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A decision-making algorithm proposal for PICCs and midlines insertion in patients with advanced kidney disease: A pilot study

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Abstract

Introduction: Kidney Disease Outcomes Quality Initiative clinical practice guidelines recommend avoiding placement of peripherally inserted vascular access devices in patients with an estimated glomerular filtration rate (eGFR) <45 ml/min. On the other hand, many patients with severe chronic kidney disease (CKD) have poor prognosis.

This study carried out a global assessment of mortality at 2 years through Charlson Comorbidity Index (CCI) and Beclap score in patients with PICCs or Midlines, assuming that in those with an estimated high mortality rate at 2 years, it could be acceptable to implant a peripheral vascular access device (PVAD) despite the presence of CKD.

Methods: We analyzed data on patients with PICCs or Midlines inserted from October 2018 to November 2019. CCI, Beclap score, and eGFR were calculated for each patient at the time of the catheter insertion. We then followed patients for 2 years to assess 2-year mortality for each.

Results: One hundred and thirty-one patients were enrolled, 49 (37.4%) had eGFR<45 ml. The 2-year mortality rate was 57.3%. The cut off derived from ROC curve analysis of 15 for Beclap score and 5 for CCI, showed good sensitivity and specificity in predicting mortality of the total population, patients without an oncological disease and patients with eGFR<45 ml/min.

Conclusion: CCI and Beclap score are good predictors of mortality at 2 years.

Physicians and nurses can use these tools in the evaluation of patients at risk for future dialysis, instead of relying exclusively on renal function to decide whether implanting PICCs, Midlines, or other vascular access devices.

Keywords

Chronic kidney disease (CKD), peripherally inserted central catheters (PICCs), midlines catheters, Charlson Comorbidity Index (CCI), Beclap score, mortality

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Introduction

Peripherally inserted central catheters (PICCs) and Midlines catheters are widely used in everyday clinical practice.[1] Unfortunately, their use could be associated with complications such as stenosis, thrombosis, and obliteration of the central and peripheral veins in which they dwell.[1] These complications are of particular concern in patients with chronic kidney disease (CKD) as they may compromise the longevity of a future possible dialysis.[2]

For these reasons the 2019 update of the Kidney Disease Outcomes Quality Initiative (KDOQI) clinical practice guidelines recommends the preservation of central and peripheral upper extremity veins from vascular damage by avoiding the placement of Peripheral Vascular Access Devices (PVAD) or PICCs in the arm or forearm in patients on dialysis or grade III B, grade IV, and grade V CKD.[3]

However, a review of the literature shows that the use of vascular catheters in patients with renal failure, especially in an intensive care unit (ICU) setting, is common in clinical practice and discordant with guidelines.[2,4]

On the other hand, the above-mentioned guidelines allow the placement of a vascular catheter in a patient with a life expectancy of less than 2 years.[3]

Many patients with severe CKD have poor prognosis. Othman et al.[2] reported an overall death rate for the year post PICC insertion of 38.7%. Because of this high mortality in the year after catheter insertion, only 8.1% of the patients with III B CKD or lower begin dialysis in the year post catheter insertion.

The Kidney Disease Improving Global Outcome[3] and the International Society of Nephrology[5] recommendations also highlight the interest of using prognostic scores to predict death or start of renal replacement therapy for shared medical decisions; the scores suggested are the GRAMS[6] and BANSAL[7] scores. Moreover, a recent review by Prouvot et al.[8] found other four equations (Schmidt et al.,[9] Weiss et al.,[10] Goldfarb-Rumyantzev et al.,[11] and Landray et al.[12]) predicting death before dialysis in CKD patients.

Unfortunately, none of these scores could be used in our study because they were only tested in a specific age or eGFR group or because they include laboratory parameters that are not routinely requested.

Many other mortality risk score are reported in the literature, the most commonly used is the Charlson Comorbidity Index (CCI)[13] that calculates the estimated mortality risk at 10 and 2 years; a newer and promising score is the Beclap score[14] assessing mortality of non-oncological patients at 3 and 6 months.

