dialyzed in a center (97.9%) using a fistula (63.8%). The 2-year all-cause mortality reached 23.9% ($N = 34$).

The main characteristics of the 697 prevalent hemodialysis patients were: 59.5% male, median age 69.5 years

**Table 1: Characteristics of the learning population and the external validation population.**

| | External validation (incident) | | | External validation (prevalent) | | |
|---|---|---|---|---|---|---|
| | Median | IQR | % | Median | IQR | % |
| 2-year all-cause mortality | | | 23.9 | | | 23.1 |
| Male sex (%) | | | 62.7 | | | 59.5 |
| Age (years) | 72.9 | 63.7–79.5 | | 69.5 | 58.7–76.3 | |
| BMI (kg/m$^2$) | 26.7 | 23.5–30.6 | | 27.6 | 23.7–31.9 | |
| SBP (mmHg) | 141 | 128–162 | | 137 | 120–153 | |
| DBP (mmHg) | 65 | 54–76 | | 61 | 51–73 | |
| CV history (%) | | | 55.6 | | | 65.0 |
| Predialysis serum creatinine (µmol/L) | 471 | 390–613 | | 588 | 467–720 | |
| Hemoglobin (g/dL) | 10.6 | 9.0–11.6 | | 11.2 | 10.5–12.0 | |
| Serum albumin (g/L) | 36.0 | 33.0–40.0 | | 38.3 | 35.0–41.0 | |
| CRP (mg/L) | 7.0 | 2.0–24.6 | | 5.0 | 2.0–12.2 | |
| PTH (ng/L) | 40 | 20–72 | | 38 | 21–61 | |
| Vascular access | | | | | | |
| AV fistula | | | 63.8 | | | 90.0 |
| AV graft | | | 0.7 | | | 1.7 |
| Catheter | | | 35.5 | | | 8.3 |
| Other | | | 0 | | | 0 |
| Dialysis facility | | | | | | |
| In-center hemodialysis | | | 97.9 | | | 97.7 |
| In-center self-care hemodialysis | | | 2.1 | | | 2.3 |
| Antihypertensive drug use | | | 82.4 | | | 71.3 |
| VKA use | | | 26.8 | | | 28.3 |

[a]P-value: external (incident or prevalent) validation vs learning database.
DBP, diastolic blood pressure; SBP, systolic blood pressure; HD, hemodialysis.

(IQR 58.7–76.3), median systolic and diastolic pressures were 137 (IQR 120–153) mmHg and 61 (IQR 51–73) mmHg, respectively, and 65.0% had a history of CV disease. The majority of the prevalent population was, unsurprisingly, on central dialysis with a fistula. The 2-year all-cause mortality reached 23.1% ($N = 161$) (Table 1).

Comparison of patient characteristics between the learning database and the external validation database of incident patients and the validation database of prevalent patients was performed (Supplementary data, Table S1).

The average percentage of missing data in the incident patient database was 4.8%, ranging from 0% for age, CV history, dialysis modality or treatments (antihypertensive drugs, and VKA) to 50.7% for PTH.

The average percentage of missing data in the prevalent patient database was 1.7%, ranging from 0% for age, BMI, CV history, dialysis modality or treatments (antihypertensive drugs, and VKA) to 17.9% for PTH.

### Performance of the external validation in incident hemodialysis patients

The performance of the 2-year all-cause mortality prediction tool was: AUC-ROC 0.73, accuracy 64.8%, sensitivity 70.6%, specificity 63.0% and F1-Score 0.49 (Table 2).

### Performance of the external validation in prevalent hemodialysis patients

The performance of the 2-year all-cause mortality prediction tool was: AUC-ROC 0.69, accuracy 71.2%, sensitivity 41.6%, specificity 80.0% and F1-Score 0.40 (Table 3).

**Table 2: Prediction performance in external validation of the tool in incident hemodialysis patients.**

| Parameters used to evaluate the performance | Value |
|---|---|
| AUC-ROC | 0.73 |
| Accuracy (%) | 64.8 |
| Sensitivity (%) | 70.6 |
| Specificity (%) | 63.0 |
| F1-Score | 0.49 |

**Table 3: Prediction performance in external validation of the tool in prevalent hemodialysis patients.**

| Parameters used to evaluate the performance | Value |
|---|---|
| AUC-ROC | 0.69 |
| Accuracy (%) | 71.2 |
| Sensitivity (%) | 41.6 |
| Specificity (%) | 80.0 |
| F1-Score | 0.40 |

## DISCUSSION

We developed a 2-year all-cause mortality prediction tool in incident hemodialysis patients using a machine-learning model [17]. The current study presents the external validation using data from a multicenter regional cohort of incident hemodialysis patients had satisfactory performance in terms of AUC-ROC, F1-Score, sensitivity and specificity. This tool, developed with a machine learning model, has the advantage of being able to

