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Urine Beta-2-Micro-Globulin Level, as a marker of renal tubular dysfunction, for screening in Patients of Congenital Heart Disease – A Cross sectional Study in Tertiary Centre

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BACKGROUND >Congenital Heart Disease (CHD) occurs in 8-13/1000 live births. Parallel to the increased survival by newer interventions , the risk of secondary renal damage has also increased. Therefore, early diagnosis of renal dysfunction can lead to better management and improvement of the life styles of such patients.Urine beta2microglobulin(B2M) is a well known marker of renal tubular injury. However, it's utility as a marker of early renal tubular injury in congenitalheart-disease(CHD) patients has not been fully explored.

OBJECTIVE> To evaluate the utility of urine beta2-microglobulin(B2M) level as a marker of early renal tubular injury in CHD patients before cardiac surgery.

STUDYDESIGN> Cross sectional study was conducted among 40 paediatric patients of age group of newborn to 14 years admitted to NICU and attended the OPD during the study period from 1st September-2020 to 30th August-2022. The patients with congenital heart disease were divided into two groups of cyanotic (n=20) and acyanotic (n=20). Congenital heart disease was diagnosed by echocardiography.Beta2-micro globulin were measured in random urine samples & compared with normal reference values. **Key Words**- Congenital Heart disease, Urine beta2 microglobulin, Renal tubular function

I. STUDY PROCEDURE

1. Consent: Patients parent/guardian were explained the benefit and harm of joining the study and freedom of withdrawing from the study any moment they would like to. A full voluntary written informed consent were obtained from each patient. Study were conducted following the principles of Helsinki after getting written permission of the institutional ethics committee. Before enrolment of first patient in this study,registration for clinical trial were done.
2. All the patients were screened before enrolment. After eliciting detailed history they undergo complete medical and laboratory evaluations.
3. The patients were either Cyanotic (Group C) or acyanotic (Group A) CHD.
4. Chest x-ray, ECG, and echocardiography were performed for all the patients.
5. Based on echocardiography and oximetry, CHD and cyanotic (Spo2<85%) or acyanotic (Spo2 >85%) diseases were diagnosed and classified.
6. Cyanotic heart disease group include patients with Tetralogy of Fallot (TOF), Single Ventricle (SV), Ventricular Septal Defect and Pulmonary Stenosis (VSD + PS), isolated critical PS, Transposition of Great Arteries (TGA).
7. The acyanotic group include patients with VSD ±PH, VSD and normal pulmonary artery pressure and VSD and mild pulmonary hypertension, Atrial Septal Defect (ASD), aortic stenosis + aortic insufficiency (AS+AI), 1 with AS, and 1 with ASD + PS.
8. Nutritional habit, absence of past medical history of known renal disease, and normal hemodynamic conditions (normal BP, no edema, no proteinuria, and no dehydration sign) were analysed. The patients with heart failure, those consuming diuretics, antiinflammatory drugs, or Angiotensin Converting Enzyme Inhibitors (ACEIs), and those with abnormal urinalysis or positive urine culture were excluded from the study.

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9.Random morning urine samples were taken to assess β2-micro globulin. 10. Adverse effects if observed will be recorded and evaluated.

II. MATERIALS AND METHODS

1. **Place of Study:** - Hitech Medical College & Hospital, Bhubaneswar,Odisha, India
2. **Duration of Study:** 1st September 2020 – 31st August 2022
3. **Study type:** - Cross-sectional study
4. **Source of data:** - 1year - 14 years with features of CHD attending OPD of Hi-Tech MCH.

Selection Criteria:-

Inclusion criteria:

1. Parent/guardian who provide written informed consent
2. Cyanotic heart disease group will include patients with Tetralogy of Fallot (TOF), Single Ventricle (SV), Ventricular Septal Defect and Pulmonary Stenosis (VSD +PS), isolated critical PS, Transposition of Great Arteries (TGA).
3. The acyanotic group include VSD ± PH, VSD and normal pulmonary arterypressure, VSD and mild pulmonary hypertension, Atrial Septal Defect (ASD), aortic stenosis + aortic insufficiency (AS+AI) 4. Patients Age = 1year – 14 years
5. Patients of either sex

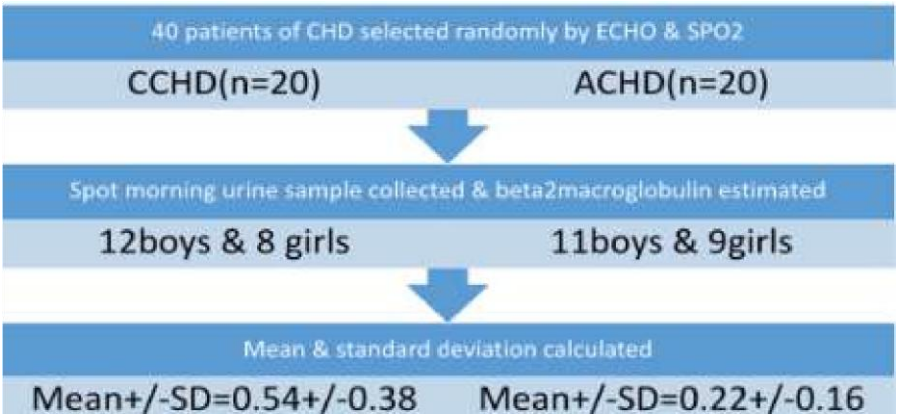
Exclusion criteria:-

1. Patients on long term anti-inflammatory drugs
2. Patients on Angiotensin Converting Enzyme Inhibitors (ACEIs)
3. Patients with positive urine culture
4. Patients with preexisting disease which have high cell turnover state

