

EVALUATION OF 24 HOURS HOLTER MONITORING IN THALASSEMIA PATIENTS

By

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ABSTRACT

Introduction: Cardiac dysfunction, including cardiomyopathy and arrhythmia are the major causes of morbidity and mortality in thalassemic patients.

Aim of Work: The aim of this study is to evaluate 24 hours Holter monitoring for detection of early ECG changes in beta thalassemic children. **Methods:** This cross – sectional case control study was conducted at the Kafr Elsheikh Insurance health hospital from May 2020 to March 2021 on 45 thalassemic children. Patients age, s range from 2 to 17 years diagnosed as beta thalassemia major with regular blood transfusion .Childern in our study were taken by simple random sample. The control group consists of 45matched healthy children of the same gender and age.

Results: There was a statistically significant increase of Interventricular Septal end diastole (IVSD), Interventricular Septal end systole and Left Ventricular Posterior Wall end diastole (LVPWD) in thalassemic children as compared to controls. The minimum and average heart rate were significantly higher in thalassemic children vs the control and heart rate variability parameters in thalassemic patients were significantly lower in thalassemic children compared to the control. Atrial fibrillation was detected in 17.8% of thalassemic children compared to the control (0%).

Conclusion: The current study showed that left ventricular hypertrophy by was detected in thalassemic children compared to control, reduced heart rate variability parameters indicating autonomic dysfunction in those children.

INTRODUCTION

The commonest single gene disorders are Thalassemia especially in the Middle East. It is a hereditary, autosomal recessive disorder due to partial or complete deficiency in the synthesis of α or β -globin chains that can result in an asymptomatic carrier status, to

mild or severe anemia (Chiruka and Darbyshire, 2011).

The most common causes of death in these patients are transfusion-related hemosiderosis. Cardiac complication is the major cause of morbidity and mortality in thalassemic patients that's mainly expressed by secondary

cardiomyopathy to iron overload that progressively leads to heart failure and death (**Shawkat and Jwaid, 2019**).

Myocardial iron overload leads to heart failure and arrhythmias, which are the most important life-threatening complications of β -thalassemia major (TM) patients. In an early stage of cardiomyopathy caused by iron overload, Arrhythmias or sudden cardiac death may be present in without overt signs and symptoms of cardiac disease (**Pepe et al., 2018**).

AIM OF WORK

The aim of this study was to evaluate 24 hours Holter monitoring for detection of early ECG changes in beta thalassaemic children.

Ethical Consideration:

1. A written informed consent was obtained from parents or the legal guardians before the study.
2. An approval by the local ethical committee was obtained before the study.
3. The authors declared no potential conflicts of interest with respect to the research, authorship and/or publication of this article.

4. All the data of the patients and results of the study are confidential & the patients have the right to keep it.
5. The patient has the right to withdraw from the study at any time.

Financial Disclosure / Funding:

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PATIENTS AND MATERIALS

STUDY DESIGN:

This case-control cross-sectional study was conducted at the Kafr Elsheikh Insurance health hospital during the period from May 2020 to march2021, on 45 cases 22 were males and 23 were females that were taken by simple random sample and 50 matched healthy children of the same gender and age. Patients' ages ranged from 2 to less than 18years. 2021. The study protocol was approved by the local Ethics Committee of AL-Azhar University, Faculty of Medicine (for Girls); council number202003209 and all procedures were in accordance with the Helsinki Declaration. An informed written consent was taken from the children parents after explanation of the work, and

they have the right to withdraw at any time.

1. Patients

Inclusion criteria:

- Children with β -thalassemia on chronic blood transfusion.
- Age: 2-17 years.
- Male and female.

Exclusion criteria:

- Children with congenital, rheumatic heart disease, heart failure or any significant cardiac disease.
- Chronic renal failure.
- Other types of chronic hemolytic anemia.

Each patient subjected to the following:

1. Full history according to predesigned questionnaire with stress on:

- Age of onset of disease.
- Onset and duration of disease.
- Frequency of blood transfusion.
- Type of chelation therapy.
- History of any cardiac problem.
- Splenectomized or not.
- Drug intake.

2. Clinical examination with stress on:

- Cardiac examination.
- Vital signs (blood pressure, heart rate and respiratory rate).
- Anthropometric measures (weight, height and BMI).
- Abdominal examination.

3-Investigations:

A. Laboratory tests:

- Complete blood picture.
- Serum ferritin.

B. Special investigations:

- Echo cardiograph.
- 24 hours Holter monitoring.

