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ORIGINAL RESEARCH

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Relationship between a diagnosis of kidney failure and heart diseases in patients with hyperkalemia

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ABSTRACT

Objectives: This study seeks to determine the association between kidney failure and heart diseases by examining how they influence the diagnosis of hyperkalemia.

Methods: We employ a fuzzy regression discontinuity design (RDD) by harnessing the inherent threshold in potassium levels, which serves as a diagnostic criterion for hyperkalemia. Simultaneously, we utilize patient diagnosis data related to kidney failure and heart diseases. This approach allows us to evaluate the causal impact of both diagnoses on hyperkalemia.

Results: Significant overall increases in the risk of developing hyperkalemia are evident subsequent to a diagnosis of kidney failure or heart disease. The study finds that the probability of receiving a kidney failure diagnosis increases by 11.2% regarding a cut-off of 6 mEq/L of potassium. In addition, there is a 6.8% likelihood of experiencing hyperkalemia in the case of a prior diagnosis of hypertension, and an 8.8% probability in the case of a diagnosis of depression. The findings remain robust when considering alternative parametric and non-parametric specifications as well as placebo tests.

Conclusions: This study provides new empirical insights into the causal impact of kidney failure and heart disease, underscoring the significance of monitoring such patients to prevent serious complications in the future.

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1. Introduction

Hyperkalaemia can be caused by several acute and chronic conditions that upset the delicate balance of potassium levels in the body[1]. Frequently, it is linked to pre-existing factors like moderate or severe kidney disease, heart failure, diabetes mellitus, or substantial tissue injuries[2]. Elevated potassium levels, a potentially life-threatening disruption of electrolyte balance, often appear in individuals with kidney problems, especially those affected by tubular disorders and reduced glomerular filtration rates, as well as in cases of heart diseases[3,4]. Patients undergoing dialysis for end-stage renal failure deserve special attention because the risk of hyperkalemia can be influenced by various factors related to their dialysis treatment[5]. Heart failure patients face an elevated risk of hyperkalemia due to various factors, including diminished renal function associated with heart failure, advancing age, and the presence of comorbid conditions like diabetes mellitus, all of which impede the body's ability to effectively eliminate excess potassium from the system[6]. In addition, the treatment of some diseases like chronic kidney disease or chronic heart failure includes drugs that increase potassium levels; thus, hyperkalemia may be iatrogenic in many patients[7].

Hyperkalaemia stands out as a particularly critical concern due to its potential to lead to arrhythmias, which can result in the potential development of life-threatening cardiac arrhythmias[5,6]. It slows down the conduction of signals within the heart muscle and speeds up the repolarization phase, leading to specific changes in the surface electrocardiogram (ECG) that are well-documented[8].

Despite this knowledge, research has revealed that identifying patients with severe hyperkalemia can be a complex task, leading to delays in administering the appropriate treatment for this condition[8]. Even with prompt and suitable medical intervention, individuals afflicted by severe hyperkalemia may encounter a mortality rate exceeding 30%[1].

This study seeks to determine the association between kidney failure and heart diseases by examining how they influence the diagnosis of hyperkalemia.

2. Materials and methods

2.1. Study population and setting

The data used in this study were obtained from the de-identified and anonymized BIG-PAC database, which is administered by experts specializing in Big Data Healthcare on Atrys Health, formerly known as Real Life Data[9]. The

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BIG-PAC database comprises information from 1.9 million patients who received treatment at healthcare centers in Spain, encompassing seven regional health systems. This database is a component of the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, an interconnected group of institutions overseen by the European Medicines Agency. Member organizations within this network consist of public institutions and contractual and research entities dedicated to pharmacoepidemiological and pharmacovigilance research. In accordance with the Organic Law on Data Protection (Organic Law 3/2018 of 5 December), the BIG-PAC database has been stripped of any data that could be used to identify individual patients.

The study included adult patients (aged 18 years or older) who had been diagnosed with hyperkalemia through the corresponding International Classification of Diseases 9th revision (ICD 9) and 10th revision (ICD 10) codes. The ICD 9 code for hyperkalaemia is 276.7, and the ICD 10 code is E87.5. These patients were further diagnosed with chronic kidney disease (CKD), heart failure, or diabetes mellitus, and they required medical attention for a hyperkalemic episode occurring between 1 January 2011 and 31 December 2018, in Spain. Exclusion criteria comprised individuals taking potassium supplements, patients with Addison's disease, congenital adrenal hyperplasia, or hyperkalemic periodic paralysis, individuals with incomplete or inconsistent data, and patients who passed away during the study duration[10].