These simple tools could add a practical and more evidence-based, individualized approach for vascular access management in patients with CKD. They could provide a prognostic evaluation in order to perform a risks and benefits assessment, assuming that in patients with estimated high mortality rate at 2 years it could be acceptable to implant a peripherally inserted central vascular access if necessary.

Thus, the aim of this study is to carry out a global assessment of mortality at 2 years through Charlson Comorbidity Index (CCI)[13] and Beclap score,[14] in order to identify patients with poor survival prognosis, assuming they would not need chronic hemodialysis. We than verified that the follow up of these patients confirmed death within 2 years and no dialysis.

Methods

In this prospective observational study, we analyzed data on patients with PICCs or Midlines inserted from October 2018 to November 2019 in internal medicine wards at L. Sacco Hospital, Milan, Italy. All catheters were implanted by the local PICC-team composed of trained physicians or nurses. The devices have been positioned following the protocol "Safe insertion of PICCs (SIP)."[15] Written informed consent to vascular procedure and study participation was obtained for all study participants.

Eligible subjects were inpatients that required a PICC or a Midline catheter because of a difficult intravenous access (DIVA) or an expected need of intravenous therapy longer than 6 days. These were patients judged clinically suitable for catheter insertion. Exclusion criteria included stay in the Intensive Care Unit or ongoing dialysis.

Charlson Comorbidity Index,[13] Beclap score,[14] and renal function were calculated for each patient at the time of the catheter insertion in order to estimate patients' prognosis and to evaluate the presence of CKD at enrollment time. We then followed patients for 2 years through the SISS regional network system (Sistema Informativo Socio Sanitario) in order to assess patients' 2-year mortality.

In this way, the estimated prognosis calculated at the time of implantation could be compared with the effective mortality rate recorded at 2 years.

A subgroup analysis was then performed taking into account patients with eGFR <45 ml/min/1.73 m^2 and without an oncological disease at baseline.

The study protocol complied with the Declaration of Helsinki and the Institutional Review Board of our University Hospital (Luigi Sacco Hospital, University of Milan, Italy) approved the study protocol.

Data were expressed as mean $\pm$ standard deviation (normally distributed data), median, and interquartile range (non-normally distributed data) or as absolute frequency and percentage (binary or ordinal data), as appropriate. Chi square or Fisher exact tests were used in the group's comparison. Student T-test was used for comparison between groups. p-Value less than 0.05 was considered statistically significant. A ROC curve analysis was performed to identify the cut offs to be used as decision values. The cutoff chosen by ROC analysis was evaluated with a Kaplan-Meier curve.

The statistical analysis of data was done by using Excel (Office program 2016) and SPSS (statistical package for social science-SPSS, Inc., Chicago, IL version 20).

Results

A total of 131 patients were enrolled; the median age was 71.8 ± 15.4, 64 (48.9%) were males. The catheters implanted were 99 Midlines (75.5%) and 32 PICCs (24.5%).

Patients with an eGFR <45 ml/min/1.73/m^2 were 49 (37.4%), no one of the CKD patients required dialysis during the 2 years of follow-up. Only a woman began strict follow-up in a pre-uremic outpatient's clinic.

Two-year mortality rate was 57.3% (13.7% during the hospital stay, 43.5% after discharge). Charlson Comorbidity Index and Beclap score were on average respectively 5.98 ± 3.12 and 19.68 ± 20.74 (Table 1).

In the subgroup analysis, patients without oncological disease and those with eGFR <45 mL/min/1.73 m^2 were considered (respectively 94 and 49 patients). In the subgroup with reduced renal function we observed a significant lower albumin levels and a worst estimated prognosis with both CCI and Beclap score (CCI 5.98 ± 3.12 in the general population vs 6.92 ± 2.28 in patients with low eGFR with $p = 0.029$; Beclap score 19.68 ± 20.74 in the general population vs 33.37 ± 23.77 in reduced eGFR subgroup with $p < 0.01$). At 2-year follow-up patients with eGFR<45 mL/min/1.73 m^2 at baseline showed a significantly higher mortality compared to the general population (57.3% in the general population vs 75.51% in the low eGFR subgroup with $p = 0.024$; Table 1).

