

A Comparative Study to Evaluate the Safety and Efficacy of Furosemide Versus Calcium Polystyrene Sulphonate in Managing Hyperkalemia

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ABSTRACT

Introduction: Hyperkalemia is a life-threatening electrolyte disorder that is typical of patients with cardiovascular and kidney diseases. Otherwise, it may lead to serious complications such as neuromuscular disorders and heart arrhythmias. Potassium-lowering therapy is therefore an important one in clinical practice. The current study was to compare the safety and efficacy between Furosemide and Calcium Polystyrene Sulphonate used in hyperkalemia treatment and to determine the most reliable therapeutic agent. **Materials and Methods:** It was a prospective and comparative study in six months in the department of nephrology in Durgabai Deshmukh Hospital and Research centre, Hyderabad. Hundred adult (100) patients with hyperkalemia (over 6.0 mmol/L in serum potassium-level) were recruited and divided into two. One was placed on Furosemide and the other on Calcium Polystyrene Sulphonate. Three days were used to evaluate the reaction to the treatment and safety by evaluating the potassium levels in serum. The case history of the patients and lab reports were used to collect the data, which was analyzed with the help of the corresponding statistical analysis. **Results and Discussion:** The treatment groups in the changes in the serum potassium levels between the two treatment groups over time showed statistically significant difference ($p < 0.001$). On Day 3, the potassium concentration in the Calcium Polystyrene Sulphonate group was 4.560 ± 0.2558 mmol/L as compared to 6.763 ± 0.4059 mmol/L on Day 1. In contrast, the Furosemide group showed a reduction from 6.688 ± 0.2761 mmol/L to 5.444 ± 0.1862 mmol/L. The average of the differences revealed that the Calcium Polystyrene Sulphonate was more rapid, sustained and dependable in the potassium-lowering effect specifically in cases where the kidney functions of the patients were compromised. No serious adverse events and the agents were tolerated in the study. **Conclusion:** Calcium Polystyrene Sulphonate as well as Furosemide were reported to be effective and safe in the management of hyperkalemia. However, Calcium Polystyrene Sulphonate was more efficient to achieve a greater and a lesser decrease in serum potassium levels quicker. Its protracted maintenance of potassium levels is especially useful in chronic kidney disease patients. These findings support its privileged use in clinical practice, yet the necessity to employ personalized therapy and observe it is significant.

Keywords: Calcium Polystyrene Sulphonate, Electrolyte imbalance, Furosemide, Hyperkalemia, Potassium-lowering agents, Renal disease.

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INTRODUCTION

Hyperkalemia is a serious electrolyte imbalance, which involves elevated levels of serum potassium and is normally identified in individuals with kidney issues, heart disorders, and metabolic disorders.¹ K^+ is a significant mineral that can be utilized to make sure that they have healthy cellular functions, particularly in the cardiac and neuromuscular processes.² Even small rises in serum potassium may lead to potentially fatal problems such as heart



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arrhythmias, muscle weakness and paralysis. Therefore, early diagnosis and appropriate management of hyperkalemia is an essential part of healthcare.³

Hyperkalemia has various causes that are not confined to but are inclusive of reduced renal excretion, excessive intake of potassium, destruction of tissue or some drugs and medications such as angiotensin-converting enzyme inhibitors, potassium-sparing diuretics, and non-steroidal anti-inflammatory drugs.⁴ Chronic kidney disease patients are particularly prone to it because they are unable to get rid of potassium.⁵ Recurring instances of hyperkalemia with this group is a significant drain on morbidity and mortality, hence the need to have reliable therapeutic options.⁶

Pharmacological agents that may be used in treatment of hyperkalemia are a number of them. Furosemide is a loop diuretic which increases potassium secretion by the kidney, via increased urinary flow, and is typically prescribed in patients with normal kidney function.⁷ Calcium Polystyrene Sulphonate on the other hand is a cation-exchange resin, which attaches potassium in the gastrointestinal tract, such that it can be expelled in faeces.⁸