METHODS:

Sample collection:

Blood sample were obtained for complete blood count (CBC) and serum ferritin. Four ml of venous blood was withdrawn and divided into two aliquots; 2ml were evacuated in EDTA tube for CBC. The remaining part was evacuated in serum-separator tube, centrifuged at 3500 rpm for 10 min; was used for serum ferritin using ELISA kit.

Method of assay:

- A. Complete blood count was done using (Coulter Counter, Beckman Inc, Florida, USA).

- B. Serum ferritin was done by Enzyme Immunoassay (ELISA READER, USA).
- C. Transthoracic echocardiographic examination is performed at echocardiography clinic. Transthoracic two-dimensional (2D) guided (M Mode) and color Doppler echocardiographic examination was performed for all children and control subjects in both supine and left lateral position using a Hewlett-Packard 5500 SONOS ultrasonic machine phased array sector scanner with the 4 and 8 MHZ probes according to age. Patient's recordings are taken while patients are in supine position without breath holding. M-mode, 2D and Doppler echocardiography parameters are averaged over 3 cardiac cycles.
- D. 24-hours holter monitoring by using CARDIOMERA digital holter ECGholter monitors are typically fitted to the patient in the cardiology department and returned by the patient when recording is complete. The recording is played back and analysed using dedicated software, The time-domain analyses included average

heart rate, average R-R intervals (NN), standard deviation of the R-R intervals over a 24-h period (SDNN), standard deviation of all 5-min mean R-R intervals (SDANN), average standard deviation of all 5-min R-R intervals (ASDNN), the percentage of R-R intervals with more than 50-ms variation (pNN50), and the square root of mean squared differences of successive R-R intervals (rMSSD).

Statistical analysis:

Data were analyzed using the Statistical Package of Social Science (SPSS) program for Windows (Standard version 21). The normality of data was first tested with one-sample Kolmogorov-Smirnov test. Qualitative data were described using number and percent. Association between categorical variables was tested using Chi-square test while Fischer exact test was used when expected cell count less than 5. Continuous variables were presented as mean \pm SD (standard deviation) for normally distributed data and median (min-max) for non-normal data. The two groups were compared with Student t test for normal data and Mann Whitney test. Pearson correlation (parametric) and Spearman correlation (Non-parametric) were used to correlate continuous variables.

RESULTS

Our results will be demonstrated in the following tables

Table (1): The Demographic of our studied children

Demographic data	Thalassemia patients group (n=45)	Control group (n=45)	Test of significance	p value
Age (years) Mean \pm SD	8.14 \pm 3.82	9.31 \pm 2.72	t= 1.67	0.097
Gender Male Female	22 (48.9%) 23 (51.1%)	26 (57.8%) 19 (42.2%)	$\chi^2=0.714$	0.398
Residence Rural urban	15(33.3%) 30(66.6%)	18(40%) 27(60%)	$\chi^2=0.714$	0.398
Father education Illiterate Primary Secondary Highly educated	5(11.1%) 8(17.8%) 12(26.7%) 20(44.4%)	3(6.7%) 10(22.2%) 10(22.2%) 22(48.9%)	$\chi^2=0.998$	0.801
Mother education Illiterate Primary Secondary Highly educated	10(22.2%) 12(26.7%) 15(33.3%) 8(17.8%)	5(11.1%) 8(17.8%) 20(44.4%) 12(26.7%)	$\chi^2=3.98$	0.267

This table shows insignificant difference between cases and

controls as regard demographic data.

Table (2): Anthropometry and Clinical data of thalassemic Group and control group

Anthropometric measures	Thalassemia patients group (n=45)	Control group (n=45)	Test of significance	p value
B.Wt.(kg)	28.43±11.28	34.26±10.51	t=2.538	0.013*
Height(cm)	123.64±19.08	138.36±15.02	t=4.063	≤0.001*
B.M.I.	17.71±1.78	17.24±3.36	t=0.829	0.409
Onset of disease (months) Median (Min-Max)	6 (4-30)			
Interval transfusion (days) Median (Min-Max)	20 (10-35)			

This table shows significant difference in height and body weight between cases and controls.

Table (3): Chelation therapy among the thalassemic children. (N=45)

History of chelation therapy	Thalassemia patients group (n=45)
Deferasirox	33 (73.3%)
Deferiperon	10 (22.2%)
Desferoxamin	36 (80.0%)

This table shows that the majority of cases depended on desferoxamin 36 (80.0%), only 10 (22.2%) taking Deferiperon and 33 (73.3%) taking Deferasirox.