2.2. Study variables

In this study, hyperkalemia was treated as a dependent variable and categorized into mild (5.0–5.9 mEq/L), moderate (6.0–6.4 mEq/L), or severe (>6.5 mEq/L)[3]. The sociodemographic factors considered included age and gender. Pre-existing clinical diagnosis considered consisted of hypertension, diabetes, dyslipidemia, obesity, smoker, heart disease, stroke, asthma, COPD, depression, neoplasm, heart, and kidney failure. More specifically, kidney failure and heart failure were identified by a binary variable that takes the value 1 if the patient is diagnosed with the diseases through the corresponding ICD 9 and ICD 10 codes and 0 otherwise. The medical records also include data on potassium levels that are commonly used to diagnose hyperkalemia. In our setting, physicians followed the national and international medical guidelines for patients with hyperkalemia, and potassium levels were used to stratify hyperkalemia patients into different groups.

In addition, the data include clinical variables, such as systolic and diastolic blood pressure (mmHg), body mass index, heart failure severity, Charlson comorbidity index (CCI), serum creatinine, glomerular filtration rate, renal disease stage, and associated comorbidities. Also, variables associated with the use of health services due to HK included hospitalization, emergency department medical visits, and medical specialist visits whose codes were related to HK were included.

2.3. Experimental methodology

A fuzzy regression discontinuity design (RDD) is utilized to take advantage of the natural break provided by the external threshold of 6.0 mEq/L for initial potassium levels utilized in the diagnosis of moderate hyperkalaemia[3]. We choose to follow a fuzzy design because physicians use more than the potassium levels to diagnose hyperkalemia, as suggested by the clinical guidelines[3,11]. Specifically, doctors use ECG changes to determine the diagnosis and severity of hyperkalemia, according to KDIGO and ESC guidelines[3,11].

Fuzzy RDD enables inferences of causality in a similar way to randomized controlled trials[12,13]. RDD can be implemented in scenarios where a cut-off rule is used to determine treatment assignment. In this setting, a continuous variable is used to determine whether an individual is assigned to treatment. Treatment assignment according to a concrete rule can be deterministic (all patients on one end of the cut-off receive the treatment and all patients on the other end do not) or probabilistic (the likelihood of receiving the treatment is higher on one end of the cut-off than on the other). A fuzzy RDD estimation is comparable to a two-stage least squares instrumental variable (2SLS-IV) model[14]. The 2SLS-IV model is described as a combination of two different equations[15]. The first-stage equation represented a dummy indicator for whether an individual was diagnosed with hyperkalemia at a given time. This dummy variable has considered other variables, including a covariate that is the centered or normalized potassium level[15].

For the second-stage equation estimation, there are two main alternatives to determine the discontinuity magnitude in the potassium level outcome: the parametric and the non-parametric approach. We have considered high order polynomials of the running variable. However, we assessed the robustness of the results by using linear polynomials and non-parametric estimations. With this second-stage equation, we estimated whether an individual was diagnosed with kidney failure or heart disease after being diagnosed with hyperkalemia.

3. Results

We first investigate whether it exists any noteworthy distinctions in predetermined attributes at the designated cut-off point. Our aim is to ideally discover no discernible impacts of the diagnosis on these attributes. Figures 1 and 2 display the graphical representation of the regression discontinuity for pre-diagnosis kidney failure, heart failure, and associated factors in relation to the potassium levels. These findings affirm the soundness of our experimental approach, as they demonstrate no significant discontinuities overall at the threshold for any of these variables.