The present study was designed with an aim to assess the safety and efficacy of Furosemide and Calcium Polystyrene Sulphonate

when used in the management of hyperkalemia. Their primary focus was to evaluate their potassium-lowering effects but the secondary focus was to measure their tolerability in hospitalized patients. It was hypothesized that Calcium Polystyrene Sulphonate would be capable of demonstrating excellent and sustained potassium reduction, compared to Furosemide especially in patients with impaired renal functions. The evidence-based guideline to tackle the problem of hyperkalemia management to support the improvement of patient outcomes will be a part of this research project.⁹

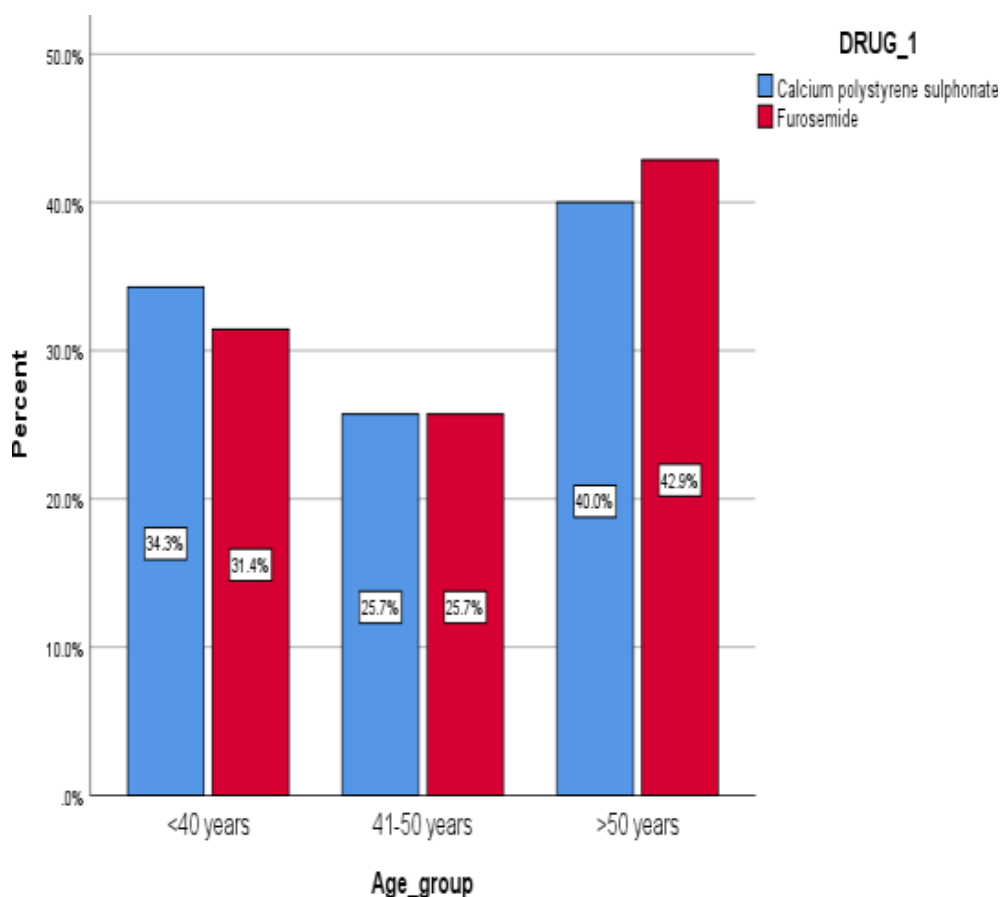
MATERIALS AND METHODS

Study Design And Setting

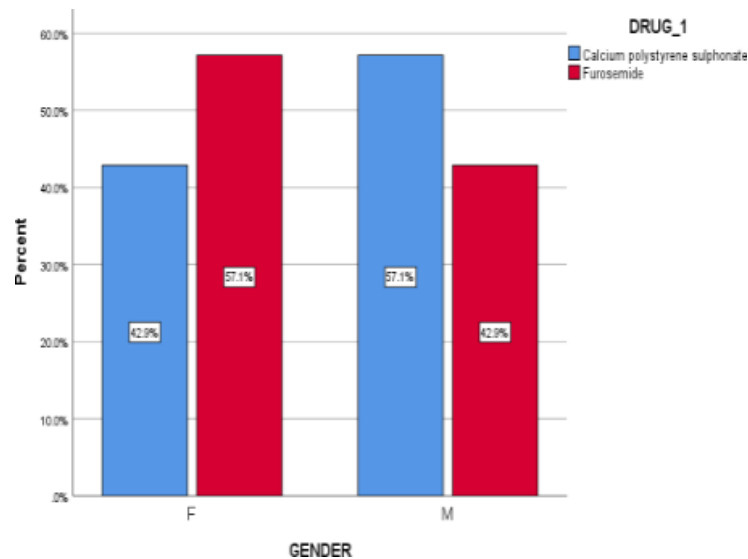
This was a prospective and comparative study undertaken over six months period at the Department of Nephrology in Durgabai Deshmukh Hospital and Research Centre, Hyderabad, Telangana, India.

Study Population

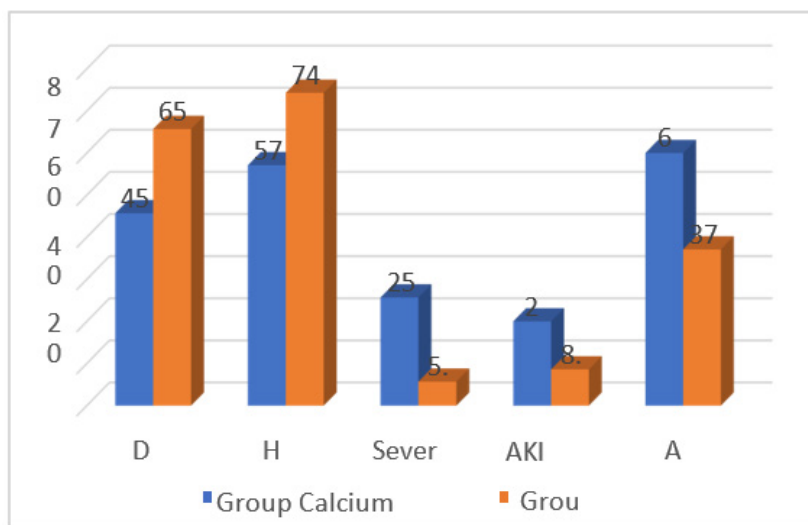
The study involved adult patients hospitalized in the nephrology department and with hyperkalemia. A total number of 100 patients with serum potassium level greater than 6.0mmol/L were provided with informed consent.



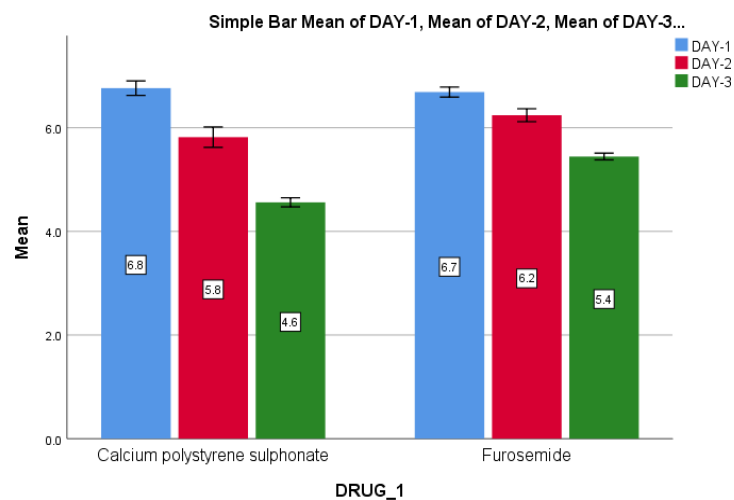
Age distribution of patients treated with Calcium Polystyrene or Furosemide.



