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A STUDY TO ASSESS THE FACTORS ASSOCIATED WITH INCREASED DURATION OF INSULIN INFUSION IN PEDIATRIC DIABETIC KETOACIDOSIS PATIENTS ADMITTED IN A TERTIARY CARE HOSPITAL

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ABSTRACT

Background: Most of the previous studies in DKA focused on precipitating factors and its management and limited studies were done on various factors in DKA which influence its prognosis specifically in correlation to duration of insulin infusion.

Aim: To study the influence of metabolic derangements and sepsis on prognosis in DKA.

Materials and methods: This was a hospital based single centered prospective cross-sectional study to assess the factors associated with increased duration of insulin infusion in pediatric diabetic ketoacidosis patients. Based on the eligibility criteria, a total of 50 children with DKA were recruited over a period of 18 months.

Results: Majority of children belonged to more than 10 years of age (52%) followed by 1-5 years of age and 6-10 years of age (18%). 6% of children belonged to <1 years of age. 72% children were female and 28% were male. 18% were in acidotic range; 20% had hypomagnesemia and 10% had phosphate level less than normal. All patient had high anion gap metabolic acidosis at presentation. With treatment, the number of patients with high anion gap metabolic acidosis decreased gradually with only a patient having high anion gap metabolic acidosis at the end of 48 hours . Normal anion gap metabolic acidosis was seen in 12hours and 24 hours, 6% in 36 hours and 48 hours. It was found that all patients who had normal electrolytes at 24 hours required insulin infusion less than 12 hours. The median insulin duration in children with abnormal electrolyte profile was found significantly higher than in children with normal electrolyte profile. Children with electrolyte disturbances at 24 hours had a statistically significant longer duration of insulin infusion requirement. It was observed that out of 50 patients 30 (60%) had sepsis. When the duration of insulin infusion and hospital stay was compared between sepsis and no sepsis groups, though there was a slight prolongation of both in sepsis group, this was not statistically significant. Only 6% children died due to DKA and 94% children were successfully discharge from our hospital.

Conclusion: Patients with electrolyte disturbances persisting at 24 hours required insulin infusion to a significantly longer duration.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

Keywords: Electrolyte disturbances, Diabetes mellitus, Anion gap.

INTRODUCTION

Diabetes mellitus is a complex metabolic disorder with numerous etiologies that is defined by persistent hyperglycemia and changes in carbohydrate, lipid, and protein metabolism as a result of deficiencies in the insulin-production, insulin secretion, insulin action, or a combination of the two.[1] While the etiology of diabetes is heterogeneous, most cases of diabetes can be classified into two broad etiopathogenetic categories: type 1 diabetes, which is characterized primarily by deficiency of insulin secretion; type 2 diabetes, which results from a combination of resistance to insulin action and an inadequate compensatory insulin secretory response for the degree of insulin resistance. Type 1 diabetes remains the most common form of diabetes in young people.[2]

Diabetic ketoacidosis (DKA) is a major complication of the childhood type 1 diabetes mellitus (T1DM) and is associated with increased risk of morbidity and mortality. About 25 to 40% of the newly diagnosed T1DM children present with DKA whereas the risk of developing DKA in established T1DM children is 1 to 8% per patient per year.[3]

The biochemical criteria for the diagnosis of diabetic ketoacidosis (DKA) are[4] Hyperglycemia (blood glucose >11 mmol/L [≈200 mg/dL]), Venous pH < 7.3 or serum bicarbonate < 15 mmol/L and Ketonemia (blood ß-hydroxybuyrate ≥3 mmol/L) or moderate or large ketonuria. DKA is the most common presentation of children with type 1 diabetes mellitus. Most of the previous studies in DKA focused on precipitating factors and its management. Not many studies were done on various factors in DKA which influence its prognosis specifically in correlation to duration of insulin infusion. This study will bring out metabolic derangements in DKA. This study will help to predict the average hospital stay and insulin infusion requirement for a patient with DKA. This study will bring out the relationship of sepsis and metabolic derangements with duration of insulin infusion and length of hospital stay.

MATERIALS AND METHODS

Place of Study: The study was conducted in the Department of Pediatrics, Niloufer hospital, affiliated to Osmania Medical College. It is the largest tertiary care center in the state of Telangana, situated in the heart of Hyderabad.

Study Design: Prospective observational study

Study period: 18 months. Jan 2020 – Jun 2021

Study Population: Children with DKA who were admitted ICU inthe Department of Paediatrics, Niloufer Hospital during the study period .

Study Sample Size: 50

METHODOLOGY:

Children with DKA satisfying the inclusion criteria were enrolled into the study and admitted after getting informed consent from the parents/guardians.

Inclusion Criteria: Age 6 months – 12 years and children whose Parents/guardians are willing to give informed consent.

Exclusion criteria: Children with DKA, who are referred from other hospitals after partial treatment **and** Children whose parents or guardians are not willing to give informed consent.