Table 1 presents fuzzy regression discontinuity design (RDD) estimates for the relationship between a diagnosis of moderate or severe hyperkalemia and the likelihood of being diagnosed with kidney failure, with a cut-off of 6 mEq/L. On the other hand, in Table 2, you can find identical results for a cut-off value of 5.5 mEq/L. The first column contains the fundamental

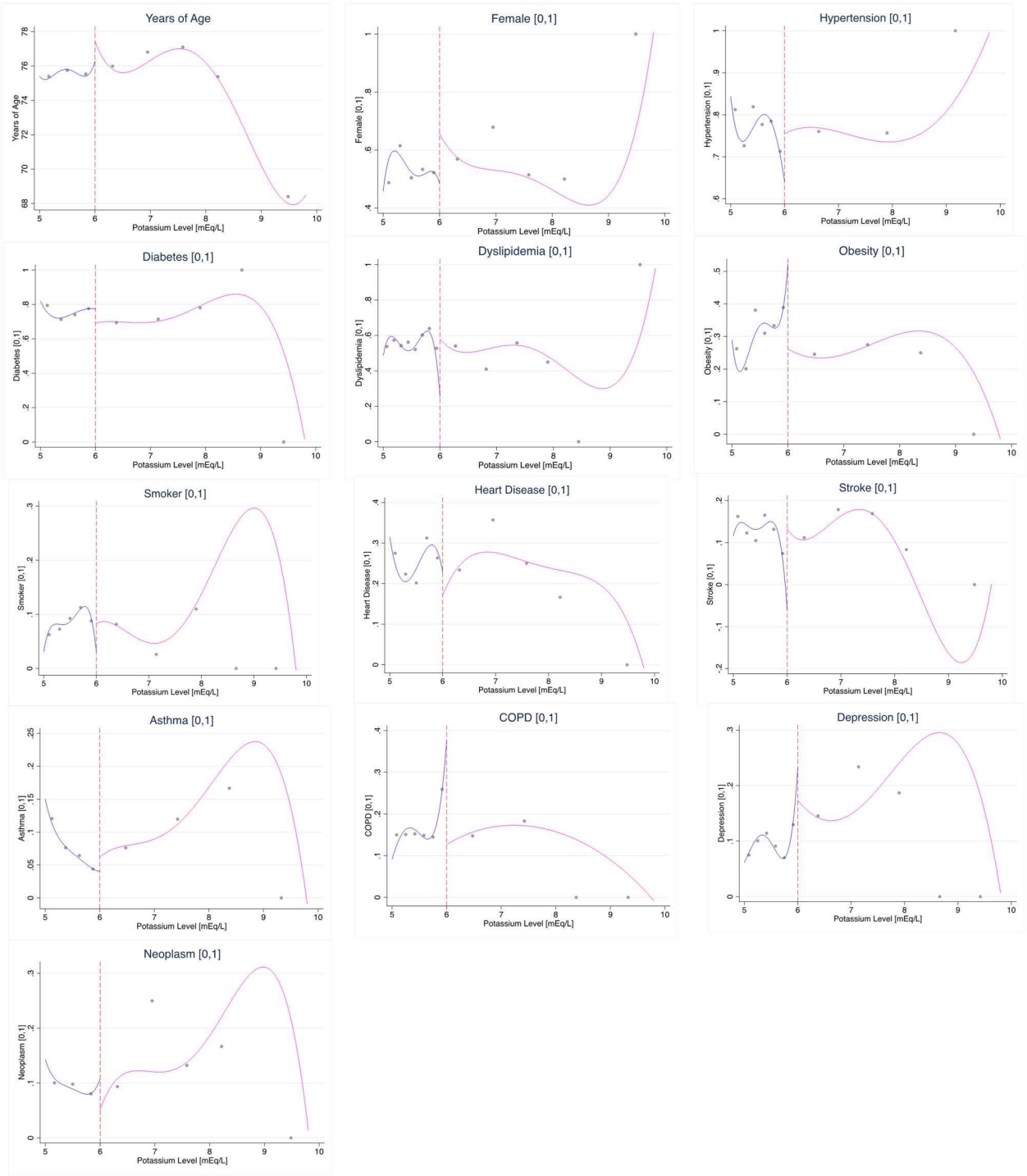

Figure 1. Continuity test.

or base estimates with no additional factors or covariates considered. The second column incorporates a set of sociodemographic attributes into the analysis, adding a layer of complexity to the estimation. The third column extends the analysis by introducing dummy variables that indicate the presence of pre-existing medical conditions, providing a more comprehensive and refined understanding of the data.

It can be observed a notable and statistically significant increase in the likelihood of kidney failure diagnosis before a diagnosis of hyperkalemia. According to our preferred model (column 3), the probability of receiving a kidney failure diagnosis increases by 11.2% regarding a cut-off of 6 mEq/L. With a cut-off value of 5.5 mEq/L, the results did not show statistical significance, as the *p*-value exceeded 0.05. Moreover, it is noted that there is a 6.8% likelihood of experiencing hyperkalemia in the case of a prior diagnosis of hypertension and an 8.8% probability in the case of a diagnosis of depression.