Table (4): Echocardiographic data among the studied children

ECHO data	Thalassemia patients group (n=45)	Control group (n=45)	Test of significance	p value
LVEF%	70.91±5.86	65.37±2.63	t=5.777	≤0.001*
LVIDD (cm)	3.96±0.51	03.92±0.45	t=0.340	0.734
LVIDS (cm)	2.50±0.62	2.46±0.34	t=0.397	0.692
IVSD (cm)	0.83±0.16	0.65±0.07	t=6.405	≤0.001*
IVSs (cm)	1.11±0.25	1.01±0.09	t=2.452	0.016*
SV	48.37±13.91	39.73±22.59	t=2.186	0.032
LVESV (ml)	22.80±6.86	23.40±6.30	t=0.432	0.667
LVEDV (ml)	67.42±22.65	60.79±26.32	t=1.281	0.204
LVPWD (cm)	0.76±0.17	0.68±0.11	t=2.343	0.021
FS%	41.22±4.33	35.34±3.08	t=7.418	≤0.001
LA (cm)	2.49±0.45	2.67±0.43	t=1.898	0.061
Ao (cm)	2.18±0.25	2.10±0.36	t=1.248	0.215

IVSd: interventricular septum (diastole); LVPWd : left ventricular posterior wall(diastole); LVIDd: left ventricular internal dimension (diastole); LVIDs: left ventricular internal dimension (systole); LVEDV: left ventricular end diastolic volumes; LVESV: left ventricular end systolic volumes; EF%: ejection fraction ;FS%: fraction shortening. LA: left atrial dimension.AO: aortic dimension.

This table shows Significant increase in interventricular (IVSs) septum thickness end systole, and end diastole ,systolic volume(SV), left ventricle posterior wall end diastole

(LVPWD) and fraction systole(FS%) in thalassemic children compared to the control group, also increased ejection fraction % in thalassemic children vs. the control group.

Table (5): Holter variability among thalassemic and control group

	Thalassemia patients group (n=45)	Control group (n=45)	Test of significance	p value
SDNN Median (Min-Max)	73 (12-200)	130 (27- 154)	Z=4.312	≤0.001*
pNN50% Median (Min-Max)	6 (0.0-50)	47 (10- 71)	Z=7.401	≤0.001*
RMSSD Median (Min-Max)	27 (0.0-109)	19 (0.00- 38)	Z=2.953	0.003*
QT average Mean ± SD	305.22±27.07	326.08±13.68	t=4.614	≤0.001*
QT maximum Mean ± SD	385.82±45.08	423.44±20.17	t=5.110	≤0.001*
QT dispersion Median (Min-Max)	62 (18-299)	91 (32- 136)	Z=3.166	0.002*
LF/HF Median (Min-Max)	1.70 (0.40-8.10)	1.20 (0.60- 2.60)	Z=2.012	0.044*
Holter average	103.02±20.14	87.46±6.07	t=4.959	≤0.001*
Minimum	74.02±17.97	59.44±6.94	t=5.075	≤0.001*
Maximum	152.77±22.31	157.91±19.27	t=-1.168	0.246

HR bpm: heart rate beat/min, SDNN, the standard deviation of all normal sinus R-R intervals in the entire 24-hour recording, rMSSD, the root mean square of the mean of the squared differences of two consecutive R-R intervals in the 24-hour recordings; LF, low frequency power; HF, high frequency power.

This table shows significant difference in holter heart rate variability parameters in thalassemic patients versus to control group.

Table (7): Holter detected arrhythmia among the studied children

	Thalassemia patients group (n=45)	Control group (n=45)	Test of significance	p value
	No %	No %		
SVE%	8 (17.8%)	7 (15.6%)	$\chi^2=0.080$	0.777
SVT	8 (17.8 %)	0 (0%)	FET	0.006*

SVE: supraventricular ectopy, SVT: supra ventricular tachycardia.

Among the studied children supra ventricular tachycardia was the most common arrhythmia detected in thalassemic patients.

DISCUSSION

The present study was a cross-sectional case control study. It was carried out on 45 β -thalassemia major patients, their mean age value was (8.14 ± 3.82) years they were 22 male and 23 females and 45 age and sex-matched healthy children as a control group, they were 26 male and 19 females. Their mean age value was (9.31 ± 2.72) . They were taken consecutively by simple random sample from pediatric department at kafr Elshiekh health insurance hospital, during the period from May 2020 to March 2021. Children with congenital, rheumatic heart disease, any cardiac disease, chronic renal failure, any chronic illness, or other types of chronic hemolytic anemia were excluded from the study.