Ethical clearance was obtained from the Institutional Ethical Committee, Department of Paediatrics, Osmania Medical College, Koti, Hyderabad.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

Procedure:

Children with DKA satisfying the inclusion criteria were enrolled into the study and admitted after getting informed consent from the parents/guardians. Diagnosis of DKA made based on the standard definition.[4]

The following details were noted in the data collection form:

Age, sex and presence of pre existing diabetes. If found to have pre-existent diabetes, duration of diabetes, insulin requirement, glycosylated haemoglobin (HbA1C) and interval between DKA and last available HbA1C were noted. Family history of diabetes was elicited. Presence of any identifiable precipitating cause like infection, stress or insufficient intake were noted.

All basic investigations were done: Arterial blood was drawn in heparinised syringe for blood gas analysis. 5 ml of venous blood was drawn using a syringe for the estimation of other blood investigations. Urinalysis reagent strips were used for testing urine ketone levels.

The above said investigations were done at the time initiation of treatment, 12hrs, 24 hrs, 36 hrs and 48 hrs. All the children admitted were treated as per standard DKA protocol.

For children who recovered or died before 48 hours, investigations were done only till that time. The time of stopping insulin infusion was noted for all patients. The clinical outcome of child and duration hospital stay were also noted.

The data was entered in Microsoft Excel 2010 version and analysed by statistical software SPSS v.23.0 and Jamovi 1.8.4. Normal distribution of data was checked by Shapiro wilk test. Non-parametric continuous data was represented as Median and IQR. Categorical data was represented as frequency and percentage.

For analysis of two independent parametric variable; independent t-test was used. For non-parametric variable; Mann-Whitney U test was used. To find association between categorial data Pearson's chi-square test was used.

P value <0.05 was considered as significant.

RESULTS

With due consideration of eligibility criteria, a total of 50 patients were enrolled in our study.

Table1: Age category of study population (n=50)

Levels	**Counts**	**% of Total**
<1 years	3	6 %
1-5 years	12	24 %
6-10 years	9	18 %
>10 years	26	52 %
Gender		
Male	14	28 %
Female	36	72 %
Preexisting DM	18	36%
New onset of DM	32	64%
Family h/o DM		
Yes	**14**	**28 %**

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

No	**36**	**72 %**
Duration		
<2 years	10	56 %
2-5 years	5	28 %
>5 years	3	17 %

Majority of children belonged to more than 10 years of age (52%) followed by 1-5 years of age and 6-10 years of age (18%). 6% of children belonged to <1 years of age. 72% children were female and 28% were male. The incidence of pre-existing diabetes was 36%. There were 64% children with new onset of diabetes.

28% of children had family history of DM. 56% of children with pre-existing diabetes had duration less than 2 years. 28% of children with pre-existing diabetes had duration of 2-5 years.17 % of children with pre-existing diabetes had duration more than 5 years

Table-2: Preceding HbA1c status in pre-existing diabetes

Preceding HbA1c	**Counts**	**% of Total**
7.5-9	7	39 %
>9	11	61 %
Preceding HbA1C gap		
< 4 months	11	61 %
4-12 months	4	22 %
> 1 years	3	17 %
Insulin dose		
0.5-1.0 IU/kg/day	4	22 %
1.0-1.5 IU/kg/day	10	56 %
>1.5 IU/kg/day	4	22 %

39% of children with pre-existing diabetes had preceding HbA1c status in range of 7.5-9%. 61% of children with pre-existing diabetes had preceding HbA1c status more than 9%. None of children with pre-existing diabetes had preceding HbA1c status less than 7.5%. **61%** of children with pre-existing diabetes had preceding HbA1c gap less than 4 months.**22%** of children with pre-existing diabetes had preceding HbA1c gap between 4 months to 12 months. **17%** of children with pre-existing diabetes had preceding HbA1c gap more than 1 year.

22% of children with pre-existing diabetes were taking insulin dose of 0.5-1.0 IU/kg/day prior to DKA onset. 56% of children with pre-existing diabetes were taking insulin dose of 1.0-1.5 IU/kg/day prior to DKA onset. 56% of children with pre-existing diabetes were taking insulin dose of more than 1.5 IU/kg/day prior to DKA onset.

Table-3:: Causes of DKA

Causes of DKA	**Counts**	**% of Total**
Infections	30	60 %
Insufficient insulin intake	5	10 %
Unknown	15	30 %

