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Evaluating the comparative efficacy of multimodal treatment strategies for hyperkalemia management in a tertiary care hospital setting: A prospective cohort study

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Abstract: Hyperkalemia poses significant risks to patients due to its potential to cause life-threatening cardiac and neuromuscular complications. This study aimed to evaluate the effectiveness of different treatment protocols for hyperkalemia in hospitalized patients. This prospective observational study, conducted at Sindh Government Hospital Korangi, Karachi, included adult patients (>18 years) with potassium levels ≥5.5 mEq/L. The study evaluated the effectiveness of different treatments in normalizing potassium levels, with treatment choices made at the discretion of the treating physicians. Among the 341 patients, treatment effectiveness varied by hyperkalemia severity. For mild hyperkalemia, D50W with insulin and sodium bicarbonate achieved normokalemia in 83.3% of cases, compared to 55% with Sodium-Polysorbate alone. In moderate hyperkalemia (189 patients), the combination of D50W, insulin, sodium bicarbonate, calcium gluconate and Sodium-Polysorbate reduced potassium levels from 6.52 to 6.01 mmol/L ($p<0.001$), with 27.2% achieving normokalemia. In severe hyperkalemia (104 patients), this regimen led to significant reductions (0.88-1.18 mmol/L, $p<0.001$), with 17.6% reaching normokalemia. Multi-drug approaches are advocated for effective hyperkalemia management, particularly for moderate to severe cases. Future research should focus on refining treatment protocols and improving adherence to guidelines to ensure consistent management outcomes.

Keywords: Hyperkalemia, hypokalemia, American Heart Association, European Resuscitation Council Guidelines.

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INTRODUCTION

Hyperkalemia is due to impaired potassium excretion or transcellular shifts and excessive potassium intake (Evans and Greenberg, 2005, Gennari, 2002). Etiology of hyperkalemia is often multifactorial including medication use, renal impairment and hyperglycemia (Fordjour *et al*., 2014).

The urgency with which hyperkalemia should be managed depends on how rapidly the condition developed, the absolute serum potassium level, the degree of symptoms, and the cause (Simon and Farrell, 2018). Treatment goals for management of acute hyperkalemia are to avert deadly cardiac conduction and neuromuscular abnormalities, move K+ inside cells, remove extra potassium out of body and put an end to underlying cause. Those who have chronic hyperkalemia must be advised to decrease dietary K + intake. Quick intervention depends upon severe hyperkalemia (>6.5 mEq/L), signs and symptoms of hyperkalemia, variations on EKG, rapid-onset hyperkalemia, or cirrhosis, renal dysfunction or underlying heart disease (Viera and Wouk, 2015). However, hyperkalemia management include three key steps: (1) reversal of cardiac consequences, (2) stimulate K + influx into cells and (3) eliminate excess K+. After treating the acute incident of hyperkalemia, patients must be placed on a maintenance regimen to avoid episodes of hyperkalemia (Hoskote *et al*., 2008). Hyperkalemia treatment must be directed by assessing serum K+ level.

The "cocktail" treatment for hyperkalemia, which involves a combination of glucose, insulin, sodium bicarbonate, and calcium gluconate, has been recognized as a cornerstone in the emergency management of this potentially life-threatening condition. This approach leverages the synergistic effects of these agents to rapidly reduce serum potassium levels: insulin and glucose facilitate the cellular uptake of potassium, sodium bicarbonate corrects metabolic acidosis (which can exacerbate hyperkalemia) and calcium gluconate stabilizes cardiac membranes, mitigating the risk of arrhythmias (Palmer *et al*., 2021, Sterns *et al*., 2016). The efficacy of this multidrug regimen has been supported by clinical practice guidelines and consensus statements from leading nephrology and emergency medicine associations, underscoring its role in acute settings (Cowan *et al*., 2017, Mount, 2013, Weisberg, 2008). Despite its widespread

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acceptance, the cocktail treatment underscores the importance of individualized patient care, as the response to treatment can vary based on underlying comorbidities and the severity of hyperkalemia. As such, continuous monitoring and adjustments to therapy are essential to ensure both efficacy and safety in the management of hyperkalemia.