As expected, a significantly better prognosis was estimated with CCI for non-oncological patients compared to the general population (CCI 5.98 ± 3.12 in total population vs 5.24 ± 2.89 in no oncological disease subgroup, $p = 0.036$). At 2-year follow-up no difference in mortality rate was assessed comparing the whole population with non-oncological subgroup (57.3% in total population vs 53.19% in the subgroup with $p = 0.54$).

Figure1 shows the ROC curve for CCI and Beclap scores in the whole population. Figure 2 shows the ROC curve for patients without an oncological disease. Figure 3 shows the ROC curve for patients with eGFR <45 ml/min/1.73 m2.

Beclap and Charlson scores cut-off derived from ROC curves showed good sensitivity (SE) and specificity (SP) in predicting the 2-year mortality of the total population: in particular, a cut-off of 5 for CCI showed a sensitivity of 0.855 and a specificity of 0.717, while a cut-off of 15 for Beclap Score showed a sensitivity of 0.652 and a specificity of 0.917 (Figure 1).

Similar results were found in the subgroup of patients with an eGFR less than 45 ml/min/1.73 m^2 (CCI: SE = 0.902, SP = 0.647; for Beclap Score SE = 0.756, SP = 0.824; Figure 3) and without oncological disease (for CCI: SE = 0.795, SP = 0.74; for Beclap Score SE = 0.636, SP = 0.92; Figure 2).

Discussion

To the best of our knowledge, this study is the first to evaluate the parameter of estimated prognosis in patients with CKD and inserted peripheral vascular access, assuming that in patients with a high mortality risk at 2 years, it could be acceptable to implant a vascular access if necessary.

A review of the literature shows that the use of vascular catheters in patients with renal failure is common in clinical practice and discordant with guidelines.

Paje et al.,[4] in a big prospective cohort study of 20,545 patients, found that approximately one of four PICCs (23.1%) was inserted in patients with eGFR <45 ml/min/1.73 m^2; the median age of the studied population was 65.1 years. Similarly, Othman et al.[2] showed a proportion of 26.7% of patients with vascular access and stage III B or more advanced CKD. In our study the percentage of patients with severe CKD was 37.4%.

The rate of patients with vascular access and eGFR <45 ml/min/1.73 m^2 in our population is higher than in the literature, possibly because the higher mean age in our study (71.8 years) compared to the published studies (65.1 years). This makes the number of patients with CKD higher and the estimated prognosis worse.

Nevertheless, no patient required dialysis. This could be due to the small cohort examined, combined with the low incidence of developing end-stage renal disease reported by the literature. Turin et al.,[16] in a Canadian cohort of patients with eGFR 30–44 ml/min/1.73 m^2, reported the following lifetime risks of developing CKD requiring dialysis: at age 60, men 16.32%, women 8.19%; at age 70, men 6.44%, women 3.05%.