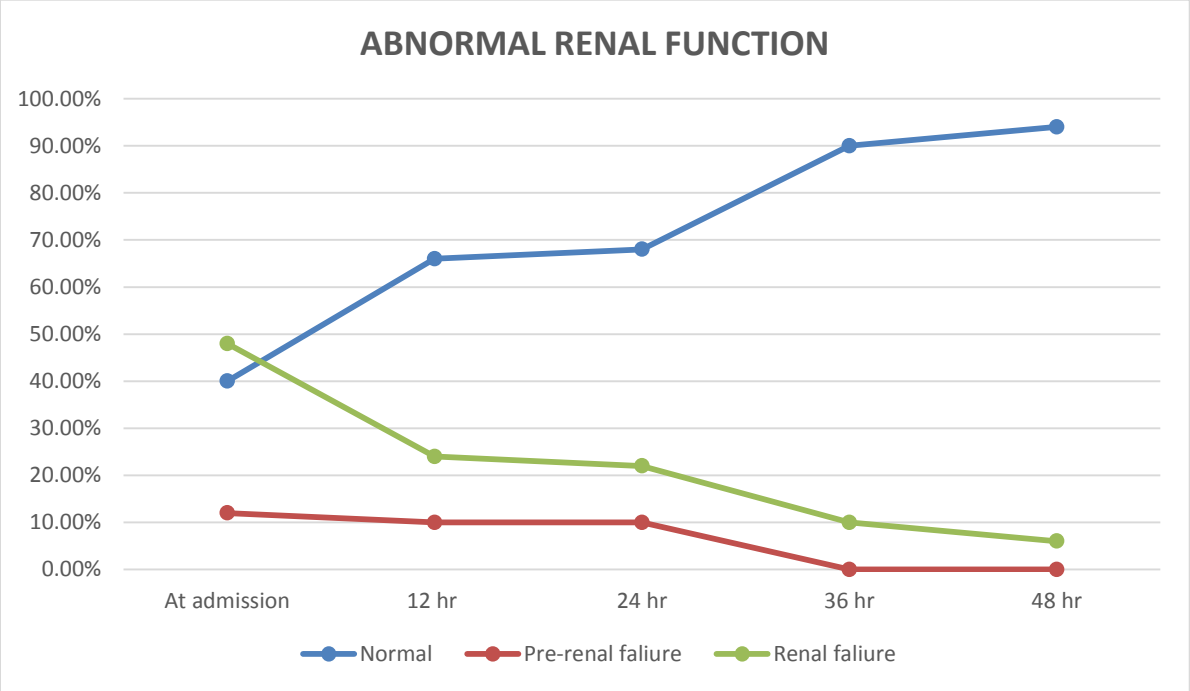
ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

Previous episode of DKA		
No	5	28 %
Yes	13	72 %
Distribution of Infections		
UTI	12	40%
Pneumonia	10	33%
Gastointestinal infections	2	7%
Skin Abscess	1	3%
Others	5	17%
Insulin infusion (in h.)		
<12 h	13	26 %
12-24h	17	34 %
24-48h	15	30 %
>48 h	5	10 %

In our study, majority of children (60%) had DKA were causes by infection and 10% DKA were caused by insufficient insulin intake. 30% causes of DKA were unknown etiology.**72%** of children who were known case of diabetes had previous episode of DKA

Out of 30; most common infection among children with DKA was UTI (40%) followed by pneumonia (33%). In this study, 26% children recovered with insulin infusion less than 12 hours, 34% within 12-24 hours and 30% within 24-48 hours. Only 10% of children required insulin infusion beyond 48 hours.

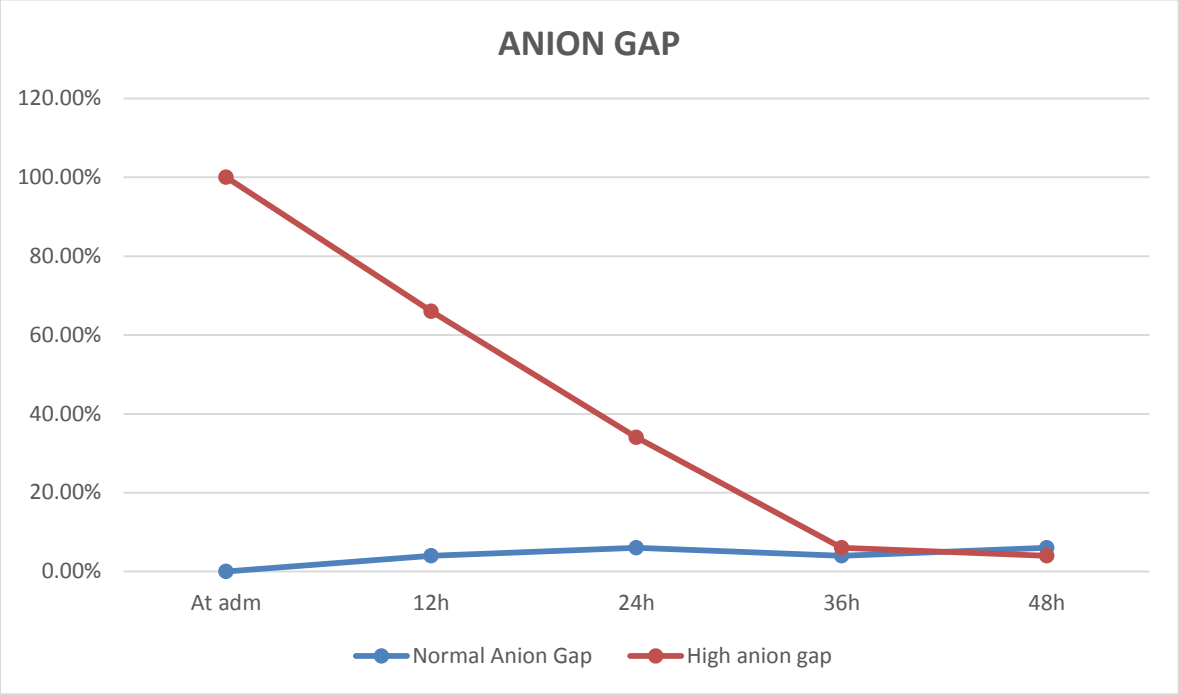
Figure-1: Abnormal renal function and DKA status



ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

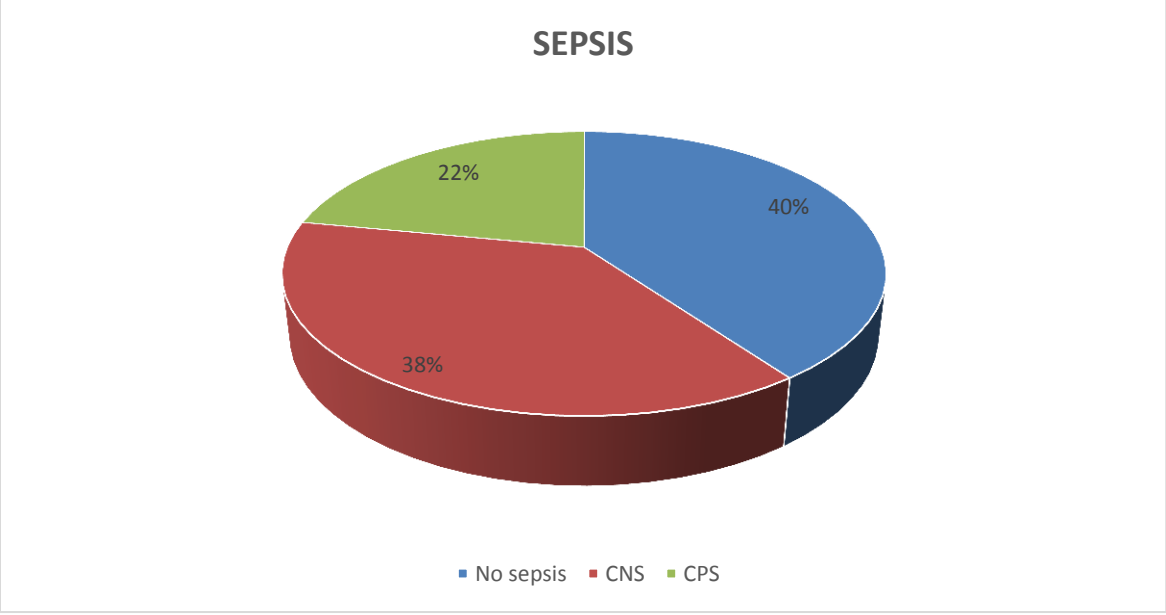
Prerenal failure seen in children at admission 12 %, at 12 hours-10%, at 24 hours -10%, at 36 and 48 hours no pre renal failure were reported. Renal failure seen in children at admission 48%,at 12 hours-24%, at 24 hours – 22%, at 36 hours-10% and 48 hours- 6%.

Figure-2: Metabolic acidosis and Anion gap



Normal anion gap metabolic acidosis seen in children at admission is absent, at 12 hours-4% ,at 24 hours -6 %, at 36 hours-4% and at 48 hours- 6% were reported. High anion gap metabolic acidosis seen in children at admission 100 %,at 12 hours-66% ,at 24 hours – 34%, at 36 hours-6% and 48 hours- 4%. were reported.