The pathogenesis of growth failure in thalassemia is multifactorial. Chronic anemia, transfusion iron overload, endocrinopathy, and chelation toxicity are contributing factors (**Arora et al., 2014**). Children with TM in the present study height were significantly decreased in comparison to their control while their weight is within normal range.

Iron overload is responsible for many complications that occur in

thalassemic patients so iron chelating agents like desferoxamine (parenteral use) and deferasirox or deferiprone (oral use) should be used early when starting transfusion therapy (**Aggarwal et al., 2014**). Among the studied 45 thalassemic patients 73.3 % of them receive deferasirox and 22.2 % receive deferiprone as iron chelation therapy.

Cardiac dysfunctions in thalassemia major have attributed to chronic anemia, infrequent transfusions, iron-overload and inadequate chelation therapy (**Elhini et al., 2011**). Cardiac magnetic resonance is the preferred technique for quantifying cardiac iron deposition. However, it is higher cost and not feasible or available for routine clinical practice. Conventional two-dimensional echocardiography remains a clinically useful method for evaluation and follows up of thalassemic patients (**Chen and Li, 2014**).

In the current study M mode echocardiography results showed that there was significant increase left ventricle (LV) wall thickness (increased IVS systole and diastole; increased LVPWD) in thalassemic group in comparison to controls in, denoting a tendency to develop left ventricular

hypertrophy (LVH). These results come in agreement with the study done by (**Bosi et al., 2003**), (**Chanpura and Modi, 2019**), (**Russo et al., 2014**). This may be explained by long-standing anemia leading to hypoxia, chamber dilatation and myocardial ion dysfunction, also regular blood transfusion leads to iron overload and the heart is the most severely affected organ (**Auger and Panell, 2016**).

The same results also were observed by another Egyptian study done by (**Salama et al., 2020**), who observed significant increase of IVSd, IVSs, LVIDd, LVIDs and LVPWd in the thalassemic patients as compared to controls.

In the current study echocardiographic study shows that increased ejection fraction % and fraction shortening (EF and FS) in thalassemic group vs the control this may explain E by hyper dynamic circulation due to anemia.

While the study done by (**Garada et al., 2010**) showed The LVEF% and fractional shortening were normal with no difference between patients with TM and the control group. And they explain that by TM patients are having minimal deleterious effect of

myocardial iron overload on myocardial systolic function.

Other study done by (**Ibrahim et al., 2016**) showed that there was no significant difference between Thalassemic children and control group regarding FS and EF.

The cardinal cardiac manifestations in TM cases with iron overload state is arrhythmia. The mechanisms for higher susceptibility to arrhythmia in these patients has been attributed to interference of accumulated iron with cardiac electrical function, free radicals, myocardial fibrosis, and apoptosis (**Faruqi et al., 2015**).

In the present study 24 holter analysis of the studied group showed that the minimum and average heart rate were significantly higher in thalassemic children vs the control could be explained by the anemia state and compensatory tachycardia and this come in agreement with (**Parsaee et al., 2020**) in study done on adolescents and adults. Also, the same results were observed by (**Kardelen et al., 2008**).

In TM Assessment of heart rate variability (HRV) is a technique that measures the beat-to-beat variability in R-R intervals. This variability reflects changes in autonomic activity and their impact on cardiovascular function.

HRV has been proposed as a potential indicator of early detection of cardiac siderosis (**Alp et al., 2014**).

In the current study the time domain (SDNN, pNN50%, RMSSD) HRV parameters in thalassemic patients were significantly lower in thalassemic children compared to the control with increased high frequency /lower frequency in thalassemic children and this indicates there is a cardiac sympathy-vagal imbalance in thalassemic patients which is generally known as “depressed HRV”.

The reduced HRV, expression of impaired sympatho-vagal activity, may be explained by the chronic anemia that characterizes TM, which may lead to a persistent, appropriate sinus tachycardia and a sustained decrease in autonomic fluctuations. Additionally, the expansion of blood volume during transfusion could represent an uncontrolled stimulation of cardiac receptors with sympathetic afferent, leading to a further decrease in vagal modulation of heart rate (**Yetimakman et al., 2014**).

Decreased HRV parameters in thalassemic children was observed by (**Kardelen et al., 2008**), and in adolescent suffering from

thalassemia major by (**Silvilaira et al., 2016**) and the same results were observed in adults thalassemia in study done by (**Wijarnpreecha et al., 2015**).