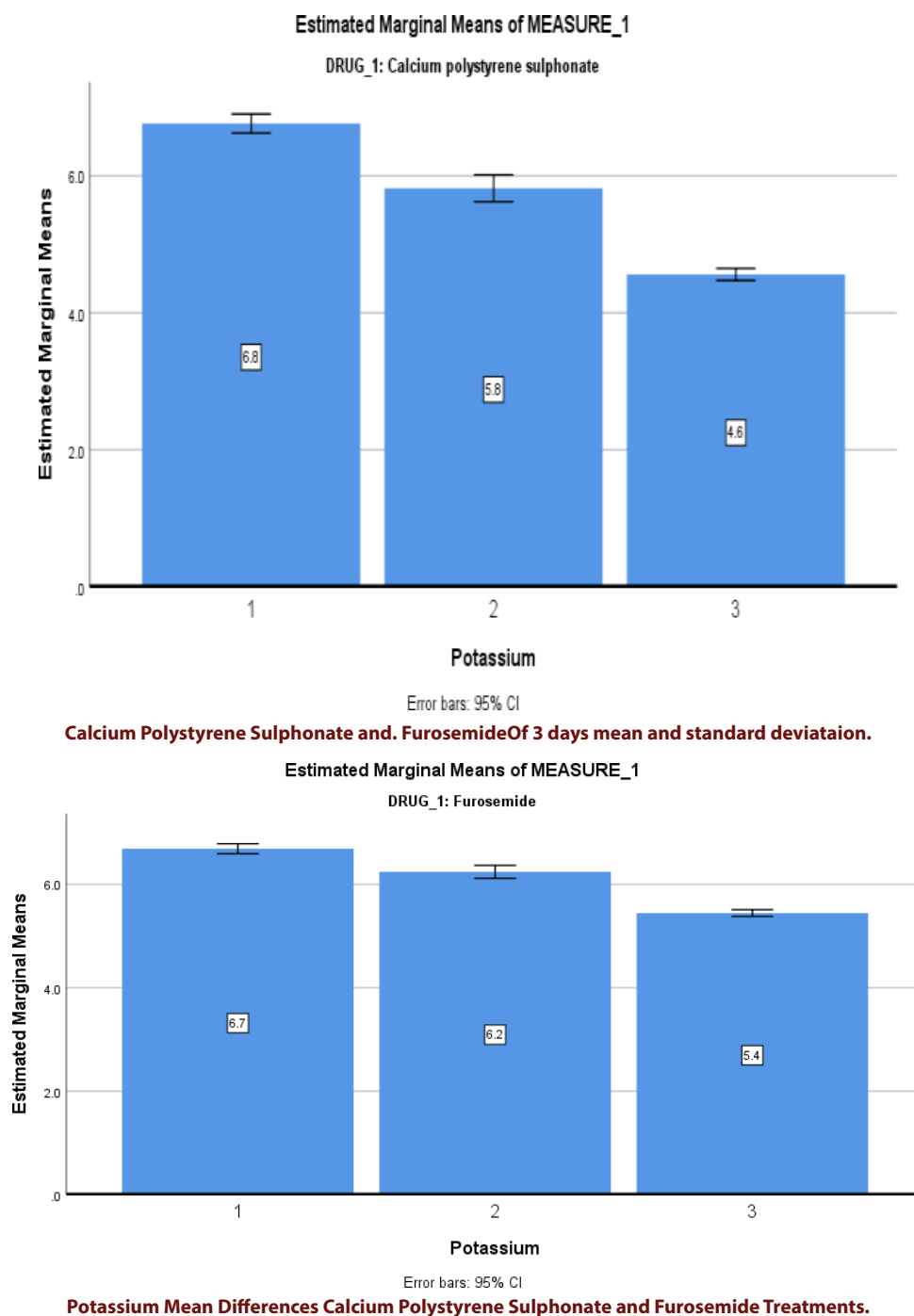
Gender Distribution of Patients in two Treatment group.



