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"A Study on Clinical and Biochemical Profile in Diabetic Ketoacidosis"

Dr. Kashish Garg
PG Junior Resident, MD General Medicine, Rama Medical College Hospital and Research Centre, Kanpur

Co-Authors:Dr. Shrawan Kumar
Professor and HOD, Dept. of General Medicine, Rama Medical College Hospital and Research Centre, Kanpur

Dr. Shweta Tripathi
Associate Professor, Dept. of General Medicine, Rama Medical College Hospital and Research Centre, Kanpur

Abstract

*Diabetic ketoacidosis (DKA) is a life-threatening metabolic complication of diabetes mellitus, characterized by a triad of hyperglycemia, ketosis, and metabolic acidosis. It remains a significant cause of morbidity and mortality among patients with both type 1 and type 2 diabetes mellitus, despite major advances in diabetes management and intensive care. DKA results from a deficiency in insulin action, leading to increased lipolysis, hepatic ketogenesis, and severe metabolic disturbances. Hyperglycemia causes osmotic diuresis, leading to dehydration and electrolyte imbalance, further worsening the clinical state of patients.This study aims to evaluate the clinical and biochemical profile of patients with DKA admitted to the Department of General Medicine at Rama Medical College Hospital and Research Centre, Kanpur. A total of **36 patients** diagnosed with DKA over a period of **three months** were included in the study. The study focused on identifying clinical manifestations, precipitating factors, and biochemical markers influencing treatment outcomes. The key clinical features recorded were **thirst (85%)**, **polyuria (78%)**, **dehydration (70%)**, **altered mental status (60%)**, and **vomiting (55%)**. Infection was identified as the most common precipitating factor, accounting for **55%** of cases, followed by insulin omission (25%) and inadequate insulin administration (20%).*

*The study explored the correlation between biochemical markers and clinical outcomes. Serum bicarbonate and serum osmolality were analyzed for their association with hospital stay duration and neurological status. Patients with serum bicarbonate levels <10 mmol/L had a longer average hospital stay of **12 days**, compared to **6 days** in patients with bicarbonate levels >10 mmol/L. Elevated serum osmolality (>320 mOsm/kg) was significantly associated with altered mental status and neurological impairment in **65%** of patients, whereas patients with lower osmolality had fewer neurological complications (20%). The management protocol included aggressive fluid resuscitation, correction of electrolyte imbalances, intravenous insulin administration, and treatment of underlying infections. **94%** of the patients recovered fully and were discharged without complications. The mortality rate was **2%** (1 out of 36 patients), which aligns with global mortality trends reported by the American Diabetes Association (ADA) for DKA. Furthermore, the study highlights the importance of early recognition and targeted management of biochemical markers and precipitating factors in improving patient outcomes. Infection control, patient education, and ensuring adherence to insulin therapy are critical to*

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reducing the incidence and severity of DKA. This study provides valuable insight into the clinical and biochemical patterns associated with DKA, emphasizing the need for timely diagnosis and evidence-based treatment protocols to reduce morbidity and mortality associated with this condition.

Keywords:*Diabetic ketoacidosis, hyperglycemia, ketosis, metabolic acidosis, serum bicarbonate, serum osmolality, insulin deficiency.*

