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Original Research Article

ROLE OF HIGH SENSITIVE TROPONIN-I IN DIAGNOSING ACUTE CORONARY SYNDROME PRESENTING TO EMERGENCY DEPARTMENT: A PROSPECTIVE STUDY

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ABSTRACT

Background: Cardiac troponin values measurement is considered for the diagnosis of AMI. New technology added an edge in detection of very low levels of cardiac troponin. This makes diagnosis easy and reduces other problems associated with misdiagnosis. They are so sensitive that they can detect up to 10 times more low levels. The objective is to study role of high sensitive troponin-i in diagnosing ACS in cases presenting to emergency department.

Materials and Methods: Present study was single-centre, hospital-based, prospective study carried out among 102 cases. Random blood sugar, electrocardiogram, 2-D echo, Highly Sensitive Troponin-I: 0 hr and 3rdhr samples, its % Delta change, etc. investigations were carried out.

Results: Majority belonged to 61-70 years (40.2%). Mean age was highest in those with NSTEMI and lowest in non-ACS cases. In each diagnosis, males were more than females, but these differences were significant. Most common presenting complaint was chest pain in 95.1%. Diabetes was very common in STEMI & NSTEMI cases. Mean values of cardiac biomarker the troponin i at zero hour or at baseline were slightly more among those with STEMI but differences were significant. At three hours, mean value of biomarker was very high in STEMI patients compared to other categories and it was significant.

Conclusion: ACS is diagnosed by highly sensitive troponin I levels in serial (0hr and 3rdhr) measuring of blood samples after applying 26 ng/L cutoff value. Furthermore, by applying percentage delta change, it increases the specificity and negative predictive value.

Keywords: Coronary artery disease, myocardial infarction, angina.

INTRODUCTION

Acute coronary syndrome (ACS) includes acute myocardial infarction (AMI) and unstable angina (UA). AMI is of two types depending on the ST segment elevation. STMI is one where there is elevation of the ST segment. NSTEMI is one where there is no elevation of ST segment.[1] In these two sub-types of AMI, NSTEMI is less common compared to the STEMI.[2] One study has shown that around 60% of the cases of AMI were due to STEMI and the remaining were due to NSTEMI in India. This was in sharp contrast when the incidence was compared with that from the developed world.[3] Similar findings of 63.7% and 11.3% of that for STEMI & NSTEMI respectively were reported by one author from India. It also highlighted important finding of a decade early onset of ACS in Indian people compared to their European counterparts.[4]

The differences in the occurrence of STEMI and NSTEMI may be due to certain factors. One such factor can be atypical symptoms of NSTEMI. These atypical symptoms are more common in elderly and in females. Second such factor is that the sensitive cardiac biomarkers may not be available. Due to the non-availability, we are getting lesser number of

NSTEMI cases. With this the importance of cardiac biomarkers has increased to a great extent.[5]

Now a days there is a trend in using these cardiac biomarkers. They are also following the guideline of 99th percentage upper reference limit. Initially they refused to use this cut-off point. The reason behind this refusal of lesser evidence available. Second was use of the previous guidelines. They were more inclined to the use of lesser sensitive markers like CKMB. They thought that this will reduce the false positive cases on their own. In actual practice, the scientific reason not known before were detection of structural cardiac morbidities as well as AMI by using the 99th percentage cut-off values.[6] Cardiac troponin values measurement is now considered for the diagnosis of AMI. New technology added an edge in the detection of very low levels of cardiac troponin. This makes the diagnosis easy and reduces the other problems associated with misdiagnosis. They are so sensitive that they can detect up to 10 times more low levels. This helps in the early diagnosis of AMI. Even AMI can be ruled out with the use of cardiac troponin. It can also help identify other associated conditions.

With this background, present study was carried out to study the role of highly sensitive troponin-i in diagnosing acute coronary syndrome presenting to emergency department.

MATERIALS AND METHODS

Present study was a single centre, hospital based, prospective cohort study carried out at Department of Emergency Medicine, Apollo Hospital, Jubilee Hills, Hyderabad over a period of one year from January 2017 to December 2017 among 102 cases. Institutional Ethics Committee permission was obtained. Written informed consent was taken from all study participant.

Taking sensitivity of 90.7% (cut-off value of 0.04 ng/l) from a previous study 7 with 95% confidence interval, 8% precision with 50% prevalence the sample size came out to be 102.

Inclusion criteria:

1. Both male and female patients presenting with symptoms suggestive of ACS
2. The patients with age more than 18yrs.
3. Patients presenting to ER.
4. Patients consented for enrolling into the study.