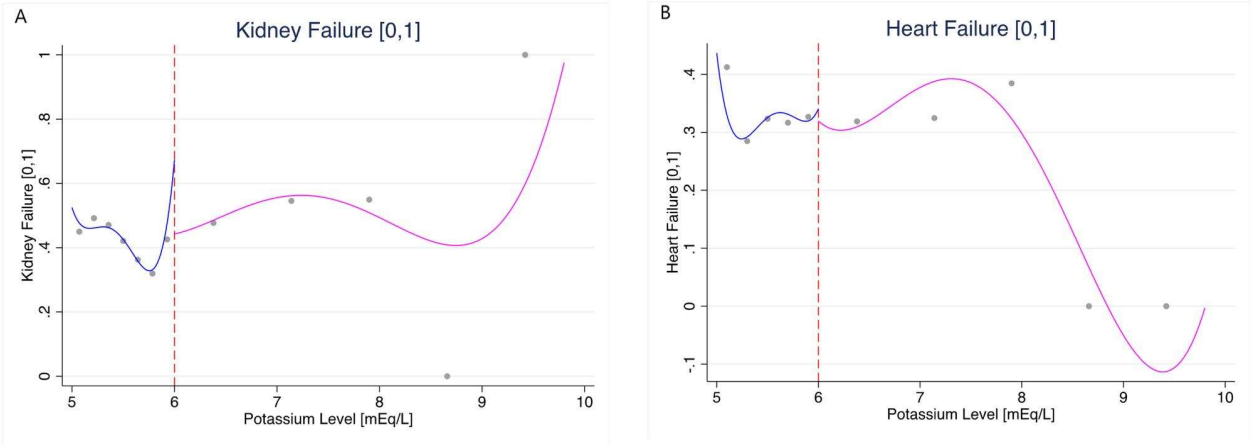

Figure 2. (A) Continuity test for kidney failure. (B) Continuity test for heart failure.

Table 1. Fuzzy RDD estimates of the impact of kidney failure diagnosis on severe hyperkalemia (cut-off: 6 mEq/L).

	(1)	(2)	(3)
Moderate or severe hyperkalemia [0,1]	0.116* (0.057)	0.116* (0.057)	0.112* (0.055)
Attributes			
Female [0,1]	–	0.041 (0.026)	0.036 (0.025)
Years of age	–	0.004* (0.001)	0.003 (0.001)
Pre-existing conditions			
Hypertension [0,1]	–	–	0.068* (0.029)
Diabetes [0,1]	–	–	−0.306* (0.024)
Dyslipidemia [0,1]	–	–	0.011 (0.025)
Obesity [0,1]	–	–	0.025 (0.028)
Smoker [0,1]	–	–	−0.047 (0.043)
Heart disease [0,1]	–	–	0.047 (0.029)
Stroke [0,1]	–	–	−0.002 (0.036)
Heart failure [0,1]	–	–	−0.105* (0.028)
Asthma [0,1]	–	–	−0.025 (0.049)
COPD [0,1]	–	–	0.036 (0.035)
Depression [0,1]	–	–	0.088* (0.038)
Neoplasms [0,1]	–	–	0.037 (0.041)
Observations	1,505	1,505	1,505

The table reports Fuzzy RDD estimates of the impact of kidney failure diagnosis on hyperkalemia. Standard errors are clustered on the running variable.
*$p < 0.05$.

Table 2. Fuzzy RDD estimates of the impact of kidney failure diagnosis on severe hyperkalemia (cut-off: 5.5 mEq/L).