Recommendations regarding threshold serum K+ level at which management must be carried out, optimal correction urgency of K+, as well as incidence and duration of K + monitoring in hyperkalemic are based on consensus and typically depend on physician and/or institutional practice guidelines (Weisberg, 2008). Given its potential severity, the management of hyperkalemia must be prompt and effective, tailored to the specific needs of the patient based on the rapidity of onset, symptomatology, underlying causes and potassium levels. Despite the established protocols for hyperkalemia management, which include reversing cardiac effects, promoting potassium influx into cells and eliminating excess potassium, there remains a lack of consensus on the optimal threshold for intervention, the urgency of correction, and the monitoring frequency and duration. This variability in practice underscores the necessity for a comprehensive evaluation of treatment modalities to identify the most effective approaches. The aim of this study is to evaluate the effectiveness of different hyperkalemia treatment strategies of for rapid correction of potassium homeostasis.

MATERIALS AND METHODS

Study settings

The study was carried out in a public sector hospital located in Karachi, Pakistan. It is the only public sector tertiary care facility in area equipped with 300 bedded. The study was carried out among the patients admitted in intensive care unit, male medical ward, male surgical ward, female surgical ward and cardiac ward of the hospital.

Study design and duration

The prospective, observational, and non-interventional cohort study was conducted over the period of four months i.e., October, 2019 until January, 2020.

Participants selection criteria

The study included individuals who were older than 18 years and had been admitted to various wards of the hospital with potassium levels equal to or greater than 5.5 mEq/L. However, we excluded from our study any patients who had experienced burns, trauma, or rhabdomyolysis. Pregnant patients were also not included. Additionally, those with severe renal impairment, defined as having a creatinine clearance above 2.0 mg/dl or those undergoing peritoneal or hemodialysis, were excluded. Cases of pseudohyperkalemia, diabetic ketoacidosis and patients who had not had blood sampling within 6 hours of receiving potassium-lowering agents were also omitted from the study. Lastly, individuals with incomplete patient records were not considered for inclusion.

Data collection

The data collection adhered to hospital protocol for monitoring and treating patients abnormal electrolyte levels. All patients are subjected to serum electrolyte testing at the time of admission, with tests repeated daily until discharge. This ensures continuous monitoring of electrolyte levels, including potassium.

Identification of hyperkalemia

Patients with serum electrolyte reports showing potassium levels above 5.5 mmol/L are identified as hyperkalemic {Rosano, 2018 #305}. This threshold is critical for diagnosing patients who may need immediate intervention. Hyperkalemia is categorized as mild (5.0–5.5 mmol/L), moderate (5.5–6.0 mmol/L), or severe (>6.0 mmol/L) {Emektar, 2023 #306}.

Treatment intervention

The patients diagnosed with hyperkalemia receive an intervention within 3 hours of diagnosis. This prompt response is essential to mitigate the risks associated with elevated potassium levels.

Treatment selection

The treatment selection for hyperkalemia was based on the discretion of the treating physicians. This means that the selection of a specific treatment approach was based on the physician's clinical judgment and experience, considering the patient's condition and underlying health factors.

Post-treatment testing

Following drug treatment to lower potassium levels, another serum electrolyte test is conducted. This step is vital for assessing the treatment's success in normalizing potassium levels.

Outcome

The primary outcome of the study was defined as the effectiveness of the treatment strategy, which was determined by the normalization of potassium levels within the target range. This outcome measure allowed for the evaluation of not only how effectively a treatment strategy corrected hyperkalemia but also its safety profile.

Study approval

The study was approved by the Medical Ethics Committee of the Sindh Government Hospital Korangi No. 5 reference no. SGHK/-2383/91 dated 29-09-2018.

STATISTICAL ANALYSIS

All statistical analyses were carried out using SPSS (Statistical Package for the Social Sciences) version 21.

Descriptive statistics were used to summarize the demographic characteristics of the patients, including mean ± standard deviation (SD) for continuous variables such as age and serum potassium levels and frequencies with percentages for categorical variables such as gender, socio-economic status, comorbidities and history of hyperkalemia. Paired t-tests were utilized to assess the significance of the mean differences in serum potassium levels before and after treatment across all patient groups. All analyses were conducted with a significance level set at $P<0.05$, indicating that results with a P-value less than this threshold were considered statistically significant.