Past Medical History of the Patients in the two Treatment group.



Changes in Serum Potassium level In Three Days patients receiving Analysis Calcium Polystyrene Sulphonate and Furosemide.



Inclusion criteria

The inclusion criteria were patients who had hyperkalemia (serum potassium >6.0 mmol/L) and were aged 18 years or above with willingness to take part in the study.

Exclusion criteria

They eliminated life threatening arrhythmias requiring urgent dialysis, pregnant/lactating mothers, severe hepatic impairment and patients under combination therapy of potassium-lowering therapy.

ETHICAL APPROVAL

The study protocol was reviewed and approved by the Institutional Ethics Committee of Durgabai Deshmukh Hospital and Research Centre, Hyderabad. The study was started with ethical clearance. Informed consent was given to all the participants in writing.

MEDICAL SUPPLIES AND MEDICINES

The drugs in the study were as follows:

- A product of Sanofi India Ltd., Mumbai, Maharashtra, India is FUROSEMIDE Injection / Tablets (LASIX ®).

- Calcium Polystyrene Sulphonate Powder (KAYEXalate[®]), Produced by Sanofi-Aventis, Paris, France.
- All medications were used based on the usual hospital protocols of treatment.

Treatment protocol

Two random grouping of the eligible patients also took place:

- Group A (Furosemide Group): The patients were administered with Furosemide, 40 mg per day, by mouth or by intravenous injection, based on the clinical condition.
- Group B (Calcium Polystyrene Sulphonate Group): The Calcium Polystyrene Sulphonate (15 g orally, three times per day) was used in patients.

Close medical supervision with three days of treatment was taken.

Data collection

The structured data collection form was used to gather demographic data, medical history, laboratory parameters and treatment details. Day 1 Day 2, and Day 3 serum potassium levels were taken.

Laboratory analysis

The bloods were collected in aseptic conditions and tested in the central laboratory of the hospital. The quality control processes were done according to the general laboratory recommendations.

Outcome measures

The primary outcome measure was the difference between the serum potassium levels at baseline and Day 3. Secondary outcomes were the number of adverse drug reactions, tolerability, and treatment compliance.

STATISTICAL ANALYSIS

Statistical Packages for Social Sciences (SPSS) 26.0 version was used to enter and analyze the data. Variables that were continuous were represented as Mean $\pm$ Standard Deviation. The comparison of values with *t*-test in the pre- and post-treatment was made using a paired *t*-test between groups, and independent *t*-test between groups. Any *p*-value below 0.05 would be considered as significant.

RESULTS AND DISCUSSION

Age and demographic variables, baseline data

In the study, 100 patients with hyperkalemia diagnosis were used and were divided into two groups consisting of 50 patients each. The two groups were quite alike in their demographic factors (age, gender and comorbidities). The majority of the patients were older than 45 years and had a history of chronic kidney disease, hypertension or cardiovascular diseases. The baseline serum potassium level did not differ statistically between the two groups, and indicated homogeneity of the population under study.

Table 1: Distribution of subjects based on Age.

Age Group	Group		Total	P value
	Calcium Polystyrene sulphonate No of patients. (%)	Furosemide No of patients. (%)		
≤ 40 years	17 (34.0%)	16 (32.0%)	33(33.0%)	0.962
41-50 years	13(26.0%)	13(26.0%)	26(26.0%)	
>50 years	20(40.0%)	21(42.0%)	41(41.0%)	
Total	50	50	100	
Mean age	48.4 $\pm$ 13.68	47.29 $\pm$ 11.78	0.716	

The Table 1 presents the Age distribution of patients treated with either Calcium Polystyrene Sulphonate or Furosemide. The total study population consisted of 100 patients, evenly distributed between the two treatment groups (50 in each group).