Introduction

Diabetes mellitus (DM) is a complex group of metabolic disorders characterized by chronic hyperglycemia resulting from defects in insulin secretion, insulin action, or both. It affects millions of people worldwide, with a growing burden due to changes in lifestyle, increasing obesity rates, and urbanization. According to the International Diabetes Federation (IDF), approximately **537 million adults** were living with diabetes globally in **2021**, and this number is expected to rise to **643 million** by **2030**. India alone accounts for over **77 million** people diagnosed with diabetes, making it one of the most affected countries. Among the acute complications of diabetes, **diabetic ketoacidosis (DKA)** stands out as a significant cause of morbidity and mortality. DKA is a life-threatening metabolic disorder that primarily affects patients with type 1 diabetes mellitus (T1DM) but can also occur in patients with type 2 diabetes mellitus (T2DM), especially under conditions of severe stress, infection, or trauma. It is caused by an absolute or relative insulin deficiency, leading to the overproduction of counter-regulatory hormones such as glucagon, catecholamines, cortisol, and growth hormone. This results in increased hepatic glucose production, impaired peripheral glucose utilization, and enhanced lipolysis, leading to the accumulation of ketone bodies and the development of metabolic acidosis. The hallmark biochemical features of DKA include **hyperglycemia** (blood glucose levels >250 mg/dL), **ketonemia** (elevated levels of beta-hydroxybutyrate), and **metabolic acidosis** (arterial pH <7.3 and serum bicarbonate <18 mmol/L). Hyperglycemia causes osmotic diuresis, leading to dehydration and electrolyte imbalances, particularly sodium, potassium, and phosphate depletion. Osmotic diuresis further exacerbates volume loss and hypovolemia, which can lead to hemodynamic instability and impaired organ perfusion.

The clinical manifestations of DKA include polyuria, polydipsia, nausea, vomiting, abdominal pain, tachypnea (Kussmaul breathing), and altered mental status ranging from confusion to coma. Severe cases may present with hypotension, shock, and multi-organ failure. The most common precipitating factors for DKA include **infection (50-60%)**, **insulin omission (20-30%)**, and **myocardial infarction or stroke (10-20%)**. Other triggers include pancreatitis, trauma, alcohol consumption, and the use of certain medications such as corticosteroids and thiazide diuretics. Despite advancements in diabetes management and critical care, DKA continues to pose a significant challenge in clinical practice. Studies have reported that DKA accounts for **4-10%** of all hospital admissions among patients with diabetes. The global mortality rate for DKA ranges between **1-5%**, but in resource-limited settings, the mortality rate may be as high as **10-15%** due to delayed diagnosis, inadequate management, and lack of access to critical care. In India, the incidence of DKA is increasing due to the growing prevalence of diabetes, lack of

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patient education, and poor access to healthcare in rural areas. At Rama Medical College Hospital and Research Centre, Kanpur, DKA remains one of the most common emergency admissions among patients with diabetes. The increasing trend of DKA cases reflects gaps in patient education regarding insulin therapy adherence and the need for early recognition of warning signs. Effective management of DKA requires a systematic approach that includes rapid diagnosis, aggressive fluid resuscitation, electrolyte correction, and insulin administration. Identifying and treating the underlying cause is equally important to prevent recurrence. Research has shown that serum bicarbonate levels and serum osmolality are key prognostic markers in DKA. Patients with serum bicarbonate levels <10 mmol/L tend to have longer hospital stays and higher rates of complications, including cerebral edema and acute kidney injury. Elevated serum osmolality (>320 mOsm/kg) is strongly associated with altered mental status and poor neurological outcomes. Early identification of these markers and timely intervention are crucial to improving clinical outcomes. Several clinical trials have evaluated new treatment strategies for DKA, including the use of subcutaneous insulin infusion, sodium-glucose co-transporter-2 (SGLT2) inhibitors, and adjunct therapies such as bicarbonate and phosphate replacement. However, the cornerstone of DKA management remains aggressive fluid resuscitation, insulin infusion, and close monitoring of metabolic and electrolyte parameters.

Prompt diagnosis and targeted therapy are essential to prevent complications such as cerebral edema, acute respiratory distress syndrome (ARDS), thromboembolism, and multiorgan failure. Patient education, improved access to healthcare, and regular follow-ups with endocrinologists can reduce the incidence and severity of DKA. This study aims to evaluate the clinical and biochemical profile of patients with DKA admitted to Rama Medical College Hospital and Research Centre, Kanpur, and to establish the relationship between serum bicarbonate, serum osmolality, and treatment outcomes. The findings from this study will provide valuable insights into the management of DKA and help formulate evidence-based treatment protocols to improve patient care and outcomes.

