

Role of Serum Albumin as a Prognostic marker of mortality and duration of hospital stay among Diabetic Ketoacidosis Patients.

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Abstract: Background: Diabetic Ketoacidosis (DKA) is an critical and menacing problem of Type 1 as well as type 2 diabetes mellitus (T2DM). DKA is associated with high amount of risk of mortality and morbidity (hospital stay). The prognostic factors of DKA are important factors affecting the outcome of the patients (as treated or death). S. Albumin is one of the prognostic factor less studied up till now.

Objectives: To determine Clinical profile of DKA patients: aetiologies, precipitating factors, biochemical parameters and other complications of T2DM patients and to correlate serum albumin level with mortality, duration of stay among DKA patients.

Methodology: This cross sectional study will be conducted among 100 diabetic patients with and without ketoacidosis from May 2019 to May 2021. Biochemical parameters: glycated Haemoglobin, urine ketones and serum albumin will be gathered to determine the prognosis. Controls will be adult diabetic patients without ketoacidosis. Data from Cases and controls will be statistically analysed and then compared accordingly.

Expected Results: It is expected that decreased Sr. albumin will be associated with poor prognosis in DKA patients. Sr. Albumin might be an indirect prognostic marker of diabetes control due anabolic effect of Insulin, which affects both ketosis possibility and glucose levels.

Conclusion: DKA is considered dangerous and life threatening complication of Diabetes mellitus and in spite of all the guidelines of DKA management, they are inadequately

managed. There are very few studies done for determining prognostic markers associated with mortality in DKA. Hence, we want to know the role of Serum Albumin in prognosis of patients with diabetic ketoacidosis.

KeyWords: *Diabetes, Diabetic Ketoacidosis, Serum Albumin, Prognostic Factors.*

Role of Serum Albumin as a Prognostic marker of mortality and duration of hospital stay among Diabetic Ketoacidosis Patients.

Introduction:

Diabetes mellitus is a state of the body where ability to secrete or react to insulin is decreased, resulting in abnormal carbohydrate metabolism and hyperglycemia. The hyperglycaemia is a delayed consequence of a reduction in insulin creation realized by β -cell harm or protection from the insulin action in liver, fats, and muscle or combination of these tissues [1-4]. DKA is a significant complication of diabetes, which is related with high measure of danger of mortality and morbidity(hospital remain). One of the fundamental deformities in the DKA treatment lies in the beginning of the board and discovery of the condition. DKA is portrayed by a gathering of three of hyperglycaemia, metabolic acidosis, and ketonemia/ketonuria. The yearly recurrence ranges between 4.6-8 cases per 1,000 diabetics [5-8]. The DKA pathophysiology includes absolute decrease of the secreted insulin levels in body either because of increased consumption or increase in hormones: glucagon, adrenaline, steroids concentrations. Absolute absence of Insulin levels in blood prompts hyperglycaemia and ketosis. DKA is a state of catabolism, where there is an adjustment of protein, sugar and lipid digestion. This protein breakdown prompts decline in Serum albumin levels. Management of DKA Comprises i) hydration and treatment of dyselectrolytemia ii) insulin infusion to treat hyperglycemia iii) treatment of the risk factors. Regardless of the treatment protocols, DKA treatment keeps on being deficiently overlooked, even in competent medical clinics [9,10]. The prognostic elements of DKA can be utilized as significant factors in the ultimate result of the patient (as treated or demise).

Aim & Objectives: The aim is to establish Serum Albumin as a Prognostic marker among Patients With Diabetic Ketoacidosis. With the main objectives to determine Clinical profile of DKA patients: aetiologies, precipitating factors, biochemical parameters and other complications of T2DM patients. To compare the serum albumin levels of DKA patient with Diabetic patients without ketoacidosis & to correlate serum albumin level with mortality, duration of stay among DKA patients.

Methodology:

All Patients with Diabetic ketoacidosis admitted in Medicine Intensive Care Unit of Jawaharlal Nehru medical college with age and Sex matched controls with Diabetes will be enrolled in this cross sectional case control study.

Type of study: Case control study

Study site: All Patients with Diabetic ketoacidosis admitted in Medicine Intensive Care Unit of Jawaharlal Nehru medical college with age and Sex matched controls with Diabetes will be enrolled in this cross sectional case control study.