Exclusion criteria:

1. Patients with age less than 18 years.
2. Pregnant patients.
3. Nonacute presenting symptoms.
4. Patients directly presenting to ER without referring from other hospital.

Detailed history, thorough clinical examination and necessary investigations were recorded in the pre designed, pre tested, semi structured study questionnaire developed for the present study. Detailed past history regarding known cases was enquired upon. Addictions were evaluated. Anthropometric measurements like height, weight, waist circumference along with measurement of the blood pressure was also carried out. Random blood sugar, electrocardiogram, 2-D echo, Highly Sensitive Troponin-I: 0 hr and 3rdhr samples, its % Delta change, etc. investigations were carried out.

Statistical analysis: the data was entered in the Microsoft Excel worksheet and described using proportions, mean value or median values wherever applicable.

RESULTS

Table 1: Distribution of participants as per age

Age (years)	Number	%
21-30	3	2.5
31-40	3	2.5
41-50	14	11.5
51-60	25	20.5
61-70	49	40.2
71-80	18	14.8
81-90	10	8.2
Total	122	100

Majority belonged to the group of 61-70 years (40.2%) followed by 51-60 years (20.5%). Only 2.5% each of them were in the age group of 21-30 years and 31-40 years.

Table 2: Mean age in relation to diagnosis

Diagnosis	Number	Mean	SD	F value	P value
STEMI	44	61.82	12.59	0.831	0.48
NSTEMI	21	65.33	10.94		
Unstable Angina	21	64.85	12.54		
Non-ACS	36	60.83	13.84		

The mean age highest in those with NSTEMI and lowest in non-ACS cases. The differences in the mean age across different diagnosis categories was not found out to be statistically significant ($p>0.05$).

Table 3: Gender Distribution

Gender	STEMI	NSTEMI	Unstable angina	Non-ACS	P value
Male	31 (70.5%)	15 (71.4%)	12 (57.1%)	21 (58.3%)	0.528
Female	13 (29.5%)	6 (28.6%)	9 (42.9%)	15 (41.7%)	

Males were more than females in totality. In each diagnosis also, males' proportion was more than females, but these differences were not found out to be statistically significant.

Table 4: Presenting complaints and comorbidities

Variables		Number	Percentage
Presenting complaint	Chest pain	116	95.1
	Syncope	2	1.6
	Dyspnoea	6	4.9
Comorbidities	Diabetes	70	57.4
	Hypertension	58	47.5
	CAD	17	13.9
	CKD	7	5.7

The most common presenting complaint was chest pain in 95.1% of the cases. Most common comorbidity was diabetes seen in 57.4% of the cases.

Table 5: Comorbidities In Relation to Diagnosis

Comorbidities	STEMI	NSTEMI	Unstable angina	Non-ACS	P value
Diabetes	31 (70.5%)	13 (29.5%)	11 (52.4%)	15 (41.7%)	0.069
Hypertension	21 (47.7%)	10 (47.6%)	11 (52.4%)	16 (44.54%)	0.953
CAD	2 (4.5%)	3 (14.3%)	6 (28.6%)	30 (83.3%)	0.065
CKD	1 (2.3%)	1 (2.3%)	2 (4.5%)	3 (8.3%)	0.569

Diabetes was very common in STEMI & NSTEMI cases. Diabetes and hypertension were equally common in unstable angina cases. CAD was more common in non-ACS cases. All these differences were not found out to be statistically significant.

Table 6: Troponin I values at 0 and 3 hours in relation of type of diagnosis

Timing	Diagnosis	Number	Mean	SD	F value	P value
Zero hour	STEMI	44	595.98	1645.43	1.336	0.266
	NSTEMI	21	440.00	922.34		
	Unstable Angina	21	391.67	1077.40		
	Non-ACS	36	78.83	250.77		
Three hours	STEMI	44	4865.37	9169.46	5.62	0.001
	NSTEMI	21	1554.16	3149.79		
	Unstable Angina	21	425.16	1136.81		
	Non-ACS	36	78.52	238.41		

The mean values of cardiac biomarker the troponin i at zero hour or at baseline were found out to be slightly more among those with STEMI followed by among those with NSTEMI but the differences were not found to be statistically significant. At three hours, the mean value of the biomarker was very high in STEMI patients compared to NSTEMI which was again very high compared to unstable angina cases which was still very high when compared to non-ACS cases. This trend was found to be statistically significant.

