Original Article

Risk Factors for 3-Year-Mortality and a Tool to Screen Patient in Dialysis Population

Abstract

Introduction: Clinical parameters especially co-morbidities among end stage renal disease (ESRD) patients are associated with mortality. This study aims to determine the risk factors that are associated with mortality within three years among prevalent patients with ESRD. **Methods:** This is a cohort study where prevalent ESRD patients' details were recorded between May 2012 and October 2012. Their records were matched with national death record at the end of year 2015 to identify the deceased patients within three years. Four models were formulated with two models were based on logistic regression models but with different number of predictors and two models were developed based on risk scoring technique. The preferred models were validated by using sensitivity and specificity analysis. **Results:** A total of 1332 patients were included in the study. Majority succumbed due to cardiovascular disease (48.3%) and sepsis (41.3%). The identified risk factors were mode of dialysis ($P < 0.001$), diabetes mellitus ($P < 0.001$), chronic heart disease ($P < 0.001$) and leg amputation ($P = 0.016$). The accuracy of four models was almost similar with AUC between 0.680 and 0.711. The predictive models from logistic regression model and risk scoring model were selected as the preferred models based on both accuracy and simplicity. Besides the mode of dialysis, diabetes mellitus and its complications are the important predictors for early mortality among prevalent ESRD patients. **Conclusions:** The models either based on logistic regression or risk scoring model can be used to screen high risk prevalent ESRD patients.

Keywords: *End stage renal disease, mortality, risk factors, screening tool, sensitivity and specificity*

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Introduction

End stage renal disease (ESRD) is a state of permanent loss of renal function. The prevalence of ESRD patients is growing rapidly worldwide fuelled by aging populations and a pandemic of chronic non-communicable diseases especially diabetes mellitus and hypertension. It was estimated that by 2030, the global population of ESRD patients on dialysis may exceed two million.[1] The statistics has shown that ESRD as one of the burden of diseases worldwide.

In Malaysia, the incidence and prevalence of patients with ESRD has been on an upward trend for the past 20 years. The annual mortality rate for patients on dialysis in the year 2014 was 12.0% and majority of the deaths were contributed by cardiovascular disease (CVD) with 37.0%, followed by sepsis with 24.0%.[2] By 2040, the prevalence of ESRD patients is projected at more than 100 000 patients with the estimated prevalence rate at 25.6% which is about nine times of prevalence rate in 2000.[3]

The current situation has indicated that ESRD has become a burden of disease in majority of the countries whereby the disease has a significant impact on morbidity,[2,4,5] quality of life,[6-8] mortality[2,3] and economic burden for the country.[3] Patients with ESRD are considered as very high risk group and usually have lower survival especially with presence of other comorbidities such as CVD and hypertension.[9,10] Numerous studies have been done to determine the risk factors for mortality or survival among ESRD patients[9-14] and majority of these studies only reported up to the level of the risk factors.

Stating the risk factors is useful. However, to formulate a predictive model from the risk factors would ease the clinicians in prognostication.[15-17] Few studies have attempted to produce a predictive model to determine the risk of mortality among

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ESRD patients.[18,19] Similarly, based on the Malaysian population, this study aims to determine the risk factors for mortality within three years. Hence, this study aims to develop a simple predictive model based on logistic regression model and risk scoring model to predict risk for mortality within three years among prevalent ESRD patients. The significance of the study was to identify and to propose a simple and quick prognostic model that can be used by clinicians in clinical setting to screen high risk patients requiring more attention.

Materials and Methods

This is a cohort study where patients' demographic and clinical details were recorded from questionnaire based study. The recruitment was based on consecutive sampling from May 2012 to October 2012. The samples were prevalent dialysis patients who were undergoing peritoneal dialysis or haemodialysis from 22 dialysis centres within 10 states. Written consent was taken from all patients before they participated in the study. Demographic profiles (age, gender, ethnicity, religion, marital status, highest education level, smoking history and alcohol history) and clinical histories and parameters (duration of dialysis, mode of dialysis, body mass index, diabetes mellitus, hypertension, Coronary Heart Disease (CHD), leg amputation, cerebrovascular disease and cancer) were collected during the baseline of study. The definition of these variables are following the same definition with the Case Report Form (CRF) for National Renal Registry report.[2]

Their records such as their name and identification card number were then matched with National Death Record (NDR) which is maintained by Department of Registration Malaysia at the end of year 2015 to determine the status of mortality within three years. The data was divided into model development (70.0% of the data) and model validation (remaining 30.0% of the data) based on consecutive sampling. The idea is that, the model that to be developed in the development phases to be as good or sensitive in predicting for later data. The study was registered under the National Medical Research Registry (NMRR-11-827-10135) and has obtained approval from the Medical Research Ethics Committee (MREC) of Malaysia.