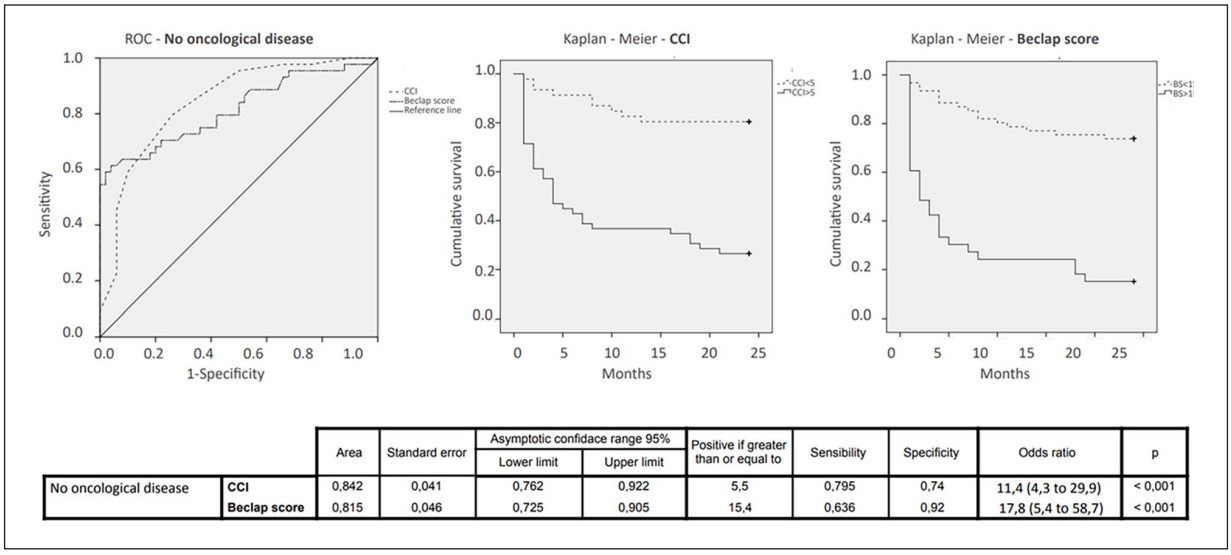
Algorithms presented in the literature leave up to the assessment of the doctor, in accordance with the guidelines, to decide on the implantation, considering the placement of a vascular catheter in a patient with a life expectancy of less than 2 years to be acceptable.[17] This strategy was also adopted during our enlistment. Nevertheless, assessing mortality is a difficult matter even for experienced physicians and is often affected by subjective bias, so results may change depending on the evaluator. Based on this issue, it is fundamental to find an objective instrument that could help clinicians to solve this problem.

The scores used in our study provide a simple tool that can be easily implemented and quickly interpreted by nurses or staff without specific knowledge. Such scores have also been shown to accurately predict short-term mortality: in the general population, the odds ratio for CCI greater than 5 was 17.4 (CI: 6.5–46.6), and for Beclap score greater than 15 was 42.9 (CI: 13.3–138.3). This

Table 1. Characteristics of patients at baseline and at follow-up in total population, in the subgroup of patients without an oncological disease and in patients with eGFR <45 ml/min/1.73 m^2.