simultaneously consider a large panel of explanatory variables of varied origin, which may be collinear with each other. The satisfactory performance of the external validation of the 2-year mortality prediction tool can be supported by the rigorous selection of predictors from the large panel of potential predictors [17], making it well suited to this specific, high-risk population. In addition to classical CV predictors (BMI, blood pressure, age, sex, CV history), our prediction tool also uses kidney-related predictors (vascular access, dialysis facility, PTH, serum albumin, hemoglobin, predialysis plasma creatinine, CRP) and of therapeutics interest (VKA, antihypertensive drugs). In cohort studies, the association between variables does not imply a causal relationship. For instance, in the present study, VKA prescription is associated with a higher CV risk and a higher mortality rate. The quality of the validation database may also explain the satisfactory performance of the prediction tool. The validation cohort that is regional and multicenter is an integral part of the national REIN registry. Data were collected and extracted by qualified clinical research assistants, and data verification was carried out for patients with questionable data. The final database was of very high quality, with a very low percentage of missing easily processed using Bayesian imputation. In order to be as exhaustive and representative as possible, we chose to include 1-year incident hemodialysis patients. To avoid the excess mortality related to the COVID-19 pandemic, the year 2016 was selected. The number of patients lost to follow-up has been reduced to zero. Due to the chronicity of hemodialysis, registers are of high level of confidence. Few patients changed of centers but remained on dialysis in an AURAL center, and very few changed region. For the latter 10 patients, a national register of deceased persons was consulted. The prediction tool was created using a national database and the last information was collected in April 2014. Thus, the data did not overlap between the training and the validation database over the data collection periods. The satisfactory performance of the external validation process, which used data from incident hemodialysis patients from the AURAL Alsace association center, which predominantly cares for a lower risk population, means that the tool can be used in this population, and supports its generalization. One of the main advantages of this tool for predicting 2-year mortality in incident hemodialysis patients relies on its simplicity of use without any compromise on its performance. Indeed, the prediction tool uses a reduced number of predictors that are easily obtainable in incident hemodialysis patients. Furthermore, the tool has the advantage of being able to handle missing data (implemented using Bayesian inference) which are frequent in clinical practice. Finally, its online availability facilitates its use. Some more complex models have better predictive performance, but their complexity reduces their acceptance in clinical practice [20].

The performance of the prediction model was also evaluated on data from prevalent hemodialysis patients from the same centers, to determine whether the use of the prediction tool could be extended to all hemodialysis patients. The performance obtained was satisfactory in terms of AUC-ROC and specificity, but unfortunately showed a lack of sensitivity. Our prediction tool can only predict 41.6% of patients who died at 2 years. On the other hand, the specificity of 80%, which reflects the test's ability to assess survival, is highly satisfactory. This result is consistent since the prediction tool was trained on a database of incident hemodialysis patients.

Our study has also some limitations. First, we were unable to head-to-head compare the performance of our predictive tool with previously developed models, due to the use of variables for which we have no data, or different outcomes or duration of follow-up [10–13, 15–37]. The performance of the previously developed and validated model in hemodialysis patients [13] had similar AUC-ROC (0.73–0.75). However, the authors do not report accuracy, sensitivity, specificity and F1-Score, making indirect theoretical comparison impossible. Secondly, development on a national database and validation on a regional database can also be seen as a limitation in terms of generalizing the validation. The model needs to be validated with different populations. Consequently, international external validations are being considered. The exclusion from the prediction tool of patients who are planning a renal transplant within 2 years of starting dialysis may also be regarded as a limitation but this was needed as the access to kidney transplantation differs from one country to another. In addition, transplant patients generally represent a younger population with fewer comorbidities, which may lead to the selection of a healthier cohort [12] and may reduce the relevance of the tool in clinical practice.

In the short term, our clinical prediction tool, available online and operating satisfactorily, could be used by healthcare professionals. Knowing the 2-year mortality risk from initiation of hemodialysis should help individualize patient management and improve the quality of the decision shared between patients and healthcare professionals, thus providing objective help in answering the question: is it in the patient's best interest to start hemodialysis?

Thanks to AI, our model has self-learning capabilities that enable it to adapt continuously to the acquisition of new data and continually increase its predictive capacities [38]. In the medium term, the merging of the learning base and the validation base will enable the model's knowledge to be enriched not only with data from incident patients, but also with data from prevalent hemodialysis patients, enabling it to be used for all incident and prevalent hemodialysis patients.

In the long term, only a randomized clinical trial, aimed at determining whether knowledge of 2-year mortality in incident hemodialysis patients would improve quality of life and/or reduce mortality, would reveal the usefulness of our tool in clinical practice. However, this type of study is very difficult to implement.

## CONCLUSION

In conclusion, the 2-year all-cause mortality prediction tool in incident hemodialysis patients, developed using a Bayesian network and 14 routinely available explanatory variables, achieved satisfactory external validation in terms of AUC-ROC, F1-Score, sensitivity and specificity. Knowing the risk of mortality at 2 years from initiation of hemodialysis should help individualize patient management and improve the quality of the decision shared between patients and healthcare professionals. The website address to calculate the individual probability (and standard deviation) of the 2-year mortality in incident hemodialysis patients is: https://www.hed.cc/?s=Fauvel&t=2-years%20All-cause%20Mortality%20Hemodialysis.

## SUPPLEMENTARY DATA

Supplementary data are available at *Clinical Kidney Journal* online.

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This research did not receive external funding.

## AUTHORS' CONTRIBUTIONS

M.G., and J.-P.F. designed the work. T.K., C.B-D., F.C., C.M., M.Délia., Y.D., T.H., S.B.-L.C. contributed to the collection and the extraction of the AURAL Alsace database. M.G., M.Ducher and J.-P.F. analyzed the data sets. M.G and J.-P.F. wrote this article. All authors have read and approved the published version of the manuscript.

## DATA AVAILABILITY STATEMENT

All databases are protected in a password-protected Excel file and stored on password-protected computers. The passwords are changed every 3 months. The databases will be destroyed in 20 years.

## CONFLICT OF INTEREST STATEMENT

The authors declare no conflict of interest.

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