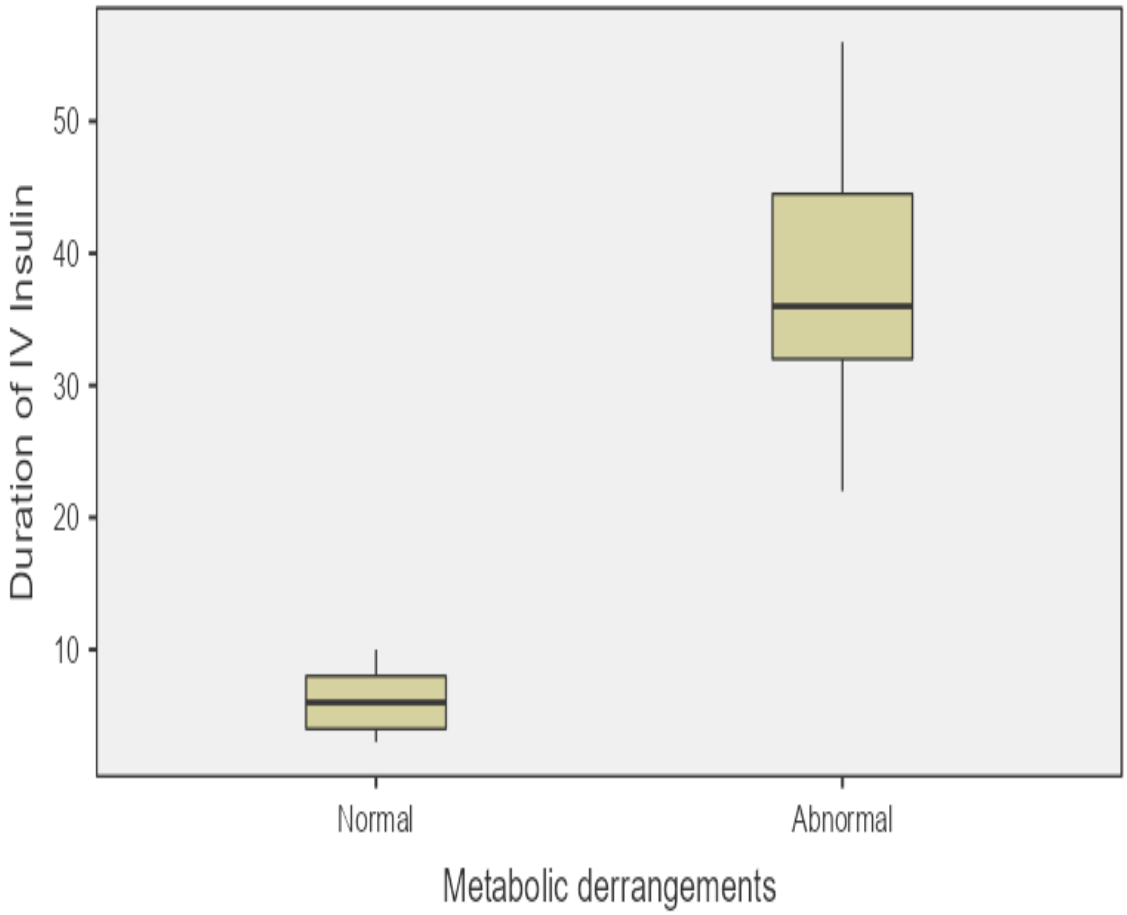
Figure-3: Pie chart showing incidence of Culture positive and negative sepsis



ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

CNS – Culture negative sepsis; CPS – Culture positive sepsis
In our study, the incidence of culture positive sepsis(CPS) was 22% and 38% had culture negative sepsis(CNS) among children with DKA. In this study DKA patient stayed in this hospital were <3 days-2%,4-7 were –8%, 7-14 were – 52% and remaining takes > 14 days patients(38%).

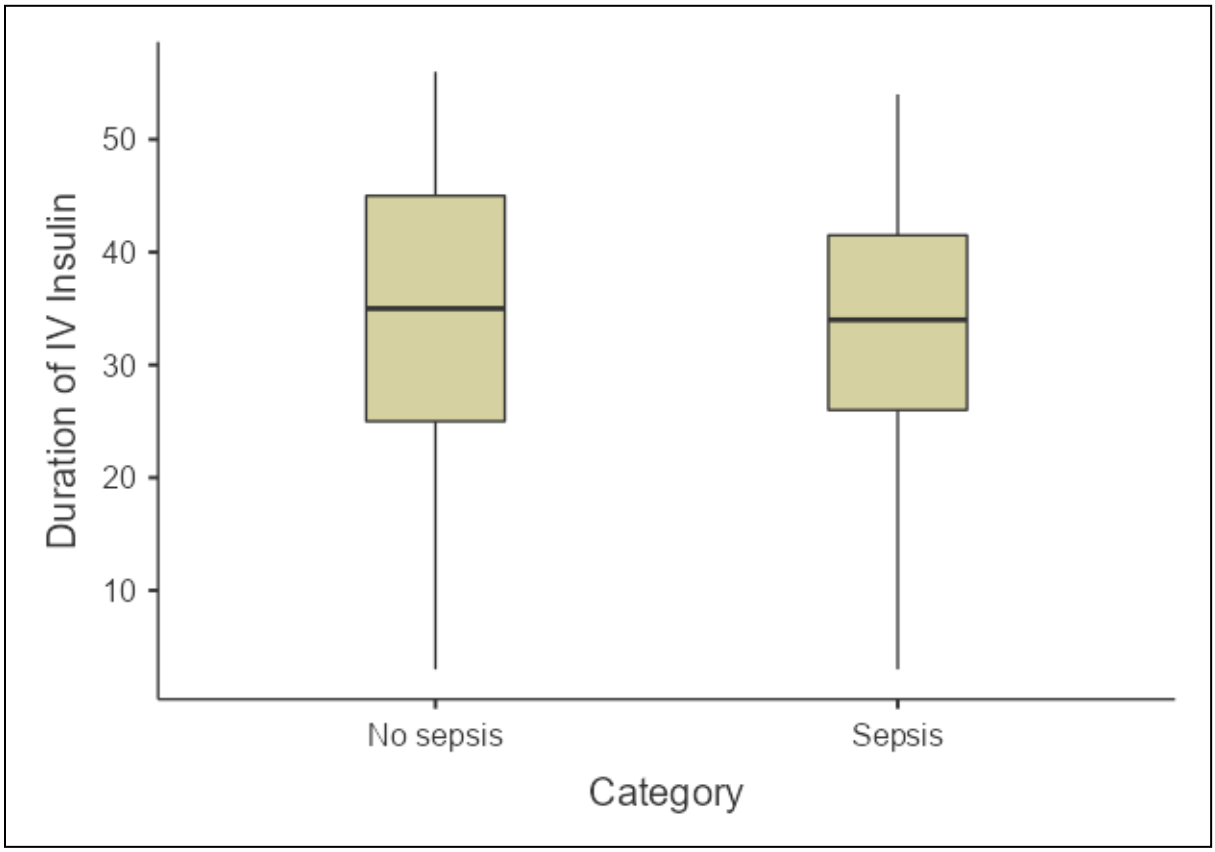
Figure -4: Insulin infusion duration among children with metabolic derangements among children with metabolic derangements