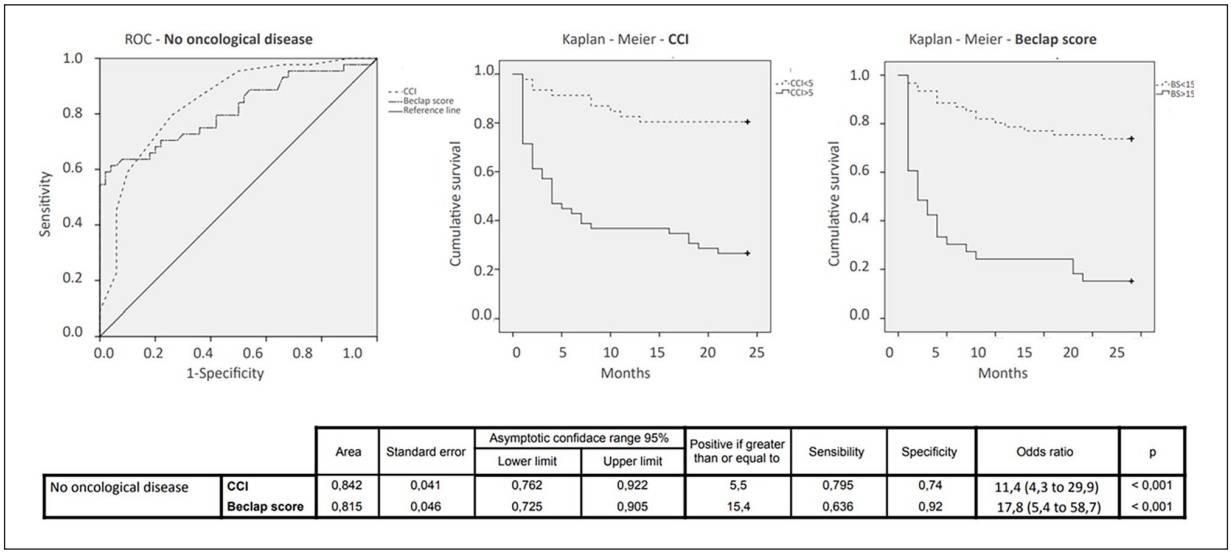
	A. Total population	B. No oncological disease	C. eGFR <45 ml/min/1.73 m^2	*p* value (A vs B)	*p* value (A vs C)
	N = 131	*N* = 94	*N* = 49		
Age (mean ± SD)	71.8 ± 15.4	70.25 ± 16.9	80.71 ± 7.46	0.239	0.5
Sex = M (%)	64 (48.9%)	41 (43.6%)	21 (42.86%)	0.437	0.473
Sex = F (%)	67 (51.1%)	53 (56.3%)	28 (57.14%)		
PICC	32	23	15		
Midline	99	71	34		
Dwell time (mean ± SD)	16.7 ± 12.3	16.95 ± 12.5	15.11 ± 8.54	0.438	0.211
Base line					
Creatinine mg/dl (mean ± SD)	1.23 ± 0.76	1.20 ± 0.8	1.89 ± 0.82	0.418	**<0.01**
eGFR ml/min/1.73 m^2 (mean ± SD)	67.52 ± 45.91	73.27 ± 50.2	29.92 ± 10.26	0.19	**<0.01**
eGFR <45 ml/min/1.73 m^2	49 (37.4%)	31 (33%)		0.83	
eGFR <30 ml/min/1.73 m^2	27 (20.6%)	18 (19.1%)		0.787	
Albumine (mean ± SD)	27.52 ± 5.66	28.09 ± 5.8	25.77 ± 5.26	0.228	**0.032**
Follow up					
Creatinine (mean ± SD)	1.17 ± 0.87	1.2 ± 0.96	1.78 ± 1.15	0.451	**<0.01**
eGFR ml/min/1.73 m^2 (mean ± SD)	70.54 ± 43.98	72.89 ± 47.71	34.63 ± 15.38	0.398	**<0.01**
eGFR <15 ml/min/1.73 m^2	3 (2.3%)	3 (3.13%)		0.679	
Prognosis index					
Charlson comorbidity index (mean ± SD)	5.98 ± 3.12	5.24 ± 2.89	6.92 ± 2.28	**0.036**	**0.029**
Beclap score (mean ± SD)	19.68 ± 20.74	17.42 ± 19.65	33.37 ± 23.77	0.208	**<0.01**
Complications					
Dislodgment (%)	6 (4.6%)	4 (4.3%)	2 (4%)		
Catheter related thrombosis (%)	2 (1.5%)	1 (1%)	1 (2%)		
Catheter related bloodstream infection (%)	0	0	0		
Mortality					
Inpatients	18 (13.7%)	16 (17.02%)	11 (22.45%)		
Outpatients	57 (43.51%)	34 (36.17%)	26 (53.06%)		
Total	75 (57.3%)	50 (53.19%)	37 (75.51%)	0.545	**0.024**

The bold are significant p value <0.05.



		Area	Standard error	Asymptotic confidace range 95%		Positive if greater than or equal to	Sensibility	Specificity	Odds ratio	p
				Lower limit	Upper limit					
No oncological disease	**CCI**	0,842	0,041	0,762	0,922	5,5	0,795	0,74	11,4 (4,3 to 29,9)	< 0,001
	Beclap score	0,815	0,046	0,725	0,905	15,4	0,636	0,92	17,8 (5,4 to 58,7)	< 0,001

Figure 1. ROC and Kaplan Meier curves evaluating mortality scores in total population.