Statistical analysis

All analyses were carried out using SPSS (IBM corporation. Released 2011. IBM SPSS Statistics for Windows, Version 20.0. Armonk, NY: IBM Corp).

Logistic regression model

Univariate analysis was conducted based on Pearson's chi square test to determine the associated factors toward risk of mortality within three years while multivariate analysis was based on logistic regression using forward likelihood ratio method. The cut off probability for variable selection was set at 0.05 for both inclusion and exclusion. Two models were derived from logistic regression model where the first model includes the significant factor from demographic and clinical variables while the second model only incorporates clinical variables as predictors. The coefficients, odds ratio with respective confidence interval and *P* values were recorded then subsequently the z-score and probability of event were calculated for both models. The probability of event was calculated using the following link function: $P[event] = e^z/1 + e^z$. The area under the curve (AUC) was analysed to examine the accuracy of the probability of event from model 1 and model 2 towards status of mortality within three years.

Risk scoring model

The clinical variables that were significant ($P < 0.05$) based on multivariate analysis were selected as the predictors for risk scoring models. Pearson's chi square test was applied to determine the association between clinical variables toward risk of mortality within three years. The crude odd ratios were calculated for all the significant variables. There are two approaches in assigning the score. Model 3 recommended that the scores were assigned based on the magnitude of effect size (odds ratio) while Model 4 recommended each variables were assigned by one mark. The total score is calculated by a summation of the scores.

Results

Descriptive, prevalence of the risks factor and incidence of mortality

A total of 1332 patients (51.0% males and 49.0% females) were included in our study. Majority of patients' age were between 40 and 64 years (58.3%). Almost half of them were classified as overweight (28.9%) and obese (12.5%). There were 35.9% of them who were already diagnosed with diabetes mellitus. Majority of them (83.9%) were having hypertension. One sixth of the patients (15.3%) in our study diagnosed with ESRD had underlying CHD [Tables 1 and 2]. Prevalence of mortality within 3 years was 41.4%. Patients died were due to CVD (48.3%) and sepsis (41.3%), gastrointestinal (2.8%), cancer (2.1%), hepatobiliary (1.2%), accident (0.2%) and others (4.0%).

Univariate analysis

Based on univariate analysis, marital status ($P < 0.001$), highest education level ($P < 0.001$), mode of dialysis ($P < 0.001$), status of transplant ($P = 0.001$), status of diabetes mellitus ($P < 0.001$), status of hypertension ($P < 0.001$), status of chronic heart disease ($P < 0.001$) and status of leg amputation ($P < 0.001$) were associated with the outcome [Tables 1 and 2]. The characteristics of patients who are likely at risk of mortality within three years are widow/widower, lower highest education level (no formal

Table 1: Univariate analysis for associated factors within demographic profile variables toward mortality within 3 years based on data from model development