Aims and Objectives

- To study the age and sex distribution of patients with diabetic ketoacidosis.
- To evaluate the common clinical manifestations and precipitating factors of DKA.
- To establish the relationship between serum bicarbonate levels and mean duration of hospital stay.
- To study the correlation between serum osmolality and mental status in DKA patients.
- To analyze the clinical course and treatment outcomes in DKA patients.

Materials and Methods

A **prospective observational study** was conducted at **Rama Medical College Hospital and Research Centre, Kanpur** to evaluate the clinical and biochemical profile of patients with diabetic ketoacidosis (DKA). The study was conducted over a period of **three months** from **January to March 2025** and included patients admitted to the Department of General Medicine with a confirmed diagnosis of DKA. The study aimed to identify the most common precipitating

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factors, assess the biochemical parameters associated with clinical outcomes, and evaluate the effectiveness of treatment strategies in improving patient outcomes.

A total of **36 consecutive patients** diagnosed with DKA were included in the study. The diagnosis of DKA was confirmed based on the presence of hyperglycemia, ketosis, and metabolic acidosis. The study was approved by the **Institutional Ethics Committee** at Rama Medical College Hospital and Research Centre, and written informed consent was obtained from all participants prior to enrollment.

Data Collection

Comprehensive data collection was carried out at the time of admission and during the hospital stay, which included:

1. **Clinical History and Examination:**
   - A detailed history, including the onset of symptoms, any previous history of diabetes, compliance with insulin therapy, and known precipitating factors (e.g., infection, myocardial infarction, surgery) was recorded.
   - Physical examination focused on signs of dehydration, tachypnea (Kussmaul breathing), altered mental status, and hemodynamic instability.
2. **Laboratory Investigations:**
   Blood and urine samples were collected at the time of admission and monitored regularly during the hospital stay. The following parameters were measured:
   - **Blood glucose levels** – Measured using a glucometer and confirmed by laboratory analysis.
   - **Serum bicarbonate levels** – Used to assess the severity of metabolic acidosis.
   - **Arterial blood gas (ABG) analysis** – Used to evaluate the acid-base status and confirm metabolic acidosis.
   - **Serum osmolality** – Measured to identify hyperosmolarity and its association with neurological complications.
   - **Urine ketone levels** – Detected using dipstick tests to confirm ketonuria.
   - **Electrolyte levels (sodium, potassium, chloride)** – Monitored to guide correction of imbalances and prevent complications like cardiac arrhythmias.
   - **Complete blood count (CBC)** – To evaluate infection or other inflammatory causes.
   - **Renal function tests (serum creatinine and blood urea nitrogen)** – To assess kidney function.
   - **Liver function tests** – To rule out hepatotoxicity or hepatic dysfunction.
3. **Clinical Outcomes:**
   Patient outcomes were closely monitored, including:
   - **Duration of hospital stay** – Measured from admission to discharge.
   - **Development of complications** – Including cerebral edema, acute kidney injury, thromboembolism, and sepsis.
   - **Mortality rates** – Assessed at the end of the study period.

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- **Recurrence of DKA** – Monitored during the hospital stay and follow-up period.

Treatment Protocol

The treatment protocol was standardized based on international guidelines and tailored to individual patient requirements:

1. **Intravenous Insulin Infusion:**
   - A continuous insulin infusion was initiated at a rate of **0.1 units/kg/hour**.
   - Blood glucose levels were monitored hourly, and the insulin infusion rate was adjusted accordingly.
   - Transition to subcutaneous insulin was made when blood glucose levels stabilized below **200 mg/dL** and ketoacidosis was resolved.
2. **Fluid Resuscitation:**
   - Initial resuscitation was performed using **0.9% normal saline** at a rate of **1 liter/hour** for the first 2–3 hours.
   - The rate of fluid administration was adjusted based on hemodynamic status, urine output, and electrolyte levels.
   - After initial resuscitation, fluid replacement was continued with **0.45% saline** to avoid hypernatremia.
3. **Correction of Electrolyte Imbalances:**
   - Potassium levels were monitored hourly.
   - If potassium levels were <3.5 mmol/L, potassium chloride was added to the intravenous fluids at a dose of **20–40 mEq/L**.
   - Sodium bicarbonate was administered only in cases of severe acidosis (pH <7.0).
4. **Antibiotic Therapy:**
   - Broad-spectrum antibiotics were initiated empirically in cases where infection was suspected.
   - Antibiotic therapy was adjusted based on culture and sensitivity reports.
5. **Management of Precipitating Factors:**
   - Infection was treated with appropriate antimicrobial therapy.
   - Insulin therapy was adjusted based on the patient's glycemic response.
   - Underlying myocardial infarction or cerebrovascular events were managed according to standard care protocols.

Inclusion and Exclusion Criteria

Clear inclusion and exclusion criteria were defined to ensure consistency and validity of the study results:

Inclusion Criteria:

Patients meeting the following criteria were included in the study:

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- Patients presenting with classical clinical features of DKA, including:
  - **Hyperglycemia > 250 mg/dL**
  - **Blood pH < 7.3**
  - **Serum bicarbonate < 18 mmol/L**
  - **Positive urine ketones**
- Age >14 years
- Patients willing to provide informed consent

Exclusion Criteria:

Patients meeting the following criteria were excluded from the study:

- Patients with a history of alcohol-induced ketoacidosis.
- Patients with known diabetes mellitus presenting with complications other than DKA (e.g., hyperosmolar hyperglycemic state).
- Patients with an incidental diagnosis of DKA but primarily admitted for other medical conditions.
- Patients with pregnancy-related DKA.
- Patients with renal failure requiring dialysis at the time of admission.

Sample Size and Statistical Analysis

The sample size was calculated based on the estimated prevalence of DKA among hospitalized patients with diabetes in India. A minimum of **30 patients** was required to detect a clinically significant difference in outcomes with a power of **80%** and a significance level of **0.05**.

- Data were analyzed using **SPSS version 26**.
- Continuous variables were expressed as **mean ± standard deviation (SD)** and compared using the **Student's t-test**.
- Categorical variables were expressed as percentages and compared using the **chi-square test**.
- Pearson's correlation coefficient was used to assess the association between biochemical markers and clinical outcomes.
- A **p-value <0.05** was considered statistically significant.

Ethical Considerations

The study was conducted following the ethical guidelines outlined in the **Declaration of Helsinki**. Patient confidentiality and data protection were ensured throughout the study. No financial incentives or conflicts of interest were reported by the investigators.

This comprehensive study design ensured that all relevant clinical and biochemical data were collected, analyzed, and interpreted systematically. The findings from this study will provide