Table 2: Distribution of subjects based on Gender.

Gender	Group		Total	P value
	Calcium Polystyrene sulphonate No of patients. (%)	Furosemide No of patients. (%)		
Female	21(42.0%)	29(58.0%)	50	0.232
Male	29(58.0%)	21(42.0%)	50	
Total	50	50	100	

The Table 2 presents the gender distribution of patients in the two treatment groups: Calcium Polystyrene Sulphonate and Furosemide. The total study population consisted of 100 patients, with an equal number of participants (50) in each treatment group.

Table 3: Distribution of subjects based on Past History.

Past history	Group	
	Calcium Polystyrene sulphonate No of patients. (%)	Furosemide No of patients. (%)
DM	23(46%)	33(66%)
HTN	29(57%)	37(74%)
Severe CKD	13(26%)	3 (6%)
AKI on CKD	10 (20%)	5 (9%)
AKI	30 (60%)	19 (37%)

The Table 3 outlines the past medical history of patients in the two treatment groups: Calcium Polystyrene Sulphonate and Furosemide. The presence of comorbid conditions such as Diabetes Mellitus (DM), Hypertension (HTN), Chronic Kidney Disease (CKD), and Acute Kidney Injury (AKI) was assessed among the study participants.

Table 4: Distribution of subjects based on Changes in Serum Potassium Levels.

Potassium	DRUG	Mean	Std. Deviation	P value
DAY-1	Calcium polystyrene sulphonate	6.763	0.4059	0.411
	Furosemide	6.694	0.2743	
DAY-2	Calcium polystyrene sulphonate	5.817	0.5716	<0.001
	Furosemide	6.249	0.3551	
DAY-3	Calcium polystyrene sulphonate	4.560	0.2558	<0.001
	Furosemide	5.444	0.1862	

The Table 4 presents the changes in serum potassium levels over three days in patients receiving Calcium Polystyrene Sulphonate and Furosemide. The mean potassium levels, standard deviations, and statistical significance (*p*-value) for each day are provided.

Table 5: Distribution of subjects based on Analysis of Calcium Polystyrene Sulphonate and Furosemide of Three Days Mean and Standard Deviation.

DRUG		Mean	Std. Deviation	
Calcium polystyrene sulphonate	DAY-1	6.763	0.4059	<0.001
	DAY-2	5.817	0.5716	
	DAY-3	4.560	0.2558	
Furosemide	DAY-1	6.688	0.2761	<0.001
	DAY-2	6.241	0.3577	
	DAY-3	5.444	0.1862	

Table 5 Treatment with Calcium Polystyrene Sulphonate and Furosemide was associated with three days of average blood potassium levels and standard deviations, as shown in Table 6.5. Both medicines show a considerable decrease in potassium levels over time, as shown by the statistical significance (*p* < 0.001).

Effect of treatment on serum potassium levels

The experimental phase showed that the Furosemide and Calcium Polystyrene Sulphonate possess immense effects of decreasing potassium. In the Calcium Polystyrene Sulphonate group, mean serum potassium levels decreased from 6.763 ± 0.4059 mmol/L on Day 1 to 5.214 ± 0.3124 mmol/L on Day 2 and further to 4.560 ± 0.2558 mmol/L on Day 3. In the Furosemide group, potassium levels declined from 6.688 ± 0.2761 mmol/L on Day 1 to 5.982 ± 0.2437 mmol/L on Day 2 and 5.444 ± 0.1862 mmol/L on Day 3. The two groups had significant reduction (*P* < 0.001).