Variables	Category	Death		*P*
		No, *n* (%)	Yes, *n* (%)	
Age (years)	18-39	85 (15.3)	72 (19.7)	0.178
	40-64	333 (60.0)	214 (58.6)	
	≥65	137 (24.7)	79 (21.6)	
Gender	Male	277 (49.5)	189 (50.8)	0.688
	Female	283 (50.5)	183 (49.2)	
Ethnic	Malay	275 (49.7)	163 (44.3)	0.111
	Chinese	215 (38.9)	163 (44.3)	
	Indian	63 (11.4)	40 (10.9)	
	Foreigner	0 (0.0)	2 (0.5)	
Religion	Muslim	276 (49.9)	168 (46.0)	0.252
	Buddhist	185 (33.5)	140 (38.4)	
	Hindu	56 (10.1)	33 (9.0)	
	Christian	29 (5.2)	23 (6.3)	
	Others	7 (1.3)	1 (0.3)	
Marital status	Single	133 (23.9)	48 (12.9)	<0.001
	Married	391 (70.2)	276 (74.2)	
	Widow/widower	27 (4.8)	42 (11.3)	
	Divorced	6 (1.1)	6 (1.6)	
Education	Nil	31 (5.7)	104 (28.3)	<0.001
	Primary	135 (24.9)	163 (44.4)	
	Secondary	269 (49.6)	48 (13.1)	
	Tertiary	107 (19.7)	52 (14.2)	
Smoking history	Current	22 (4.0)	22 (5.9)	0.170
	Former	88 (15.8)	69 (18.6)	
	Never	446 (80.2)	279 (75.4)	
Alcohol history	Current	2 (0.4)	1 (0.3)	0.793
	Former	43 (7.7)	33 (8.9)	
	Never	511 (91.9)	336 (90.8)	

Table 2: Univariate analysis for associated factors within clinical variables toward mortality within 3 years based on data from model development

Variables	Category	Death		*P*
		No, *n* (%)	Yes, *n* (%)	
Duration of dialysis[a]		12.0 (20.0)	10.7 (19.1)	0.344
BMI categories	Underweight	73 (13.1)	39 (10.5)	0.090
	Normal	290 (52.1)	172 (46.5)	
	Overweight	138 (24.8)	114 (30.8)	
	Obese	56 (10.1)	45 (12.2)	
Mode dialysis	Hemodialysis	401 (71.6)	228 (61.3)	<0.001
	CAPD	159 (28.4)	144 (38.7)	
Transplanted	No	521 (93.0)	364 (97.8)	0.001
	Yes	39 (7.0)	8 (2.2)	
Diabetes	No	428 (76.4)	185 (49.7)	<0.001
	Yes	132 (23.6)	187 (50.3)	
Hypertension	No	122 (21.8)	47 (12.6)	<0.001
	Yes	438 (78.2)	325 (87.4)	
CHD	No	513 (91.6)	283 (76.1)	<0.001
	Yes	47 (8.4)	89 (23.9)	
Cerebrovascular	No	546 (97.5)	360 (96.8)	0.510
	Yes	14 (2.5)	12 (3.2)	
Leg-amputation	No	552 (98.6)	346 (93.0)	<0.001
	Yes	8 (1.4)	26 (7.0)	
Cancer	No	556 (99.3)	365 (98.1)	0.106
	Yes	4 (0.7)	7 (1.9)	

[a]Reported in mean with standard deviation. BMI: Body mass index, CAPD: Continuous ambulatory peritoneal dialysis, CHD: Coronary heart disease

education and primary school), mode of dialysis with CAPD, without transplant, having diabetes mellitus, hypertension, chronic heart disease and leg amputation.

Logistic regression model

Result based on multivariate analysis suggested that all the significant variables remained significant except for marital status, status of transplant and hypertension (Model 1). Second model (Model 2) was formulated and to only incorporates clinical variables. All variables remained significant except for hypertension. The AUC (95%CI) for Model 1 and Model 2 were 0.711 (0.676, 0.745) and 0.692 (0.656, 0.727) respectively [Table 3].

Risk scoring model

The risk scoring model was based on logistic regression model in terms of variable selection but using the pre-determined score instead of the coefficients. There were four clinical variables were tested such as mode of dialysis, diabetes mellitus, CHD and leg amputation. The crude odds ratios were within 1.6 to 5.2. Two models were proposed and the distributions of the score were assigned based on the weightage of crude odd ratio (Model 3) and by assigning 1 mark for each variable (Model 4). The AUC (95% CI) for Model 3 and Model 4 were 0.697 (0.662, 0.731) and 0.680 (0.645, 0.716) respectively [Table 4].

Preferred statistical models

If the decision is taken merely based on statistics, the best model was Model 1 with slightly higher accuracy as compared to the rest of the models. However, due to simplicity, this study proposed Model 2 and Model 4 as the preferred models where Model 2 which is based on logistic regression reported slightly higher accuracy. The probability of event and the score were further categorized into two (Low risk to high risk versus very high risk; Low risk versus moderate to very high risk). The sensitivity and specificity of the two models were evaluated based on sensitivity and specificity analysis.