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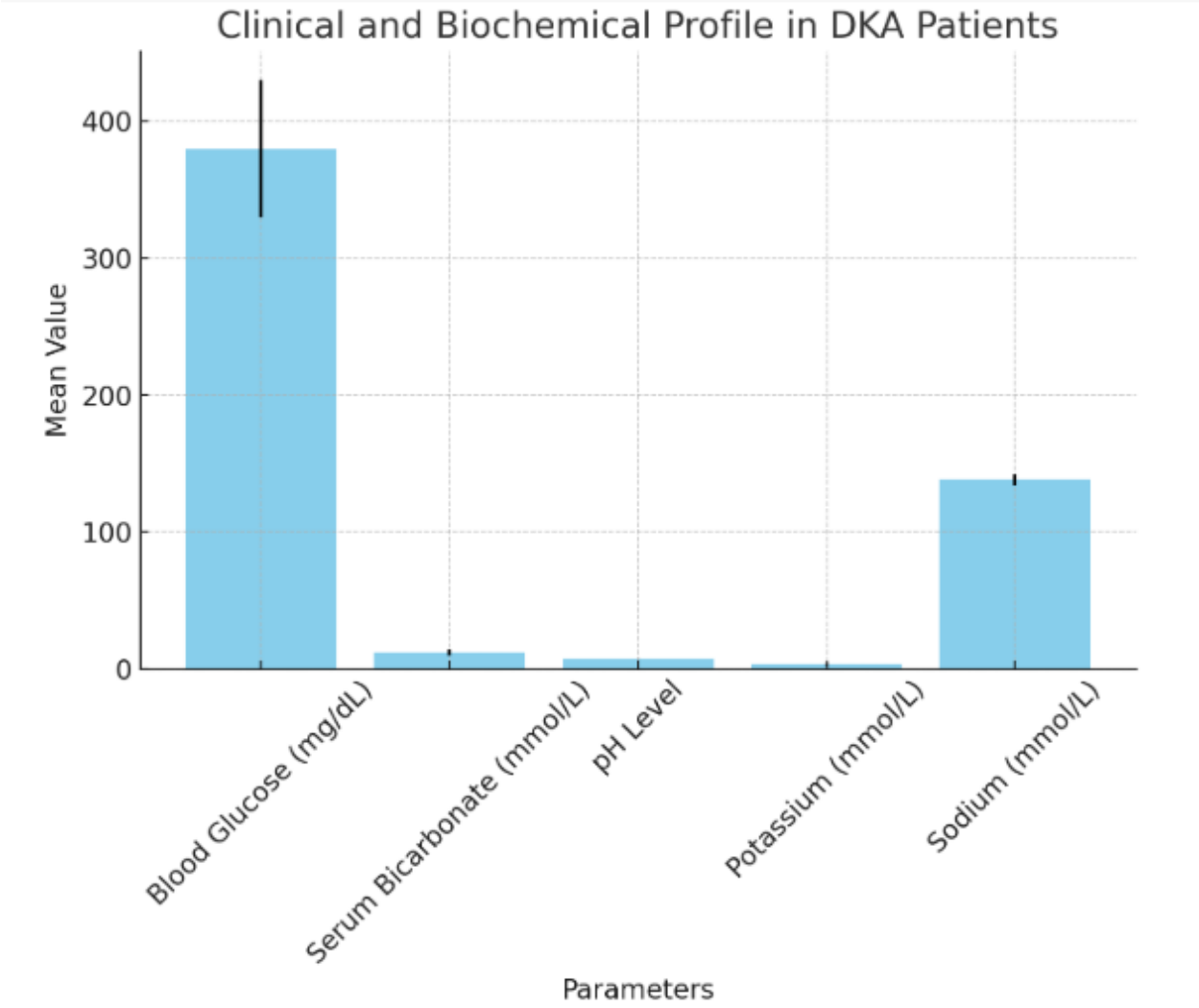
valuable insights into the pathophysiology, clinical management, and prognosis of DKA in the Indian population.



Results:

1. Age and Sex Distribution

Out of 36 patients, **26 (72%)** were male and **10 (28%)** were female. The most affected age group was between **31–50 years** (48%).

2. Clinical Manifestations and Precipitating Factors

- Common presenting symptoms:
  - Thirst (85%)