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No oncological disease	**CCI**	0,842	0,041	0,762	0,922	5,5	0,795	0,74	11,4 (4,3 to 29,9)	< 0,001
	Beclap score	0,815	0,046	0,725	0,905	15,4	0,636	0,92	17,8 (5,4 to 58,7)	< 0,001

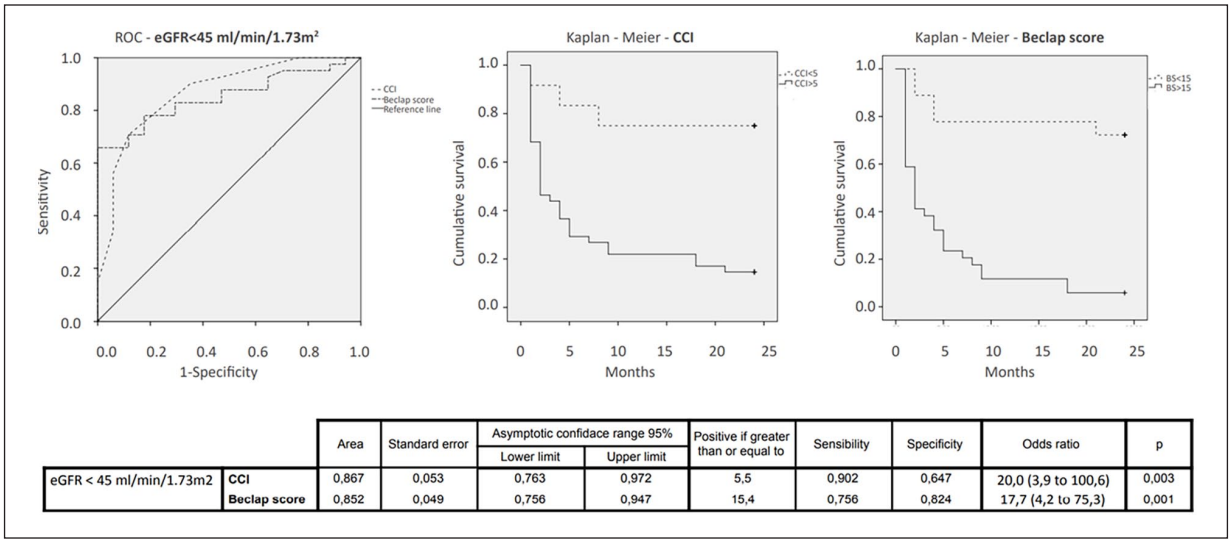
Figure 2. ROC and Kaplan Meier curves evaluating mortality scores in patients without an oncological disease.

demonstrates the validity of these scores and the chosen cut-offs. Moreover, the combined use of the two scores balances the weakness of single tool: CCI's cut off has high SE and low SPE, Beclap score is specular with high SPE and low SE.

Although this is a small observational study with a limited number of patients and further research is needed to make this evidence stronger, considering the data collected we propose a new decision algorithm for vascular access insertion in patients with CKD.

In particular, our new algorithm suggests the insertion of PICCs or Midline catheters in cases of eGFR >45 ml/min/1.73 m^2 or in cases of eGFR <45 ml/min/1.73 m^2 but high probability of death at 2 years (Beclap score >15 points, CCI >5 points). Catheter insertion is not recommended in patients with advanced CKD stage III B or more but with a good chance of survival at 2 years and therefore a high probability of dialysis, in order to preserve vascular access for possible future dialysis. (Figure 4). In patients with Beclap score <15 and CCI >5 or with Beclap score >15 and CCI <5 a case-by-case evaluation of the specialist is necessary. CCI and Beclap score discordance occurred in 29.8% of the total study population and 20.4% of patients with eGFR <45 ml/min. Using the proposed algorithm, only about one in five cases would then need the specialist's case-by-case evaluation.