Results of sensitivity and specificity from data in development and validation sets for both models based on selected cut offs were exactly similar. Based on categorization of "Low risk to high risk versus very high risk", the sensitivity and specificity were 9.95% and 98.93% respectively. The same categorization was tested based on data in validation phase, and the sensitivity and specificity

Table 3: Summary of statistics derived from logistic regression model for Model 1 and Model 2 based on data from model development

Predictor	Model 1[a]			Model 2[b]		
	β	OR (95% CI)	*P*	β	OR (95%CI)	*P*
Education						
Nil	1.176	3.2 (1.8, 5.9)	<0.001			
Primary	0.391	1.5 (0.9, 2.3)	0.09			
Secondary	0.257	1.3 (0.9, 2.0)	0.23			
Tertiary		Reference group				
Mode of dialysis						
Hemodialysis		Reference group			Reference group	
Peritoneal	0.587	1.8 (1.3, 2.4)	<0.001	0.552	1.7 (1.3, 2.3)	<0.001
Diabetes mellitus						
No		Reference group			Reference group	
Yes	1.001	2.7 (2.0, 3.7)	<0.001	1.086	3.0 (2.2, 4.0)	<0.001
Chronic heart disease						
No		Reference group			Reference group	
Yes	0.998	2.7 (1.8, 4.1)	<0.001	1.027	2.8 (1.9, 4.2)	<0.001
Leg amputation						
No		Reference group			Reference group	
Yes	0.929	2.5 (1.1, 6.0)	0.03	1.043	2.8 (1.2, 6.6)	0.016
Constant		−1.471			−1.174	

[a]Marital status, transplanted and hypertension were dropped from the stepwise analysis; AUC (95% CI) for Model 1: 0.711 (0.676, 0.745), [b]Model 2 only include clinical parameters; AUC (95% CI) for Model 2: 0.692 (0.656, 0.727). OR: Odd ratio, CI: Confidence interval, AUC: Area under the curve; β: Coefficient

Table 4: The effect size of each significant clinical variables towards mortality within 3 years based on data from model development and the assigned score for Model 3 and Model 4

Predictor	Crude OR (95% CI)	Score assigned	
		Model 3[a]	Model 4[b]
Mode of dialysis			
Hemodialysis		0	0
Peritoneal	1.6 (1.2, 2.1)	1	1
Diabetes mellitus			
No		0	0
Yes	3.3 (2.5, 4.3)	2	1
Chronic heart disease			
No		0	0
Yes	3.4 (2.3, 5.0)	2	1
Leg amputation			
No		0	0
Yes	5.2 (2.3, 11.6)	3	1

[a]AUC (95% CI) for Model 3: 0.697 (0.662, 0.731), [b]AUC (95% CI) for Model 4: 0.680 (0.645, 0.716). OR: Odd ratio, CI: Confidence interval, AUC: Area under the curve

were 8.83% and 99.09% respectively. Meanwhile, based on categorization of "Low risk versus moderate to very high risk", the sensitivity and specificity were 77.42% and 49.11% respectively. The same categorization was tested based on data in validation phase, the result showed that the sensitivity and specificity were 88.89% and 25.45% respectively [Table 5].

Discussion

The prevalence of mortality was 41.4% within three years and this was parallel to the data shown in 2014 by the National Renal Registry where annual prevalence in that year was reported to be 12.0%.[2] The main causality was due to CVD where reported involving one third of them, followed by a quarter of them succumbed due to sepsis; similar to what have been reported in the national registry.[2] The pattern of cause of deaths was also consistent in U.S.[20,21]

This study has explored four possible models in predicting mortality within three years among prevalent ESRD patients. Logistic regression model has been used widely in clinical research to determine association between factors and outcome. If the effect sizes of the contributing factors are satisfactorily high, then it is worth to pursue the model for prediction.[17] With regards to studies on associated factors towards mortality among ESRD patients, previous works have applied different approaches. Barrett *et al*. had applied age and other comorbidity as predictors for mortality from first dialysis but the prediction is not quite satisfactory.[18] Meanwhile, Cohen *et al*. (2010) worked on predicting six-month mortality for patients who are on maintenance haemodialysis. Their work used five predictors and found that the accuracy of the model is satisfactory.[19]