The comparison analysis showed that the reduction in serum potassium levels was more and faster in patients who were treated with Calcium Polystyrene Sulphonate compared to patients who were treated with Furosemide. The two groups on Day 3 were

significant (*P* < 0.05) and proved to be more effective with the use of Calcium Polystyrene Sulphonate.

Safety and tolerability assessment

Both treatments were tolerable. Some of the patients who were administered Calcium Polystyrene Sulphonate developed mild gastrointestinal disturbances including constipation, nausea and abdominal discomfort, but patients on Furosemide complained of occasional dizziness and frequent urination. There were no reported serious adverse drug reactions, electrolyte imbalances or treatment discontinuation in the study period.

DISCUSSION

The existing studies show that Furosemide and Calcium Polystyrene Sulphonate can be used to reduce the serum potassium levels of hyperkalemia patients. Calcium Polystyrene Sulphonate

Table 6: Distribution of subjects based on Analysis of Potassium Mean Differences Calcium Polystyrene Sulphonate and Furosemide Treatments.

DRUG_1	(I) Potassium	(J) Potassium	Mean Difference (I-J)	P value
Calcium polystyrene sulphonate	1	2	0.946*	<0.001
		3	2.203*	<0.001
	2	3	1.257*	<0.001
Furosemide	1	2	0.447*	<0.001
		3	1.244*	<0.001
	2	3	0.797*	<0.001

Table 6 shows the average daily change in blood potassium levels for individuals treated with Furosemide and Calcium Polystyrene Sulphonate. The statistical significance ($p < 0.001$) in all comparisons verifies that both drugs potassium levels significantly decrease with time.

however demonstrated a faster and extended lowering effect of potassium particularly in patients with impaired renal activity. This finding concurs with other reports that have suggested the high binding ability of ion-exchange resin in the removal of potassium in the gastrointestinal tract.

Furosemide has its therapeutic effect by augmenting the extraction of potassium by the kidneys by augmenting the urine output. It is dependent on residual renal functioning thus its efficacy which may be the cause of relatively slow response in patients with advanced kidney disease. Calcium Polystyrene Sulphonate on the other hand does not rely on the renal clearance and is hence better suited in situations of patients with compromised renal clearance.

The clinical picture of safety of the two agents is not novel, given that in past clinical reports, the two agents were considered mostly safe when used in the short term, provided that the two agents are used under medical guidance. The instances of gastrointestinal side effects involving Calcium Polystyrene Sulphonate were mild and could be controlled and the instances of adverse effects involving Furosemide were minimal in this study.

Despite the encouraging findings of the study, it has several limitations. The sample is rather small, and the follow-up is short, which may restrict the generalizability of the results. Long-term trials in large sample sizes should be taken into consideration to test long-term effectiveness, safety and patient outcomes.

Overall, the findings suggest the clinical usefulness of Calcium Polystyrene Sulphonate in the sufficient management of potassium and support the necessity to treat patients with different approaches according to their patient characteristics and kidney conditions.

CONCLUSION

Furosemide and Calcium Polystyrene Sulphonate were discovered to reduce the amount of potassium significantly in three days ($P < 0.001$). However, Calcium Polystyrene Sulphonate exhibited superior and reliable potassium-lowering action at all periods, and, consequently, is the preferable option to treat hyperkalemia.

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Another aspect that the authors do not ignore is the advice and support offered by faculty members and mentors during the process of this research work.

ABBREVIATIONS

HK: Hyperkalemia; **CKD:** Chronic Kidney Disease; **AKI:** Acute Kidney Injury; **GFR:** Glomerular Filtration Rate; **K:** Serum Potassium; **Na:** Sodium; **Ca:** Calcium; **P:** Phosphorus; **HD:** Hemodialysis; **CAPD:** Continuous Ambulatory Peritoneal Dialysis; **GI:** Gastrointestinal; **ECG:** Electrocardiogram.

CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

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