RESULTS

During the study period, a total of 341 patients who met the eligibility criteria were enrolled in the study. The average age of the participants was 53.5+8.74 years. The cohort predominantly consisted of male patients, who represented 58% of the study population (198 out of 341 patients), and the average weight of the participants was recorded at 80±12 kg The study revealed that 35.8% of participants had cardiac issues, 31% had multiple comorbidities, while 20% had none, showing a diverse health profile. Notably, around 88% patients were experiencing hyperkalemia for the first time. The patient demographic characteristics are summarized in table 1.

A total of 48 patients were diagnosed with mild hyperkalaemia during the study period. table 2 summarizes the comparative efficacy of different treatment protocols for mild hyperkalemia treatment. Sodium-Polysorbate alone showed a modest reduction in potassium levels, with a non-significant p-value of 0.092, and 55% of patients achieving normokalemia. The combination of Sodium-Polysorbate and Furosemide also resulted in a non-significant potassium reduction ($p=0.081$), with 50% reaching normokalemia. Notably, the combinations of Dextrose 50% water (D50W) with 10 units insulin, and Sodium-Polysorbate ($p=0.0025$), as well as D50W with 10 units insulin and Sodium Bicarbonate combination ($p=0.0028$), demonstrated significant potassium level reductions and high rates of normokalemia (83.3% and 91.6%, respectively), underscoring their effectiveness in hyperkalemia management.

Table 3 presents a comparative analysis of the efficacy of various treatment protocols for moderate hyperkalemia in patients. The overall analysis included 189 patients, showing a significant reduction in K+ levels from 6.52± 0.27 mmol/L to 6.01±0.32 mmol/L ($p<0.001$), with 16.9% of patients returning to normokalemia. Among the treatments, the combination of D50W with 10 units insulin + Sosium Bicarbonate + Calcium gluconate + Sodium-Polysorbate was the most effective, resulting in the largest average decrease in K+ levels (1.04 mmol/L, $p<0.001$) and the highest proportion of patients achieving normokalemia (27.2%). In contrast, treatments with Sodium-Polysorbate alone or in combination with Furosemide were least effective, with only 4.7% and 4.17% of patients, respectively, returning to normokalemia. Notably, all treatment protocols significantly reduced K+ levels, but the degree of effectiveness and the proportion of patients achieving normokalemia varied, highlighting the superior efficacy of combining multiple treatments for managing moderate hyperkalemia.

Table 4 summarize a comparative analysis of the efficacy of different treatment protocols in 104 severe hyperkalemia diagnosed patients. Overall, a statistically significant reduction in potassium levels from 7.46±0.23 to 6.83±0.41, with a mean difference of 0.51 was observed. However, only 32 (16.9%) patients achieved normokalemia, while 157 (83.1%) remained hyperkalemic. Among the treatment protocols, the combination of D50W with 10 units insulin + Sodium bicarbonates + Calcium Gluconate, either with or without Sodium-Polysorbate, showed the most significant reductions in potassium levels, with P-values <0.001 and mean differences of 0.88 and 1.18, respectively. The latter combination also had the highest proportion of patients moving to normokalemia (17.6%).

DISCUSSION

The management of hyperkalemia, a life-threatening condition, remains a challenge in clinical practice. This study evaluated the efficacy of various treatment protocols across mild, moderate and severe cases. For mild hyperkalemia, the combination of D50W, insulin, and sodium bicarbonate was the most effective in reducing potassium levels. In moderate and severe cases, combining pharmacological agents proved beneficial, emphasizing the need for a stratified approach based on severity to optimize outcomes.

For managing mild hyperkalemia, the combination of D50W with insulin and sodium bicarbonate is effective. Insulin promotes potassium uptake into cells, while bicarbonate corrects metabolic acidosis, which can worsen hyperkalemia. This rapid potassium shift from extracellular to intracellular spaces makes insulin a commonly used agent due to its quick onset, ease of use, and proven efficacy {Larivée, 2023 #307}. This mechanism is thoroughly discussed in the work by Sterns *et al*., who also review newer treatment modalities (Sterns, Grieff *et al*., 2016). Additionally, the role of bicarbonate in treating hyperkalemia, especially in the context of acidosis, is further elaborated by Kim HJ and Han SW, providing insight into its direct and indirect effects on potassium levels (Kim and Han, 2002).