On applying chi square test a significant reduction in duration of insulin infusion was demonstrated in children whose electrolyte levels normalised at 24 hours. When the duration of insulin infusion in patients who had normal and abnormal electrolyte at 24 hours was compared , it was found that all patients who had normal electrolyte at 24 hours required insulin infusion less than 12 hours ($p<0.001$).The median insulin duration in children with abnormal electrolyte profile was found significantly higher in children with normal electrolyte profile ($p<0.001$).

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

Figure-5: Duration of insulin infusion among children with sepsis.



There was no significant difference between median insulin infusion duration in children with sepsis as compared with children no sepsis (p=0.808).

Table-4: Relation between metabolic derangements and duration of hospital stay

Duration of stay		Metabolic derangements		Total
		Normal (12)	Abnormal (38)	
<3	Observed	2	0	0
	% within row	100%	0 %	100%
3-7	Observed	0	3	3
	% within row	0 %	100 %	100 %
7-14	Observed	7	19	26
	% within row	27 %	73 %	100 %
>14	Observed	3	16	19
	% within row	16 %	84 %	100 %
Chi-square test,p=0.524				

The duration of stay is more in patients who had abnormal electrolyte level at 24 hours – Only 24 % of patients with normal electrolyte level at 24 hours stayed beyond 14 days, while 84% of patients with electrolyte disturbances persisting at 24 hours stayed beyond 14 days. But this difference was not statistically significant (p=0.524).

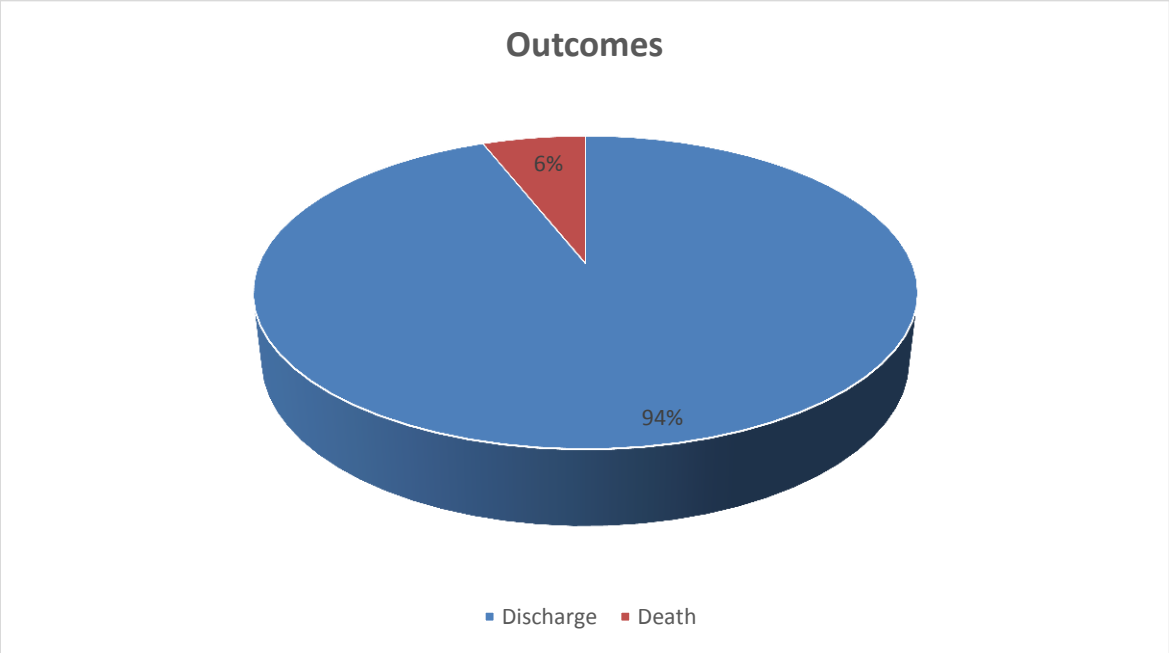
ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

Table-5: Relation between sepsis and duration of hospital stay

Duration of stay (in days)		Sepsis			Total
		No sepsis	CNS	CPS	
<3	Observed	1	0	0	1
	% within row	100 %	0 %	0 %	100 %
3-7	Observed	3	1	0	4
	% within row	75 %	25 %	0 %	100 %
7-14	Observed	11	10	5	26
	% within row	42 %	38 %	19 %	100 %
>14	Observed	5	8	6	19
	% within row	26 %	42 %	32 %	100 %

Though the duration of stay is more in patients who had sepsis, this was not statistically significant (p=0.460).