Inclusion Criteria-

Diabetic patients admitted in the Medicine ICU of JNMC with blood glucose level of >250 mg/dl, Arterial pH of less than 7.30 (acidosis), Urine ketones present of more than 1 + will be included in the study.

Exclusion Criteria-

Children (<18 yr age), Pregnant females, Alcoholic ketosis, Starvation ketosis, Lactic acidosis, Chronic Kidney disease, Chronic liver disease, chronic diarrhoea will be excluded.

After early examination and investigations, the patients will be scored according to Glasgow Coma Scale (GCS) and SOFA Score.

Sample size calculation:

$$N=Z^2 p(1-p)/d^2$$

where, Z is the Z value (e.g. 1.96 for 95% confidence level) ,p = percentage of people with diabetes (may or may not have ketoacidosis) represented in decimal (.5 used for sample size needed), d = confidence intervals, represented in decimal. Proportion of diabetic ketoacidosis =0.14%=0.0014 [7] ,D=desired precision 10%=0.10 therefore, N=100.

Statistical analysis will be made by inferential and descriptive statistics using chi square test and unpaired t-test. Other tests are multivariate logistic model and non-parametric test.

Data collection: Consecutive patients with increased RBS or known diabetes or patients showing symptoms of DKA (like nausea, vomiting, thirst, abdominal pain, dehydration, shortness of breath), who are admitted in Medicine ICU of AVBRH will be evaluated clinically and their history and examination will be recorded. Patients will be assessed on the basis of their symptoms and initial lab investigations. DKA is defined by three main parameters. These are Serum glucose >250 mg/dl, Arterial ph <7.30 (acidosis), Urine ketones present of more than 1 +. The patients matching this criteria will be included in the study. Their demographic information like Name , age, sex , address will be taken followed by general examination including gcs score, temperature, pulse, respiratory rate, blood pressure will be noted. Lab investigations will include complete blood count, liver function tests, kidney function tests, serial blood sugar levels, arterial blood gases, blood urea nitrogen, serum electrolyte levels and urine ketone and sugar levels. The tests will be recorded and qSOFA score will be assessed on this basis.

Expected Outcomes:

DKA is one of the dangerous complication of Diabetes mellitus. In spite of all the guidelines of DKA management, they are inadequately managed. Sr. albumin might be an indirect but sensitive indicator of 'insulin secretory reserve'. Both diabetes ketosis risk and glucose level are affected by insulin secretory reserve in the body.[7] Hence, this study will determine the role of Albumin levels as a prognostic marker of mortality and morbidity in DKA patients, potential risk factors of DKA. Study will find out the aetiologies, other diabetes related complications among DKA.

Discussion:

DKA is one of the most life threatening complication of diabetes mellitus, the prognosis of the patient in DKA is decided by time elapsed between onset of symptoms and recognition of

the condition along with time between diagnosis and starting the treatment. The diagnosis of DKA is made by trio of- uncontrolled hyperglycemia with high anion gap metabolic acidosis and presence of ketones in blood/urine. The prevalence of DKA in diabetic population is 4.6-8 cases in every 1000 patients. The mortality rate of patients with DKA is 2 -10%. Age, gender, type of diabetes , decreased blood pressure, leucocytosis, azotemia, hypomagnesemia , hyperosmolarity, acidosis and hypoalbuminemia are predictors of mortality in DKA. A number of articles related to different aspects of this study were reviewed [11-12]. Gaidhane et al assessed perceptions of primary care doctors towards type 2 diabetes mellitus and challenges for care at primary care level in India[13]. Gondivkar et al conducted evaluation of gustatory function in patients with diabetes mellitus type 2 [14]. Khatib et al suggested M-Health intervention for type 2 diabetes mellitus patients in Indian rural areas[15]. Related studies were also reported by Ray et al [16] and Shrivastava et al [17]. Female gender, severe acidosis, leucocytosis and hyperosmolarity were associated with mortality in study done by A. Agrawal 2016 [[4],18].In a study by P. Cheng et al it was found that diabetic patients with decreased serum albumin levels were susceptible to ketosis (higher ketonuria an increased ketonemia). So hypoalbuminemia may be a useful indication of ketosis suggesting serum albumin may reflect patient's insulin reserve (which is an indirect marker of glucose control).One of the profits of using serum albumin as prognostic marker for DKA is that its half-life is 21 days, which makes it a better time sensitive glycemic measure than HbA1c.One of the main limitation of this study is retrospective type of study, so a selection bias may occur.

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