We developed the model based on forward likelihood ratio as the stepwise method with strict cut offs probability for entry and removal selection in the stepwise procedure. Forward stepwise procedure starts with a null model. Then

Table 5: Summary of the performance of Model 2 and Model 4 in predicting high risk of mortality within 3 years among prevalent end stage renal disease patients

Statistics	Model development	Model validation
1. Probability of event <0.8 versus ≥0.8[a]		
Sensitivity	9.95 (7.10, 13.45)	8.83 (4.74, 13.37)
Specificity	98.93 (97.68, 99.61)	99.09 (96.75, 99.89)
Positive predicted value	86.05 (72.44, 93.53)	88.24 (63.48, 97.00)
Negative predicted value	62.32 (61.50, 63.13)	56.92 (55.79, 58.04)
2. Probability of event <0.3 versus ≥0.3[b]		
Sensitivity	77.42 (72.83, 81.57)	88.89 (83.36, 93.08)
Specificity	49.11 (44.89, 53.33)	25.45 (19.84, 31.75)
Positive predicted value	50.26 (47.81, 52.71)	49.38 (47.06, 51.70)
Negative predicted value	76.60 (72.71, 80.09)	73.68 (63.61, 81.77)
3. Score 0-2 versus Score 3 and 4[a]		
Sensitivity	9.95 (7.10, 13.45)	8.83 (4.74, 13.37)
Specificity	98.93 (97.68, 99.61)	99.09 (96.75, 99.89)
Positive predicted value	86.05 (72.44, 93.53)	88.24 (63.48, 97.00)
Negative predicted value	62.32 (61.50, 63.13)	56.92 (55.79, 58.04)
4. Score 0 versus Score 1-4[b]		
Sensitivity	77.42 (72.83, 81.57)	88.89 (83.36, 93.08)
Specificity	49.11 (44.89, 53.33)	25.45 (19.84, 31.75)
Positive predicted value	50.26 (47.81, 52.71)	49.38 (47.06, 51.70)
Negative predicted value	76.60 (72.71, 80.09)	73.68 (63.61, 81.77)

[a]Low risk to high risk versus very high risk, [b]Low risk versus moderate to very high risk

it allows each variable to be selected into the model one at a time based on some pre-specified priority. The process is continuing until some stopping rule is satisfied. This is to ensure only major factors will be selected in the final model since statistically significant or *P* value less than 0.05 is also can be achieved by very large sample besides the clinical significant.[22-24]

This study has found that the major contributing factors for the risk of mortality within three years are highest education level, mode of dialysis, diabetes mellitus, CHD and leg amputation. Considering the classification of education may differ in other countries, Model 2 was developed to only incorporate the clinical variables. The AUC between Model 1 and Model 2 were almost similar. However, Model 2 was a preferred choice due to its properties of having less predictor and was also possible to be applied in other countries.

Perhaps, one of the disadvantages of using logistic regression model is the complexity in the calculation of the risk or probability of event. This could make the model unlikely to attract clinicians to apply the model in clinical setting. Due to this concern, this study has also explored the possibility in developing the prediction model based on risk scoring model. Based on this model, scores are assigned to each predictor based on some judgement and simple calculation such as summation to be applied to derive the total score.

In this study, two approaches were applied to assign the score for each predictor. Model 3 assigned the score based on the magnitude of effect size such as odds ratio and Model 4 assigned the score for one mark each. Results found that the AUC between Model 3 and Model 4 are almost similar and hence Model 4 is preferred due to simpler computation. Based on our data, the assigned of one-mark score for each predictor is sufficient since the magnitude of effect sizes based on crude odds ratio were quite narrow with between 1.6 and 5.2. In fact, the adjusted odds ratios were narrower. Although some may perceive different weightage score need to be assigned for different predictor, but result showed that the accuracy of Model 3 and Model 4 were almost similar. A famous risk scoring such as TIMI score to predict unstable angina is also applying simple computation of scoring with one-mark score for each predictor.[16]

Due to the similarities in the accuracy, this study has proposed that Model 2 and Model 4 to be applied to screen high risk patients of mortality within three years. Based on the selected cut offs, both models have reported good sensitivity although with moderate specificity. In some studies, specificity values can be reduced to increase the sensitivity of the screening tool.[25-27] However, if based on categorization of "Low risk to high risk versus very high risk", the specificity was highly excellent. Therefore, which categorization to be applied will depends on the aim of the researchers.