Figure -6: Outcomes among children with DKA



In our study, only 6% children died due to DKA and 94% children were successfully discharge from our hospital.

DISCUSSION

DKA accounts for nearly 0.6% of total intensive care admissions in PICU[62]. DKA admissions in PICU are increasing not only because of increasing prevalence of T1DM but they are often missed due to inherent difficulties in diagnosing diabetes mellitus for the first time in children. The classical history of diabetes is generally unavailable in children leading to more chance of missed diagnosis and ultimately ending up in DKA. Lack of awareness regarding signs and symptoms of T1DM among general

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

population and primary care physicians contributes to T1DM complicating as DKA. Omission of insulin either deliberately or inadvertently is responsible for DKA in established diabetic children. Most of the previous studies in DKA focused on precipitating factors and its management and limited studies were done on various factors in DKA which influence its prognosis specifically in correlation to duration of insulin infusion.

Hence, This was a hospital based single centered prospective cross-sectional study to assess the factors associated with increased duration of insulin infusion in pediatric diabetic ketoacidosis patients. Based on the eligibility criteria, a total of 50 children with DKA were recruited over a period of 18 months.

The main objectives of this study were (i) To study the metabolic derangements in DKA and determine its relation with duration of insulin infusion and hospital stay and (ii) To determine the relation between sepsis in DKA with duration of insulin infusion and hospital stay.

In our study; majority of children belonged to more than 10 years of age (52%) followed by 1-5 years of age and 6-10 years of age (18%). 6% of children belonged to <1 years of age.

Table-6: Comparision of our study with other studies

Study	year	Sample size	variable	N%
			Age	
Our study	**2021**	**50**	**<1 years**	**6 %**
			1-5 years	**24 %**
			6-10 years	**18 %**
			>10 years	**52 %**
Kanwal et.al.[5]	**2011**	**55**	**0-5 years**	**25.54%**
			5-12 years	**60%**
			12-18 years	**14.45%**
Bhardwaj P et.al.[6]	**2020**	**354**	**0-5 years**	**13.5%**
			6-10 years	**27.6%**
			11-15 years	**37.9%**
Gender				
Kanwal et.al.[5]	**2011**	**55**	**Male**	**49.00%**
			Female	**51%**
Andrew et.al.[7]	**2012**	**84**	**Male**	**41%**
			Female	**60%**
Bhardwaj P et.al.[6]	**2020**	**354**	**Male**	**55.1%**
			Female	**44.9%**
Our study	**2021**	**50**	**Male**	**28 %**
			Female	**72 %**

In our study, 72% children were female and 28% were male. In the present study, among the study population, 64% had denovo diabetes mellitus. 36% were known cases of diabetes.

In Present study 64% had denovo diabetes mellitus. 36% were known cases of diabetes. Our study is in comparision with other studies Del Pozo P et.al.[8] 67.2% had denovo diabetes

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

Bhardwaj P et.al.[6] Past history of diabetes was present in 51.8%, denovo diabetes was present in 48.2% Garima A. Varshney et.al.[9] Past history of diabetes was present in 66.66%, denovo diabetes was present in 33.33%

Infections were noted as the precipitating factor in 60% of the cases in our study, similar to the findings of Desse TA et.al.[10], who observed infections as the precipitating factor in 59% of the cases, with UTI being the cause in 64.2% of the patients followed by pneumonia in 13.7%. UTI(40%) followed by pneumonia(33%) were the leading causes of infections noted in our study, in line with the finding of Tigestu Alemu Desse et.al.[10]

In this study, at the time of admission , **Sodium-** 26 % children were hyponatremic, 58% were in normal range and 16% had hypernatremia. The study done by Kanwal et. al.[5] observed that at the time of admission only 20% were hypernatremic. Another study done by Andrew E Edo showed that about 36.9% had hyponatremia and 1.2% had hypernatremia at admission.[7]

Serial monitoring of sodium in this study showed that with treatment, hyponatremia decreased and hypernatremia increased up to 24 hours after which sodium levels gradually stabilised to normal level.

Potassium-24% had hypokalemia, 46% had normal range and 30% were in hyperkalemia at admission.

