BACKGROUND

• Hyperkalemia (HK) refers to an increased serum potassium concentration in the blood, due to the disabled excretion of potassium in the kidney. [1,2]

• Hyperkalemia can lead to muscle weakness. Furthermore, critical effects on cardiac conduction, arrhythmias or sudden death are also reported. [3]

• It commonly occurs in patients with chronic kidney disease (CKD), heart failure (HF) or diabetes mellitus (DM). HK can be amplified by medications, e.g. inhibitors of the renin-angiotensin-aldosterone system (RAAS).

• There are deviating treatment options for HK, which depend on if HK is considered as acute or chronic. Acute - often life threatening - HK is associated with serious health effects and is most treatable inpatient. Chronic HK creates the necessary continuous treatment and monitoring and in turn is associated with outpatient treatment.

• The aims of this study were to assess health-relevant outcomes of non-acute outpatient treated HK patients and in particular chronic HK patients and to compare healthcare costs as well as dialysis initiation between HK patients and non-HK patients. Additionally, specified underlying comorbidities and treatment patterns of HK patients were assessed.

METHODS

• A retrospective study design was applied using claims from the “Institut für angewandte Gesundheitsforschung, Berlin” (inGeF) research database, which includes approximately 4 million covered lives structured to represent the German population in terms of age and gender (structure of index and gender according to the Federal Office of Statistics (DESTATIS)).

• For this analysis, data from January 1st, 2014 through December 31st, 2016 was used. The index period for the patient selection spanned from January 1st, 2015 through December 31st, 2015, to allow for an individual pre-index period of 4 quarters (Q1/2014 to Q3/2015) as well as an individual post-index period including the index quarter (defined as the first observable HK diagnosis or prescription of polystyrene sulfonate in 2015) and 3 consecutive quarters (Q1/2015 to Q3/2016).

• Two cohorts of HK patients, those with non-acute outpatient treated HK (cohort 1a) and with chronic HK (cohort 1b), were identified in the database based on ICD-10-GM (International Statistical Classification of Diseases and Related Health Problems, 10th revision, German Modification) diagnoses codes of E87.5 “Hyperkalemia” or prescriptions of polystyrene sulfonate (Anatomical-therapeutic-chemical classification system (ATC) code: V03AE01), which indicates necessary HK treatment. Due to the strongly deviating treatment options of acute life-threatening and chronic hyperkalemia, solely inpatient treated hyperkalemia considered as life-threatening, was excluded from the analysis.

• Assignment of patients to cohort 1a and 1b is displayed in Figure 1.

• Each identified hyperkalemia patient of cohort 1a and cohort 1b was matched 1:1 to a patient without hyperkalemia.

• Patient characteristics of both HK cohorts were assessed by including demographics in the index quarter. Specified underlying comorbidities, such as CKD, HF and diabetes mellitus type 2 (T2DM) as well as the updated Charlson Comorbidity Index (CCI) were assessed and classified as pre-index period.

• All-case and HK-related hospitalizations were analyzed in the 3 quarters following the index quarter in terms of numbers of patients with hospitalization and days of hospitalization. The index quarter was not taken into account as the number of hospitalizations in the index quarter was used as matching parameter.

• Concomitant treatment was identified by ATC codes. Additionally, prescriptions were analyzed in terms of mean number of prescriptions for SPS/CPS.

• Healthcare costs in the post-index period were assessed in total and stratified by different healthcare sectors. The cost assessment was conducted for all HK patients of cohort 1a and 1b with the respective comparison groups.

• Time to dialysis initiation was assessed for all HK patients suffering from CKD (all stages) who did not have dialysis in the pre-index period and was analyzed using the Kaplan-Meier method.

RESULTS

• In total, 3,333 patients with non-acute outpatient treated HK and 1,692 chronic HK patients who were at least 18 years of age were identified in the database in 2015.

• Non-acute outpatient treated HK patients (1a) were 70.6 years old on average (SD: 13.3, range: 18-102) and chronic HK patients (1b) were 71.2 years old on average (SD: 12.7, range: 21-101). 42.6% of the non-acute HK patients and 43.9% of the chronic HK patients were female.

• CKD had the highest prevalence of the specified underlying comorbidities with 52.1% among outpatient treated (1a) and 50.8% among chronic HK patients (1b). When considering patients with CKD, most patients (91.3%) and cohort 1a (93.3%) had CKD stage 5. Of these patients with CKD stage 5, 81.7% (1a) and 80.1% (1b) received dialysis treatment, indicated by the respective dialysis treatment coding.

• HF had the lowest prevalence of the specified underlying comorbidities with 20.4% in the outpatient HK cohort (1a) and 18.9% in the chronic HK cohort (1b), respectively.

• Most patients in both cohorts presented with CKD and T2DM and no HF (17.5% and 17.4%) when considering different combinations of distinct comorbidities (see Table 1).

• The assessment of SPS/CPS prescriptions, indicated for the treatment of hyperkalemia, showed that 73.3% of the outpatient treated and 79.0% of the chronic HK patients did not receive specific HK related treatment. Patients who were treated with SPS/CPS had on average 3.4 prescriptions (1a) and 5.1 prescriptions (1b) (see Figure 2).

• The proportion of patients with dialysis initiation events was over twofold higher for both cohorts 1a and 1b with 118 (10.5%) and 51 (8.7%) in comparison to their matched controls 62 (4.8%) and 28 (4.2%), respectively.

• However, the average time until dialysis initiation was significantly higher for both hyperkalemia cohorts in comparison to their matched counterparts (1a mean in quarters 1.3 vs. 2a mean in quarters 1.0; ps0.01 and 1b mean in quarters 1.0 vs. 2b mean in quarters 0.8; ps0.01) (see Table 2).

CONCLUSIONS

• To our knowledge, this is the first study in Germany assessing the burden of hyperkalemia irrespective of the concomitant diseases. However, this study should be noted that, similar to previous analyses, patients are multi-morbid and present with an increased prevalence of CKD, HF and diabetes.

• The disease burden of patients with outpatient treated or chronic hyperkalemia was significantly higher than in their matched controls, suggesting a necessity for treatment improvement.

• Only a minority of patients suffering from HK receive specific potassium lowering medication as SPS or SPS.

• In the respective patient population, HK is a risk factor for early onset of dialysis.

LIMITATIONS

• In general, claims data analyses are subject to limitations as they are primarily collected for accounting purposes, and therefore clinical parameters (e.g. severity grades, laboratory results), dosage and intake of medication, or additional information (e.g. quality of life) are not covered.

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REFERENCES


Figure 3. Mean healthcare costs