Cost effectiveness of sodium zirconium cyclosilicate for the treatment of hyperkalemia in Mexico

Díaz-Álvarez, O[1]; Buritica MP[1]; Rubio-Ponce, RA[1]
1. AstraZeneca, S.A. de C.V., Mexico City, Mexico

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INTRODUCTION

Hyperkalemia (HK) is an abnormally high concentration of serum potassium (K^+s) , defined by a serum concentration above 5.0 mmol/L. Those patients with chronic kidney disease (CKD), heart failure and/or diabetes mellitus, have an incremented risk of presenting HK, mainly due to deficiency in insulin, hypertonicity, and comorbidities such as hypertension and renal impairment[1].

HK increases the risk of present adverse clinical events, such as heart failure, arrythmia, acute myocardial infraction, decreased kidney function, and mortality for any cause. Associated with these complications, the risk of hospitalization is also higher in patients with HK[2].

There is a lack of clinical guidelines for the treatment of HK, but some consensus propose the use of gluconate-based solutions, beta 2 agonists, and diuretics, for the management of an acute event of HK, mainly in an emergency room. However, nowadays in México there are no approved medicines in the Public Health System for the management of HK, which represents an unmeet need for the management of K^+s, both in an acute event and in long term[3].

Sodium zirconium cyclosilicate (SZC) is a non-absorbed, non-polymer inorganic powder with a uniform micropore structure that preferentially captures free potassium ions within the gastrointestinal tract lumen, in exchange for hydrogen and sodium cations, increasing the elimination in feces of potassium and, therefore, lowering the amount of potassium that reach the bloodstream. SZC can normalize the K^+s levels within the first 48 hours of treatment (K^+s < 5.0 mmol/L) and maintaining these levels in a long-term period. The efficacy of SZC was consistent between different subgroups, such as patients with CKD, HF, DM, and patients that use Renin-Angiotensin Aldosterone inhibitors (RAASi) [4, 5, 6, 7].

OBJECTIVE

To perform a cost-effectiveness evaluation from the perspective of the Mexican Health System (MHS), of the use of sodium zirconium cyclosilicate (SZC) for the treatment of hyperkalemia (HK) in patients with chronic kidney disease (CKD) and/or heart failure (HF).

METHODS

A cost-effectiveness evaluation was performed using a patient-level, fixed-time increment stochastic simulation designed to predict the natural history of disease in patients with CKD and/or HF, and quantify the costs and benefits associated with using SZC for serum K^+s management. In addition, treatment-specific K^+s trajectories are modelled at the patient-level according to the data presented in protocols ZS-004 and ZS-005 ;and linked to the risk of fatal and nonfatal events including: Major Adverse Cardiovascular Event (MACE), hospitalizations, adverse events, acute HK and changes in RAASi use (Figure 1). A lifetime horizon was considered.

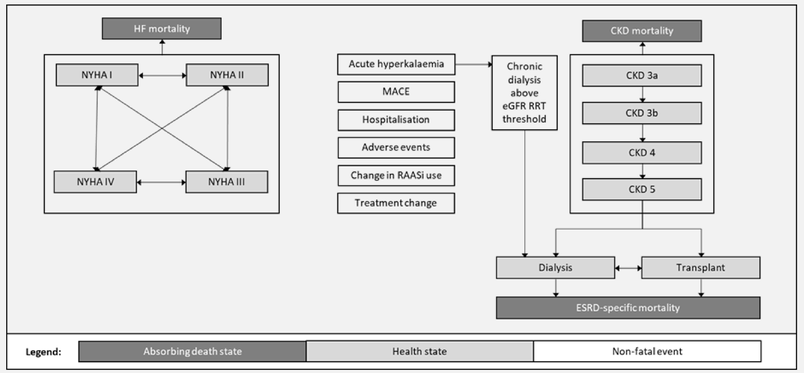
The analysis was conducted from the payer perspective, considering the MHS. The willingness to pay (WTP) threshold in México is 1 PIB per capita = $11,473. Only direct medical costs were included in the analysis. All cost were obtained from institutional sources. The management of HK considered the use of calcium gluconate, insulin, glucose, salbutamol, sodium bicarbonate and furosemide. In the acute phase of HK, SZC was added to standard of care (SoC) and compared with SoC alone. The long-term management of HK considered changes in lifestyle and diet, due, no direct medical costs were considered.

SZC is presented in sachets of 5g with powder for oral suspension in water, therefore, there are no costs of administration. The treatment of HK with SZC consider two phases:

1) Correction phase: Starting dose of 10g, administered three times a day for 3 days.

2) Maintenance phase: When normokalemia has been achieved, a dose of 5g once daily is recommended.

Figure 1. Flow diagram of health states and events in the model



RESULTS

According to the results obtained within a life-time horizon, the use of SZC was associated with more life years gained, compared with standard treatment (4.23 vs 2.81; Δ=1.34). The total cost of SZC was $39,996, while for standard of care was $22,896.46, resulting in an incremental cost of $14,099. The ICER was $10,490, which is less than the WTP ratio in México (1 PIB per capita: $11,473). The results obtained in the deterministic and probabilistic sensitivity analysis were consistent with the main analysis, showing that the analysis is robust (Table 1).

Table 1. Cost-effectiveness analysis

Treatment	Cost	Incremental cost	Effectiveness (LY´s)	Incremental effectiveness	C/E	ICER
SOC	$22,896	$14,099	2.891	1.344	$7,919	**$10,490**
SZC	$39,996		4.235		$8,735	

CONCLUSIONS

SZC should be considered a **cost-effective alternative** for treating HK in patients with CKD and/or HF in the MHS, based on the conventional WTP threshold in Mexico.

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