5.Parent/guardian doesn't provide written informed consent

III. STATISTICAL ANALYSIS

The continuous data were expressed as mean (+/-) SD and the categorical data were expressed as proportions. The difference between the groups on continuous data were analysed by ttest or Mann-Whitney U test based on the normality of the data. Normality were assessed by Shapiro-Wilk test. The difference in the categorical data between the two groups were analysed by Fisher's exact test. Data were analysed by repeated measures ANOVA for within the group analysis and generalized mixed effect modelling for between the group analysis. The relationship between the continuous outcome and various variable were dealt by linear regression techniques. The missing values were treated by multiple imputation techniques. P<0.05 were considered significant. The data will be analysed using SPSS program.



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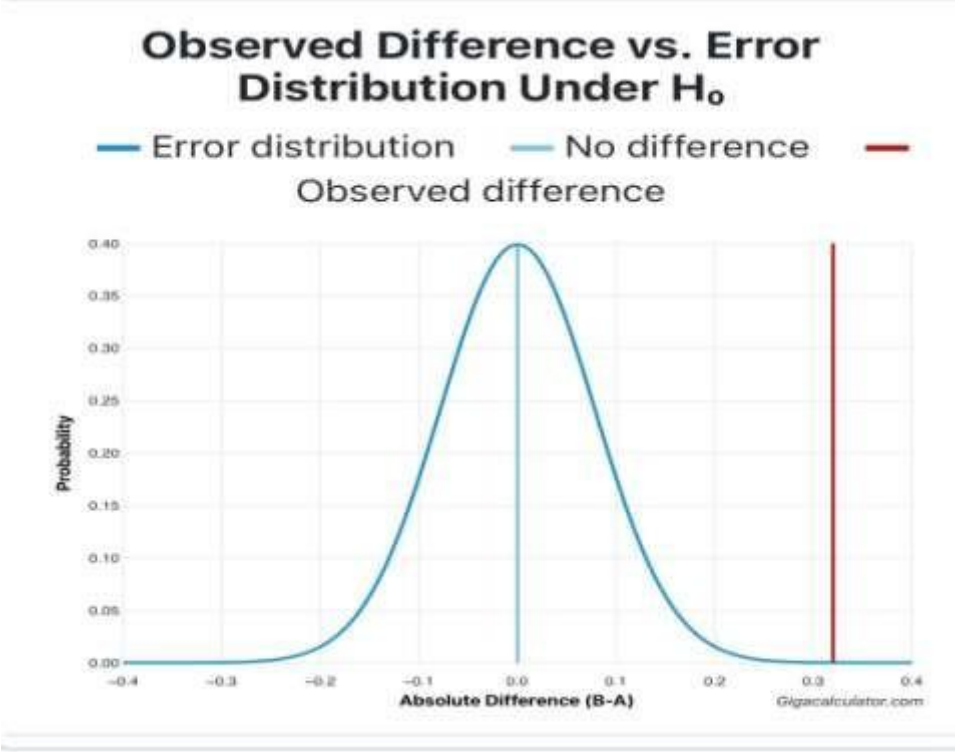
Calculation results	
P-value (X; H_0: B ≤ A)	0.000109
T-score	4.087011
Degrees of freedom	38
Significance level	99.99%
Pooled SEM	0.078297
Sample size A	20
Sample size B	20
Mean A	0.2175
Mean B	0.5375
Difference (B-A)	0.32



IV. RESULT

- The normal laboratory reference value of urine compared with the mean values obtained from the two groups (CCHD & ACHD).

beta2macroglobulin was taken as ≤0.33mg/L • The ACHD group has mean value of 0.22mg/L for age group of 1year to 14years from and it shows no increase as compared to reference books and previous studies and reference value.

- But the CCHD group has mean value of 0.54mg/L and it shows a significant increase as compared to reference value.
- Apart from that there are 6 patients (4boys & 2girls) whom urine beta2microglobulin levels shows a significant higher values as compared to others in the CCHD group.
- If we calculate the mean & SD of these 6 patients then it is coming out to be 1.01mg/L+/-0.08.
- By taking these values into consideration if we calculate Prevalence of tubular injury in CCHD patients = 30%, which is a significant percentage among CCHD patients.

V. CONCLUSION

The results of the current study showed that renal tubular function was affected in the patients with CHD, specially in CCHD patients. Thus, early diagnosis of tubular dysfunction is essential for a better management of these patients before cardiac surgery and in later stages of life. Measurement of Beta2-microglobulin is suggested for an early diagnosis of tubular dysfunction in the patients with CHD.

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