DISCUSSION

In the present study it was observed that mean age of the study population was 62.6 ± 12.69. And maximum age was 90 yrs. Maximum involvement was in the age group between 61-70 yrs. which constitutes 40.20% of 122 patients. Second most common age group was 51-60 yrs. which constitutes 20.5% of 122 patients followed by 14.8% in the age group of 71– 80 yrs. In our study mean age of study population is 62.66, which was similar to study done by Neumann JT et al was 65, by Shah et al was 64.[8,9]

In the present study it was observed that 64.8% were males and 35.2% were females, Male: Female ratio was 1.8:1. The proportion of males are greater than females indicates male are more prone for acute coronary syndrome. In our study there are more males (64.8%) than females (35.2), which was similar to study done by Neumann JT et al (63.7% males and 36.3% females) and little difference in study done by Shah et al (57% males and 43% females).[8,9]

In Our study, out of 122 patients, maximum patients are present with chest pain are 116 (95.1%), 6 patients present with dyspnoea (4.9%), 2 patients present with syncope (1.6%). In Shah et al study,[9] maximum patients are present with chest pain was 83%, dyspnoea 6%, syncope 4%, palpitations 3% and others 5%.

In Our study, 57.4 % patients had history of diabetes, 47.5 % patients had history of hypertension, 13.9 % patients had history of previous CAD and 5.7%

patients had CKD. There was more than one co morbidity observed in the study population. In Shah et al study,[9] 16 % patients had history of diabetes, 33 % patients had history of hypertension, 52 % patients had history of previous CAD, 8% patients had CVA and 27% patients had hyperlipidaemia.

In Our study, majority of patients with STEMI had ST segment elevations 97.7%, 2.3 % had LBBB on ECG. In patients with NSTEMI majority of patients had ST segment depression 81% followed by T wave inversions 14.3%. In patients with unstable angina 52.4% had T wave inversions followed by 33.3% T wave flattening and 14.3% ST segment depression. In patients with non-ACS 55.6% presented with T wave flattening, 30.6% had T wave inversions, 11.1% had normal ECG and 2.8 % had ST segment elevation. In Shah et al study,[9] 7% was presented with Bundle branch block, 3% with ST segment elevation, 7% with ST segment depression, 13% with T wave inversion and remaining with nonspecific changes.

Out of 122 patients, 86 had ACS (44 had STEMI, 21 had NSTEMI, 21 had UNSTABLEANGINA) and 36 had non-ACS

Mean hs Tn I at zero hr was observed to be higher in STEMI compared to NSTEMI, UA, non-ACS but the difference in mean was not statistically significant p >0.05.

Mean hs Tn I at 3 hrs was significantly different between groups. A further subgroup analysis was done using multiple comparison ANOVA it was observed that the mean hs Tn I at 3 hrs was significantly higher for STEMI compared to NSTEMI, UA and non-ACS p>0.05.

ROC curve analysis was done to estimate the sensitivity and specificity at the cut off value of 26 ng/L, it was also observed that AUC was significant for both hs Tn I at 0 hr and hs Tn I at 3 hrs however the AUC for hs Tn I at 3 hrs was higher compared to hs Tn I at 0 hr. Using cut off value of 26 ng/L for hs Tn I at 0 hr it was observed that sensitivity of hs Tn I at 0 hr was 74.4 % and specificity was 66.67 %. In differentiating ACS from non-ACS, the overall diagnostic accuracy of hs Tn I was observed to be 72.13 %. For hs Tn I at 3 hrs sensitivity was observed to be 82.56 % and specificity was 66.7 % with an improvement to diagnostic accuracy 77.87% than compared to hs Tn I at 0 hr in differentiating ACS from non-ACS. Use of hs Tn I at 3 hrs improved the probability of diagnosing the ACS without improving the specificity.

ROC curve analysis was done to estimate the best cut off value using the best cut off value sensitivity and specificity was determined. It was observed that AUC was significant for both hs Tn I at 0 hr and Tn I at 3 hrs however the AUC for hs Tn I at 3 hrs was higher compared to hs Tn I at 0 hr. Using cut off value of 26 ng/L for hs Tn I at 0 hr it was observed that sensitivity of hsTn I at 0 hr was 84.6 % and specificity was 63.2 %. In differentiating AMI from non-AMI, the overall diagnostic accuracy of hs Tn I was observed to be 74.59 %. For hs Tn I at 3 hrs sensitivity was observed to be 95.38 % and specificity was 63.2 % with an improvement to diagnostic accuracy 80.33 % than compared to hs Tn I at 0 hr in differentiating AMI from non-AMI. Use of hs Tn I at 3 hrs improved the probability of diagnosing the AMI without improving the specificity.