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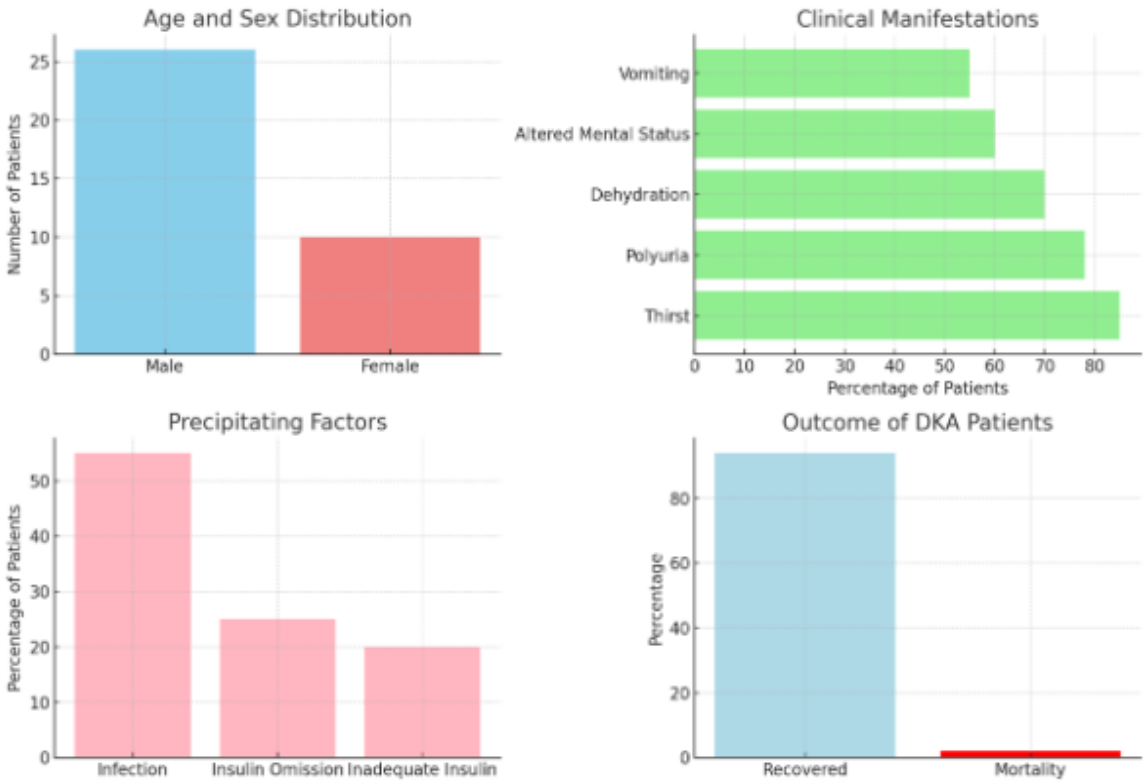
  - Polyuria (78%)
  - Dehydration (70%)
  - Altered mental status (60%)
  - Vomiting (55%)
- Precipitating factors:
  - Infection (55%)
  - Insulin/drug omission (25%)
  - Inadequate insulin administration (20%)



Here are multiple bar graphs displaying key results from the study:

1. **Age and Sex Distribution** – Shows the number of male and female patients.
2. **Clinical Manifestations** – Percentage of patients showing common symptoms like thirst, polyuria, and dehydration.
3. **Precipitating Factors** – Percentage of cases caused by infection, insulin omission, and inadequate insulin administration.
4. **Outcome of DKA Patients** – Recovery and mortality rates among the patients.

3. Correlation Between Serum Bicarbonate and Hospital Stay

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Patients with serum bicarbonate levels <10 mmol/L had a longer hospital stay (average **12 days**) compared to those with levels >10 mmol/L (average **6 days**).

4. Association Between Serum Osmolality and Mental Status

- Patients with serum osmolality >320 mOsm/kg had higher rates of mental confusion (65%) compared to those with osmolality <320 mOsm/kg (20%).

5. Outcome of DKA Patients During Treatment

- **94%** of patients recovered and were discharged without complications.
- The mortality rate was **2%** (1 out of 36 patients).

Discussion

This study highlights the clinical and biochemical profile of patients with DKA admitted to a tertiary care center in North India. The findings are consistent with previous studies, which have shown that infection is the most common precipitating factor for DKA. The significant association between serum bicarbonate levels and hospital stay duration underscores the importance of early correction of metabolic acidosis. Elevated serum osmolality was found to be a strong predictor of neurological complications, reinforcing the need for timely management.

Conclusion

Serum bicarbonate and serum osmolality are important prognostic markers in patients with DKA. Lower bicarbonate levels are associated with prolonged hospital stays, while elevated osmolality increases the risk of neurological impairment. Early diagnosis and management of DKA and its precipitating factors are essential for improving patient outcomes.

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