Depressed HRV in thalassemia patients has been shown to be associated with cardiac autonomic dysfunction and might be considered as early sign of detection of iron overload cardiomyopathy (**Kumfu et al., 2012**).

The precise incidence of arrhythmias in b-TM population is still challenged. Atrial fibrillation (AF), atrial flutter and intra-atrial reentrant tachycardia are the most common clinically relevant arrhythmia in thalassemia (**Russo et al., 2014**). The early detection of AF was essential for early management. In the current study, comparison was made between the studied children regarding ECG changes, supra ventricular tachycardia was detected in 17.8% of thalassemic children vs. the control.

In the study done by (**Neha et al., 2016**); Out of 60 thalassemic children, ECG changes were present in 9 (51.6%) and (48.3%) had normal ECG. Among those with ECG changes (40%) had tachycardia, patients (5%) had bradycardia, (23.3%) had arrhythmia.

CONCLUSION

Left ventricular hypertrophy caused by iron overload was detected in thalassemic children, reduced heart rate variability parameters indicating autonomic dysfunction in those children.

Conflict of interest:

The authors report no conflicts of interest in this work.

RECOMMENDATION

Frequent follow up by echocardiography and holter for thalassemic children is essential to detect early asymptomatic cardiac events.

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تقييم هولتر ٢٤ ساعة في مرضي أنيميا البحر الأبيض المتوسط

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قسم الاطفال* والقلب** بجامعة الازهر بنات (القاهرة)

مقدمة: يعتبر ضعف القلب بما في ذلك اعتلال عضلة القلب وعدم انتظام ضربات القلب من الأسباب الرئيسية للمرض والوفيات في مرضي انيميا البحر الابيض المتوسط الكبري.

الهدف من الدراسة: الهدف من هذه الدراسة هو تقييم تخطيط القلب ٢٤ساعه في الأطفال المصابين بأنيميا البحر المتوسط الكبري والكشف عن تغييرات نظم القلب في وقت مبكر لديهم.

المواضيع والطرق: الدراسة الحاليه هي عبارة عن دراسة مقطعيه، ستجري علي 45 طفلاً تتراوح أعمارهم ما بين (2-17) عاماً، تم تشخيصهم علي أنهم مرضي أنيميا البحر الأبيض المتوسط الكبري وليس لديهم اي عيوب خلقية ف القلب حمى القلب الروماتيزمية، فشل بالقلب، فشل كلوى مزمن، الانيميا التوكسيرية غير التلاسيميا أوامراض مزمن. تم أخذ الاطفال الوجودين في الدراسه بطريقه عشوائيه وتجري ايضا الدراسه علي مجموعه ضابطه من 45 طفلاً صحياً متطابقاً لهم من نفس الجنس والعمر. اجريت الدراسه في قسم الاطفال في مستشفى العبور للتأمين الصحي بمحافظة كفر الشيخ في الفتره من مايو 2020 إلى مارس 2021.

النتائج: كانت هناك زيادة ذات دلالة إحصائية في انبساط نهاية الحاجز بين البطينين، وانقباض نهاية الحاجز بين البطينين، وانبساط نهاية الجدار الخلفي البطيني الأيسر في أطفال أنيميا البحر الأبيض المتوسط مقارنة بالأطفال الأصحاء من نفس العمر و كان معدل ضربات القلب الأدنى والمتوسط أعلى بشكل ملحوظ عند الأطفال المصابين بمرض البحر الأبيض المتوسط مقابل مجموعة الأطفال الأصحاء داخل الدراسة وكانت متغيرات تقلب معدل ضربات القلب في مرضى البحر الأبيض المتوسط الكبرى أقل بشكل ملحوظ في الأطفال المصابين بأنيميا البحر الأبيض المتوسط مقارنة مع مجموعة الأطفال الأصحاء. تم أيضا الكشف عن الرجفان الأذيني في 17.8% في الأطفال المصابين بأنيميا البحر الأبيض المتوسط مقارنة بمجموعة التحكم (0%).

الإستنتاج: أظهرت الدراسة الحالية أنه تم الكشف عن تضخم البطين الأيسر الناجم عن زيادة الحديد في الأطفال المصابين بمرض انيميا البحر الأبيض المتوسط مقارنة بمجموعة الأطفال الأصحاء، ووجود انخفاض في متغيرات معدل ضربات القلب في مرضى انيميا البحر الأبيض المتوسط الكبرى والتي تشير إلى الخلل الوظيفي اللاإرادي لدى هؤلاء الأطفال.