In a study conducted by Andrew E Edo he observed that 21% had hyperkalaemia at admission and only 3% had hypokalemia.[7] Similarly study conducted by Kanwal SK.et.al[5] showed only 14.5% had hypokalemia.[57] Moulik et.al. observed in their study that 59.6% were hypokalemic.[69]

Moulik et.al.[11] showed that there was significant fall in potassium level 6 hours after therapy with 100 % of mal nourished children and 72.7% of children with normal nutrition developing hypokalaemia during therapy. This is similar to findings of our study which showed that prevalence of hypokalaemia increases from 24% at admission to maximum of 48% at 12 hours.

Chloride- In this study estimation of chloride levels showed that 16% had hyperchloremia on admission which increased to maximum of 24% at 12 hours. There after chloride levels normalized with only 4% having hyperchloremia at 48 hours.

Calcium- 82% had hypocalcaemia and18% has normal value. Hypocalcaemia improved gradually with therapy, with only 16% being hypocalcaemic at the end of 48 hours. Hypocalcaemia is common in children DKA due to volume depletion , sepsis, rhabdomyolysis, and low magnesium level in blood.

Magnesium- At admission, majority (54%) had normal magnesium levels. 40% had hypomagnesemia which increased to a maximum of 72% at 12 hours. **Phosphates-** In our study, at admission, 54% had hyperphosphatemia and the rest had normal phosphate levels.

In a study conducted by T.Shen and S.Braude[10], it was observed that 63% of episodes were hyperphosphatemic, 33% within the normal range and 5% hypophosphatemic at time zero. Serum phosphate dropped during the course of the admission, reaching a nadir on average 22 h after initiating treatment. This is similar to the findings of our study, where 54% of the cases were hyperphosphatemic at time zero. A drop in phosphate levels was noted with insulin treatment, with 54% patients becoming hypophosphatemic 12 hours after initiation of treatment.

In this indexed study; 6% had hypernatremia; 14% had hypokalemia; 4% had hyperchloremia; 16% had hypocalcemia; 18% were in acidotic range; 20% had hypomagnesemia and 10% had phosphate level less than normal.

All patient had high anion gap metabolic acidosis at presentation with treatment the number of patients with high anion gap metabolic acidosis decreased gradually with only 2 patients having high anion gap metabolic acidosis at the end of 48 hours . Normal anion gap metabolic acidosis was seen in 4% at

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

12hours, 6% at 24 hours, 4% in 36 hours and 6% at 48 hours .Hyperchloremia could be contributed to normal anion gap metabolic acidosis observed in this study.

In this study during the time of admission 48% had renal failure and 12 % had pre renal failure. A study conducted by Otieno et al.[12] on adults observed that 71.5% had abnormal renal parameters. Against this Moulik et al [11]observed that only 9% had renal failure at admission.

This deranged renal function was transient as evidenced by gradual decrease in proportion of children with renal failure with treatment. At 48 hours after treatment only 6% had renal failure.

It was observed in our study that most of the electrolyte disturbances were at 12 hours after which they started to decline gradually.

When the duration of insulin infusion in patients who had normal and abnormal electrolytes at 24 hours was compared, it was found that all patients who had normal electrolytes at 24 hours required insulin infusion less than 12 hours. The median insulin duration in children with abnormal electrolyte profile was found significantly higher in children with normal electrolyte profile.

The duration of insulin infusion and hospital stay were compared for children with normal and abnormal electrolyte at 24 hours. Children with electrolyte disturbances at 24 hours had a statistically significant longer duration of insulin infusion requirement. However, this did not result in a significant prolongation of hospital stay.

It was observed that out of 50 patients, 30(60%) had sepsis, similar to the findings of Desse TA et.al.[10], who observed infections as the precipitating factor in 59% of the cases. Desse TA et al. also observed that sepsis is an independent predictor of mortality. In this study, when the duration of insulin infusion and hospital stay was compared between sepsis and no sepsis groups, though there was a slight prolongation of both in sepsis group, this was not statistically significant.

In our study, only 6% children died due to DKA and 94% children were successfully discharged from our hospital. In study done by **Andrew et.al.**[7]5.7% children died due to DKA and 88.6% children were successfully discharged, , **Kanwal et.al.**[5]12.7% children died due to DKA and 87.2%% children were successfully discharged which is in coincidence with our study

Limitations of study

The major drawbacks of our study were

(i) Small sample size

(ii) Corrected sodium not calculated and analysed, this is to bring out the actual abnormality in patients.

CONCLUSION

- The relative proportions of various metabolic derangements in children were described over 48 hours or till the resolution of DKA, whichever is earlier.
- Patients with electrolyte disturbances persisting at 24 hours required insulin infusion to a significantly longer duration.

Recommendations

For practice

- Monitoring of electrolytes on admission and at regular intervals are mandatory for any patients with DKA.

ISSN: 0975-3583,0976-2833 VOL14, ISSUE 01, 2023

- Sepsis screening has to be done in all patients with DKA as sepsis has an implication on duration therapy.

For research

- Further studies in this line with larger sample size can throw more light on complex electrolyte abnormalities encountered in DKA and help in prognostication.

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