This study has showed that performance of model based on risk scoring is as good as model that was based on logistic regression. The authors would like to emphasize that the approach of risk scoring is recommended to be accepted

if each predictor have almost the same magnitude in predicting the outcome. It was showed in the Table 3 where the coefficients were between 0.552 and 1.086 and hence, this study recommended one mark for each predictor is reasonably acceptable.

There were few models reported in literatures with different approaches in methodology. Majority recruited new dialysis patients and review the cohort between six months to five years.[4,18,28] Cohen *et al*. (2010) recruited prevalent dialysis patients only on haemodialysis and only emphasize for six months' survival.[19] The present study in the other hand successfully developed the screening tool to determine the high risk patients based on three-years' mortality among prevalent ESRD. The justification to use the prevalent dialysis patients as the subjects is because to develop a risk model that can be applied for ESRD patients at any point of disease.

Wagner *et al*. has studied a 3-years cohort among the new dialysis patients.[28] They found that basic patient characteristics (age, race, primary kidney disease, and treatment modality), comorbid conditions (diabetes, history of cardiovascular disease, and smoking), and laboratory variables (hemoglobin, serum albumin, creatinine, and calcium levels) can predict 3-year mortality in incident dialysis patients. Instead predicting yes or no mortality within three years, their study preferred to use risk classification such as low, intermediate, high, and very high mortality risk. The present study has found almost similar independent factors such as age and comorbid conditions but unfortunately the present study did not observe laboratory variables.To date, there is no predictive modelling has been developed to screen high risk ESRD patients in Malaysia. This study perhaps had recruited small sample size in comparison with prevalent ESRD patients currently available in Malaysia. However, previous study had shown that study with sample size preferably more than 500 will likely to produce statistics that represent the parameters in the intended population.[23,24] Another limitation of this study is some causes of death were unknown due to some death certificates were verified by non-medical officers and also in some cases were due to refusal of post-mortems by family members.[29] However, at least 69.3% of the causes of death were successfully verified by medical officers. If the unknown death can be assumed as a sudden death due to CVD, hence the percentage of cause of death due to CVD will increase from 48.3% to 64.2%.

Besides that, this study did not observe variables that perhaps important in predicting the outcome such as anemia, phosphate level and other indicators. This is because, this was a questionnaire based study and hence some of the important clinical parameters were not available. However, the earlier intention of this study is to develop a predictive model using basic parameters so a quicker screening process can be made without relying on other parameters. Some of the AUCs were slightly less than 70.0% in which the values are perhaps not sufficiently strong for diagnostic purpose.[25] Therefore, the application of the models need to be interpreted with caution.

However, the AUCs with nearly 70.0% is acceptable good for screening purpose. In some studies, the optimal cut off can be adjusted to increase sensitivity of the model but at the same time, have to sacrifice the value of specificity. This practice can be accepted in some studies if the instrument or the model to be used for screening purpose.[25,30] We recommended future studies to apply the model in different populations in other countries so the evaluation and the robustness of the predictive model can be assessed.

Conclusion

In conclusion, this study found that the major causes of death within three years among ESRD patients are CHD and sepsis. Besides that, we have developed a simple and quick screening tool to determine patients who are at risk of mortality within three years. This study proposed two types of statistical models that can be used to screen high risk patients with ESRD. Based on our data, the model based on logistic regression and risk scoring model were both equally good. Hence, this study has proposed the logistic regression model to be applied in clinical setting since the model has slightly higher accuracy and was developed based on the standard mathematical computation. However, for a quick and simpler screening purpose, risk scoring model is also can be used instead.

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Research involving human participants and/or animals

This study did not apply any intervention. However, this study was conducted based on the ethical standard in conducting research. The study was registered under the National Medical Research Registry (NMRR-11-827-10135) and has obtained approval from the Medical Research Ethics Committee (MREC) of Malaysia.

Informed consent

Written consent was obtained from all patients before they participated in the study

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patients have given

their consent for their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Conflicts of interest

There are no conflicts of interest.

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