Certainly, in those patients in whom it is decided to implant a PICC or a Midline after applying the score, it is



		Area	Standard error	Asymptotic confidace range 95%		Positive if greater than or equal to	Sensibility	Specificity	Odds ratio	p
				Lower limit	Upper limit					
eGFR < 45 ml/min/1.73m2	**CCI**	0,867	0,053	0,763	0,972	5,5	0,902	0,647	20,0 (3,9 to 100,6)	0,003
	Beclap score	0,852	0,049	0,756	0,947	15,4	0,756	0,824	17,7 (4,2 to 75,3)	0,001

Figure 3. ROC and Kaplan Meier curves evaluates patients with eGFR <45 m/min/1.73 m^2.

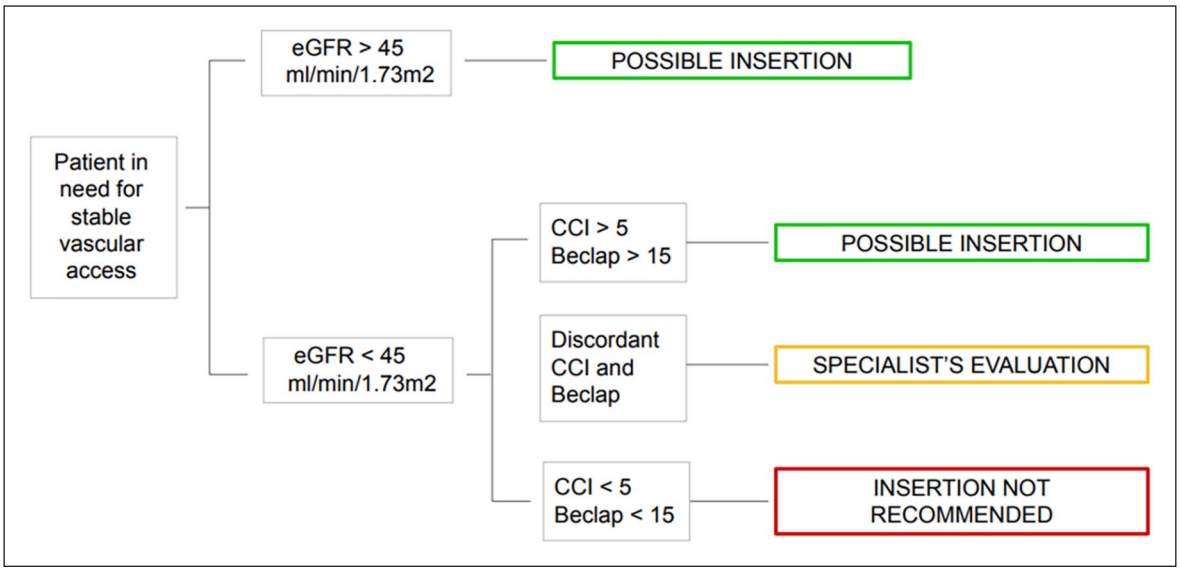


Figure 4. The proposed algorithm tries to determine the possibility to place a vascular access line given the patient's renal function, Beclap score, and CCI.

good practice to apply all precautions to minimize the risk of complications. For example, it is known that limiting the catheter's diameter may reduce the risk of PICC or Midline related venous thrombosis.[2,18,19]

We note some limitations of our findings. First, this report includes a limited number of patients; furthermore, this is a single-center study enrolling patients admitted to an internal medicine department; finally, Beclap score has been validated by only one study.[14] For these reasons our results require confirmation in larger multicenter studies.

In conclusion, we can affirm that CCI and Beclap score are good predictors of 2 years mortality in patients with PICC or Midline catheters.

Nephrologists, physicians, and nurses can use these tools before insertion of the catheters in the evaluation of patients at risk for future dialysis, instead of relying exclusively on renal function to decide whether implanting peripheral venous accesses.

Indeed, in many cases the need for reliable vascular access for infusion of drugs such as antibiotics, hydration or diuretics is crucial for the patient and can significantly change the subject's quality of life and outcomes.

Furthermore, this tool could be useful to identify the frailest patients that could benefit more from a nephrological consultation focused on improving their prognosis and not only to allow vascular access implantation.

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Declaration of conflicting interests

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Data availability statement

The data supporting the findings of this study are available from the corresponding author upon reasonable request.

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