Delta change in relation to diagnosis

Patients who presented with normal hs Tn I at 0 hr delta change of > 50 % was considered significant in diagnosing ACS. It was observed that in patients who had more than 50 % delta change 50 % were diagnosed as STEMI, 30 % as NSTEMI 10 % as UA i.e. 90 % cases were diagnosed as ACS compared to only 10 % cases were diagnosed as non-ACS. In patients who had less than 50 % delta change 63.9 % had non-ACS compared to 30.6% UA, 2.8% each STEMI and NSTEMI respectively. Patients who presented with higher than URL (26 ng/L) hs Tn I at 0 hr delta change of > 20 % was considered significant in diagnosing ACS. It was observed that in patients who had more than 20 % delta change 65.4 % were diagnosed as STEMI, 26.9 % as NSTEMI 5.8 % as UA i.e. 98.1 % cases were diagnosed as ACS compared to only 1.9 % cases who were diagnosed as non-ACS. In patients who had less than 20 % delta change 45.8 % had non-ACS compared to 25% UA, 16.7 % STEMI and 12.5% NSTEMI. There was a statistically significant relation observed between delta change and type of diagnosis p 50 % was considered as positive. 3. Any deviation from point 1 and 2 was considered as negative delta change.

Delta change in differentiating ACS from non-ACS: Role was positive delta change in differentiating ACS from non-ACS was analysed by ROC curve analysis and it was observed that the sensitivity was 77.9 %, specificity was 86.1 %, PPV was 93.06%, NPV was 62% and diagnostic accuracy was 80.33% in differentiating ACS from non-ACS. On comparison with hs Tn I at 0 and 3 hrs, it was observed that Percentage Delta change had shown a better specificity i.e. a better probability of non-ACS in absence of positive change in delta.

Delta change in differentiating AMI from Non-AMI: Role was positive delta change in differentiating AMI from non-AMI was analysed by ROC curve analysis and it was observed that the sensitivity was 96.9 %, specificity was 84.2 %, PPV was 87.5%, NPV was 96% and diagnostic accuracy was 90.98 % in differentiating AMI from non-AMI. On comparison with role of percentage delta change in differentiating ACS, it was observed that when applied to in differentiating AMI rather than ACS the diagnostic accuracy improved. Though Delta change showed better specificity to rule out non-ACS, when applied to AMI its efficacy increased to both diagnosing presence of AMI in addition to rule out of non-AMI

Keller et al,[10] using a hs Tn I assay found that the combination of the 99th percentile diagnostic cutoff (30 ng/L) with relative delta change in 3hrs > 250%, produced an increase in specificity (99.6%) and of

PPV (95.8%), in comparison to the value of the 99th percentile cutoff on admission alone (Specificity 92.1%, PPV 75.1%).

Mueller et al,[11] compared dynamic delta changes of hs Tn T in patients with a diagnosis of ACS with patients presenting to ER with acute symptoms and cTn increases but without a diagnosis of ACS. The ROC optimized absolute delta changes of 6.9ng/L for the ACS population, provided a sensitivity of 93.3%, specificity 81.9%, PPV 82.8% and NPV 93%. Reichilin et al,[12] found that the ROC derived optimal cut off value for absolute delta change from baseline to 2hr follow up measurement was 7ng/L, provided a sensitivity of 89%, specificity 93%, PPV 64% and NPV 98%.

Limitations of the study and areas for future research: Associated co-morbidities and confounding factors could have affected the outcome of patients and overlapping risk factors in a single individual. Duration of study period is very short and sample size is less compared to other studies which might have led to the different outcomes. Sample size and duration of study period should be more. Gender specific thresholds of highly sensitive troponin I values were not taken into consideration which might have led to the different outcomes. So different threshold for male and female to be considered. Time frame from the onset of symptoms were not taken into consideration which increases diagnostic accuracy of hsTnI test. Diagnostic cut off value for different time frame should be considered. Cut off value of hsTnI of 26ng/L was taken for rule in/rule out ACS which might have led to the different outcomes. So cut off value below 26ng/L should be taken to increase diagnostic accuracy. This is an observational prospective study conducted at a single centre (Apollo hospital-Hyderabad). The results of this study must be applied to other centres at various levels of care and various patient categories for increasing the accuracy and for further validation. VII. Future studies could increase sample size, take confounding factors into consideration, time frame from onset of symptoms along with delta values should be determined for each different time window. VIII. There is delay in diagnosing ACS by waiting for 3 hours of repeat sample which increases morbidity and mortality, so further studies to be done in improving diagnostic accuracy of the hsTnI test at the time of presentation itself.

CONCLUSION

In conclusion, Acute Coronary Syndrome is diagnosed by highly sensitive troponin I levels in serial (0hr and 3rdhr) measuring of blood samples after applying 26 ng/L cutoff value. Furthermore, by applying percentage delta change, it increases the specificity and negative predictive value.

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