Table 1: Demographic characteristics of patients

Characteristics	Frequency	%
Age (Years)		
Mean ± SD	53.5 ± 8.74	
Range	33- 74	67.2
Gender		
Male	199	58.3
Female	142	41.6
Socio-economic Status		
Low income (less than 50 k / month)	224	65.7
Middle income (from 51- 100 k rupees / month)	103	30.2
High income (More than 100 k rupees / month)	14	4.1
Common Comorbidities		
Diabetes	53	15.5
Hypertension	91	27.6
Congestive Heart Failure	31	9.1
Respiratory Complications	35	10.3
Liver complications	29	8.5
No comorbidity	71	20.8
History of Hyperkalemia		
Yes	47	13.8
No	294	86.2

The limited effectiveness of Sodium-Polysorbate monotherapy aligns with broader clinical observations, as shown in a study by Alam *et al*. where a single dose of sodium polystyrene sulfonate significantly reduced potassium levels (0.61 mmol/L) but caused changes in other serum electrolytes, including an increase in sodium and decreases in magnesium and calcium (Alam *et al*., 2019). Kamel and Halperin's work on potassium balance underscores the complexity of managing hyperkalemia and why certain treatments may underperform owing to the complexity of potassium homeostasis (Halperin and Kamel, 1998).

The addition of calcium gluconate for moderate hyperkalemia, particularly in the context of cardiac toxicity risk, represents a critical intervention. While it does not lower potassium levels, calcium gluconate stabilizes the cardiac membrane, reducing the risk of arrhythmias (Mount, 2013). The synergistic effect of combining D50W with 10 units insulin, sodium bicarbonate and calcium gluconate, possibly with the addition of Sodium-Polysorbate, for more effective potassium reduction, is supported by the multi-faceted approach to hyperkalemia treatment. This strategy is in line with the recommendations from the Kidney Disease: Improving Global Outcomes (KDIGO) 2020 clinical practice guideline on the management of blood pressure in chronic kidney disease, which indirectly addresses the management of hyperkalemia due to its frequent occurrence in this patient population (Cheung *et al*., 2021).

For severe hyperkalemia, the combination of D50W, insulin, sodium bicarbonate, calcium gluconate and Sodium-Polysorbate proved highly effective in our study. This aligns with findings by Rafique *et al*. who highlighted the importance of aggressive, multidrug regimens in severe cases (Rafique *et al*., 2021). The multifactorial mechanisms of action -promoting potassium uptake, enhancing renal excretion and stabilizing cardiac membranes- are essential for effectively lowering potassium levels. Despite advancements in treatment strategies, achieving normokalemia in patients with severe hyperkalemia remains challenging. However, achieving normokalemia remains challenging, stressing the need for further research into more effective treatments such as newer agents like patiromer and sodium zirconium cyclosilicate (Kovesdy, 2015).

While the study provides valuable insights into the management of hyperkalemia, several limitations should be considered. First, the generalizability of the findings is limited due to the single-center setting, which may not reflect the patient demographics or treatment protocols of other hospitals, particularly in different geographic or resource-constrained environments. Secondly, the study population had a wide age range and included patients with a history of hyperkalemia, but the impact of these factors on treatment efficacy was not thoroughly analyzed. Future studies should explore whether age, prior hyperkalemia episodes, or other patient characteristics, such as comorbidities, influence treatment outcomes. Thirdly, the non-randomized design of the study allowed treatment selection to be based on physician discretion, potentially introducing bias in treatment outcomes.

Table 2: Comparative efficacy of different treatment protocols for mild hyperkalemia in patients

Treatment	No. of Patients (n)	Pre- Treatment K+ Level (Mean ± SD)	Post Treatment K+ Level (Mean ± SD)	Mean difference	P-Value	No. of patients moved to normokalemia	No. of patients remain hyperkalemia
Overall	48	5.63 ± 0.28	5.34 ± 0.29	0.38	<0.001		
Sodium-Polysorbate	20	5.60 ± 0.33	5.45 ± 0.20	0.15	0.092	11 (55%)	9 (45%)
Sodium-Polysorbate + Furosemide	10	5.72 ± 0.29	5.49 ± 0.29	0.23	0.081	5 (50%)	5 (50%)
D50W with 10 units Insulin + Sodium-Polysorbate	6	5.85 ± 0.21	5.36 ± 0.28	0.49	0.0025	5 (83.3%)	1 (16.7%)
D50W with 10 units Insulin + Sodium Bicarbonate	12	5.80 ± 0.28	5.30 ± 0.42	0.5	0.0028	11 (91.6%)	1 (8.43%)