	(1)	(2)	(3)
Moderate or severe hyperkalemia [0,1]	0.032 (0.120)	0.022 (0.120)	0.075 (0.115)
Attributes			
Female [0,1]	–	0.044 (0.026)	0.039 (0.025)
Years of age	–	0.004* (0.001)	0.003 (0.001)
Pre-existing conditions			
Hypertension [0,1]	–	–	0.070* (0.030)
Diabetes [0,1]	–	–	−0.310* (0.024)
Dyslipidemia [0,1]	–	–	0.009 (0.026)
Obesity [0,1]	–	–	0.017 (0.028)
Smoker [0,1]	–	–	−0.055 (0.045)
Heart disease [0,1]	–	–	0.044 (0.029)
Stroke [0,1]	–	–	−0.004 (0.036)
Heart failure [0,1]	–	–	−0.107* (0.028)
Asthma [0,1]	–	–	−0.013 (0.050)
COPD [0,1]	–	–	0.034 (0.035)
Depression [0,1]	–	–	0.102* (0.038)
Neoplasms [0,1]	–	–	0.043 (0.041)
Observations	1,505	1,505	1,505

The table reports Fuzzy RDD estimates of the impact of kidney failure diagnosis on hyperkalemia. Standard errors are clustered on the running variable.
*$p < 0.05$.

Table 3. Fuzzy RDD estimates of the impact of heart disease diagnosis on hyperkalemia (cut-off: 6 mEq/L).

	(1)	(2)	(3)
Moderate or severe hyperkalemia [0,1]	0.134* (0.057)	0.123* (0.057)	0.124* (0.057)
Attributes			
Female [0,1]	–	−0.018 (0.024)	−0.015 (0.024)
Years of age	–	0.004* (0.001)	0.004* (0.001)
Pre-existing conditions			
Hypertension [0,1]	–	–	−0.024 (0.028)
Diabetes [0,1]	–	–	0.073* (0.029)
Dyslipidemia [0,1]	–	–	0.039 (0.025)
Obesity [0,1]	–	–	−0.021 (0.027)
Smoker [0,1]	–	–	0.109* (0.045)
Heart failure [0,1]	–	–	0.135* (0.028)
Stroke [0,1]	–	–	0.016 (0.036)
Kidney failure [0,1]	–	–	0.025 (0.025)
Asthma [0,1]	–	–	−0.015 (0.045)
COPD [0,1]	–	–	0.035 (0.034)
Depression [0,1]	–	–	−0.024 (0.038)
Neoplasms [0,1]	–	–	−0.021 (0.039)
Observations	1,505	1,505	1,505

The table reports Fuzzy RDD estimates of the impact of heart failure diagnosis on hyperkalemia. Standard errors are clustered on the running variable.
*$p < 0.05$.

Table 4. Fuzzy RDD estimates of the impact of heart disease diagnosis on hyperkalemia (cut-off: 5.5 mEq/L).

	(1)	(2)	(3)
Moderate or severe hyperkalemia [0,1]	0.126 (0.112)	0.105 (0.112)	0.097 (0.111)
Attributes			
Female [0,1]	–	−0.012 (0.024)	−0.011 (0.024)
Years of age	–	0.004* (0.001)	0.004* (0.001)
Pre-existing conditions			
Hypertension [0,1]	–	–	−0.025 (0.028)
Diabetes [0,1]	–	–	0.073* (0.028)
Dyslipidemia [0,1]	–	–	0.036 (0.024)
Obesity [0,1]	–	–	−0.032 (0.027)
Smoker [0,1]	–	–	0.099* (0.045)
Heart failure [0,1]	–	–	0.133* (0.027)
Stroke [0,1]	–	–	0.014 (0.035)
Kidney failure [0,1]	–	–	0.037 (0.026)
Asthma [0,1]	–	–	−0.002 (0.046)
COPD [0,1]	–	–	0.031 (0.034)
Depression [0,1]	–	–	−0.011 (0.037)
Neoplasms [0,1]	–	–	−0.014 (0.040)
Observations	1,505	1,505	1,505

The table reports Fuzzy RDD estimates of the impact of heart failure diagnosis on hyperkalemia. Standard errors are clustered on the running variable.
*$p < 0.05$.

Table 3 provides fuzzy RDD estimates for the association between a diagnosis of moderate or severe hyperkalemia and the probability of being diagnosed with heart failure, employing a cut-off point of 6 mEq/L. In contrast, Table 4 offers the same results for a cut-off value of 5.5 mEq/L.

The study findings reveal distinctive patterns. We observed a noteworthy and statistically significant upsurge in the likelihood of being diagnosed with heart disease before hyperkalemia in our study. In line with our preferred model (column 3), the probability exhibits a 12.4% increase following a hyperkalemia diagnosis, specifically when the cut-off value is set at 6 mEq/L. Notably, when the cut-off value is lowered to 5.5 mEq/L, our results did not display statistical significance, as the associated *p*-value exceeded the 0.05 threshold. Additionally, our analysis points out the following associations: a 7.3% likelihood of developing hyperkalemia after a prior diagnosis of diabetes, a 10.9% probability if the patient is a smoker and a 13.5% chance of experiencing hyperkalemia in the event of a heart failure diagnosis.

4. Discussion

No discontinuities have been shown in any of the variables when assessed. Regarding the Fuzzy regression, a notable and statistically significant increase in the likelihood of kidney failure diagnosis before a diagnosis of hyperkalemia was identified. The increased probability of receiving a kidney failure diagnosis is 11.2% in patients with hyperkalemia.

The occurrence of hyperkalemia in hospitalized patients varies between 1.3 and 10%[16,17]. It fluctuates based on the specific patient group under investigation and the criteria used to define it[18]. Some use a cut-off to define moderate hyperkalemia of 6.0 mEq/L, while others use a cut-off of 5.5 mEq/L[3,10]. It is observed that with a cut-off of 6 mEq/L, the results are statistically significant, whereas with a cut-off of 5.5 mEq/L, the results do not reach significance. The primary risk factor for the development of hyperkalemia is impaired kidney function, which is present in 33–83% of all cases[17]. Impaired kidney function is commonly known to

result in the mentioned outcome[19,20]. Conversely, it represents a life-threatening concern frequently encountered by individuals with heart failure[21]. It is apparent in Tables 1 and 3. Patients with heart failure often exhibit a significant occurrence of chronic kidney disease, thereby increasing the susceptibility to hyperkalaemia[22].

As evident from Tables 3 and 4, a relationship is observed between individuals with hyperkalemia and those who have diabetes. It is more common in individuals with diabetes mellitus than in the overall population[23]. Individuals with concurrent medical conditions, such as insulin deficiency, are at a higher risk of developing hyperkalaemia[24]. A relationship was found between kidney failure and depression, this could be elucidated by the fact that individuals suffering from different types of chronic illnesses often bear a significant load of physical symptoms, a reduced quality of life, and limitations in their daily activities, which can potentially make them more susceptible to developing depression[23]. Lastly, a correlation was found between smoking and the occurrence of hyperkalemia, possibly because cigarette smoking has been linked to multiple factors associated with cardiac dysfunction[25].

Regarding the data period that has been used for this study, although it could be considered a bit aged, it is not critical for the results of this study because hyperkalemia is not a clinical area that has experienced disruptive events in diagnosis or therapy. Therefore, we considered the data to be appropriate for this study, as the results may be independent of the time at which the data were obtained.

Although clinicians are aware of the side effects of an increase in serum potassium level of some drugs to treat patients with kidney and heart disease and they are monitoring the potassium level of these patients closely, it seems that new monitoring methods or a closer monitorization of these patients is needed.

5. Conclusions

Our findings indicate a statistically significant association of both kidney failure and heart diseases in the diagnosis of hyperkalemia. To be more specific, there are notable overall increases in the risk of developing hyperkalemia following a diagnosis of kidney failure or heart disease. Our findings may suggest a potential policy recommendation, which entails closely monitoring individuals at risk of hyperkalemia. This monitoring should aim not only to mitigate the expected physical health complications but also to proactively prevent the development of other significant health conditions, such as kidney failure or heart diseases. This close monitoring can lead to a reduction in healthcare costs by reducing the number of visits to doctors, emergency rooms, and other healthcare resources.

Transparency

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Declaration of financial/other relationships

The authors affirm that they do not have any conflict of interest.

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

Authors contributions

JD played a significant role in the investigation, particularly in result analysis and substantial intellectual content revision. AA and MA were responsible for analyzing and interpreting the statistical data and made substantial contributions to manuscript writing. All authors have reviewed and approved the final manuscript.

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Data availability statement

Atrys Health, formerly Real Life Data, supplied data under an agreement that does not allow researchers to share the database with any other third party.

Ethical approval

This research did not entail the participation of human subjects, and it did not entail access to identifiable information. Consequently, in this instance, Spanish legislation does not necessitate patient consent or ethics committee approval. There was no disclosure of healthcare centers or medical histories, and to uphold anonymity in accordance with the principles of Good Clinical Practice and the Declaration of Helsinki, all records underwent recoding.

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