Table 3: Comparative efficacy of different treatment protocols for moderate hyperkalemia in patients

Treatment	No. of Patients (n)	Pre- Treatment K+ Level (Mean ± SD)	Post Treatment K+ Level (Mean ± SD)	Mean difference	P-Value	No. of patients moved to normokalemia	No. of patients remain hyperkalemia
Overall	189	6.52 ± 0.27	6.01 ± 0.32	0.51	<0.001	32 (16.9%)	157 (83.1%)
Sodium-Polysorbate	21	6.29 ± 0.24	6.03 ± 0.19	0.26	<0.001	1 (4.7%)	20 (95.3%)
Sodium-Polysorbate + Furosemide	24	6.41 ± 0.27	6.10 ± 0.36	0.31	0.0015	1 (4.17%)	23 (95.8%)
D50W with 10 units Insulin	12	6.45 ± 0.36	5.97 ± 0.33	0.48	0.0025	2 (16.7%)	10 (83.3%)
D50W with 10 units Insulin + Sodium-Polysorbate	7	6.63 ± 0.30	6.11 ± 0.27	0.52	0.0052	1 (14.3%)	6 (85.7%)
D50W with 10 units Insulin + Sodium Bicarbonate	29	6.50 ± 0.28	5.91 ± 0.32	0.59	<0.001	4 (13.7%)	25 (86.2%)
D50W with 10 units Insulin + Sodium Bicarbonate + Calcium Gluconate	52	6.69 ± 0.29	5.95 ± 0.36	0.74	<0.001	11 (21.2%)	41 (78.8%)
D50W with 10 units Insulin + Sodium Bicarbonate + Calcium Gluconate + Sodium-Polysorbate	44	6.83 ± 0.15	5.79 ± 0.42	1.04	<0.001	12 (27.2%)	32 (72.7%)

Table 4: Comparative efficacy of different treatments protocols for severe hyperkalemia in patients

Treatment	No. of Patients (n)	Pre- Treatment K+ Level (Mean ± SD)	Post Treatment K+ Level (Mean ± SD)	Mean difference	P-Value	No. of patients moved to normokalemia	No. of patients remain hyperkalemia
Overall	104	7.46 ± 0.23	6.83 ± 0.41	0.51	<0.001	32 (16.9%)	157 (83.1%)
Sodium-Polysorbate + Furosemide	4	7.21 ± 0.21	6.95 ± 0.29	0.26	0.19	0	4 (100%)
D50W with 10 units Insulin	3	7.23 ± 0.15	6.84 ± 0.15	0.39	0.03	0	3 (100%)
D50W with 10 units Insulin + Sodium-Polysorbate	7	7.51 ± 0.27	6.97 ± 0.23	0.54	0.0017	0	7 (100%)
D50W with 10 units Insulin + Sodium Bicarbonate	33	7.46 ± 0.20	6.89 ± 0.69	0.57	<0.001	0	33 (100%)
D50W with 10 units Insulin + Sodium Bicarbonate + Calcium Gluconate	23	7.65 ± 0.29	6.77 ± 0.81	0.88	<0.001	3 (13.4%)	20 (86.9%)
D50W with 10 units Insulin + Sodium Bicarbonate + Calcium Gluconate + Sodium-Polysorbate	34	7.73 ± 0.26	6.55 ± 0.74	1.18	<0.001	6 (17.6%)	28 (82.4%)

CONCLUSION

The current study advocates for a multi-drug approach in hyperkalemia management, highlighting the effectiveness of combining D50W with 10 units insulin, sodium bicarbonate and calcium gluconate, with Sodium-Polysorbate as a potential addition for severe cases. This tailored strategy aligns with a growing body of literature suggesting a shift towards complex treatment protocols, particularly for moderate to severe hyperkalemia. However, our findings also reveal a significant gap between established guidelines and their practical application, indicating a need for improved guideline adherence among healthcare providers. The discrepancy in treatment outcomes suggests that enhancing education and training is crucial for aligning clinical practices with evidence-based recommendations. Future research should focus on refining these drug combinations and exploring new agents, while also emphasizing the importance of guideline adherence to ensure consistent and effective hyperkalemia management across patient populations.

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