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A study on high sensitive C-Reactive protein as a diagnostic marker in preschool asthmatics

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ABSTRACT

Introduction: Childhood asthma has a hazardous impact on the growth, social & emotional aspect of the life thereby affecting the quality of life. Hence, early diagnosis & identification of symptoms can help prevent the co-morbidities. High sensitive C-Reactive protein (hsCRP) a known marker of systemic inflammation is evaluated in the current study as a marker of asthma in the preschool children.
Objective : To evaluate the efficacy of serum hsCRP as a diagnostic marker & to find out the correlation of serum hsCRP level among the different grades of severity of asthma in pre-school children.
Materials and Methods: A cross-sectional analytical study was designed with 811 samples equally divided between the case & health matched control groups.GINA-2018 definition was used to recruit subjects & classify the severity. One time serum hsCRP was estimated in the subjects among both the cases & controls, & correlated with other variables in the study.
Results: A total of 811 participants were included in the final analysis with 402participants in asthmatics category & 409 participants in healthy children category. Out of the 402 asthmatics,362 (90.05%) subjects tested to be positive(higher than 3mg/L) & only 40 subjects (9.95%) were negative. Similarly out of 409 healthy subjects, only 36 (8.8%) were positive while majority i.e. 373(91.2%) were found to be negative. The test was evaluated to be having a sensitivity of 90.05%, specificity of93.32% with a diagnostic accuracy of 91.66%. The diagnostic accuracy of hsCRP in severe asthma was 63%, & the specificity was 58%, whereas in case of mild asthma it was79% & 73% respectively with statistical significance.
Conclusion: hsCRP is a reliable diagnostic marker in preschool asthmatics to besides clinical correlates.

1. Introduction

Asthma is a heterogeneous sickness, ordinarily described by persistent aviation route irritation. It is characterized by history of respiratory side effects like wheeze, windedness, chest snugness, & hack that shift additional time & in force, along with variable expiratory wind current limit.[1]

Asthma influences 2 to 23% populace in India.[2] Youth asthma is probably going to affect the social & profound parts of lives of the youngsters & their families & is one of the normal purposes behind kid's infection non-attendance influencing kid's scholarly exhibition. This prompts development hindrance, practice bigotry, loss of rest due to nighttime wheezing, & in the long run lessening the personal satisfaction of the youngster.

In asthma other than aviation route irritation, foundational irritation likewise exists.[2] CRP is so named for its ability to hasten substantial cell polysaccharide of streptococcus pneumoniae is a delicate marker of intense fundamental aggravation & tissue damage.[3] The cytokines interleukin-1, interleukin-6 manage high responsiveness CRP (hsCRP) & assume a part in aviation

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route inflammation.[4] It is essentially orchestrated by the liver & is controlled by supportive of fiery cytokines basically TNF-alpha andIL-6. An intense stage reaction causes quick expansion underway of CRP bringing about the arrival of expanded amount in the flow. Standard measures of CRP misses the mark on responsiveness expected to decide the degree of irritation & consequently clinical utility of standard CRP assessment is very restricted. Late improvement brought about another age of exceptionally delicate measures that can identify CRP levels 100fold lower than prior assays.[5] Elevated levels of hsCRP are essentially connected with respiratory capability hindrance & bronchial hyper responsiveness.[6] So, it is sensible to consider the presence of a relationship between's asthma control (fiery confusion) & hsCRP levels. In asthma as a feature of intense stage reaction to irritation, there is a fast creation of CRP which fills in as an overall forager protein & helps in opsonization, phagocytosis & cell intervened cytotoxicity. Hence, there is a positive relationship between seriousness of asthma & high delicate CRP levels (hsCRP).

The finding of asthma in youngsters under the age gathering of 5 years, is testing since there are a ton of asthma imitates & consequently, the greater part of the kids are undertreated & furthermore over treated in non-industrial nations. Subsequently, there is a requirement for making the conclusive finding of asthma & to characterize them in light of seriousness & recurrence of side effects & treat them in like manner to work on their development & improvement. This will assist with forestalling movement of aviation route re-displaying & to lessen aviation route hyper-responsiveness.

Analysis of asthma in pre-younger students is undeniably challenging by examinations like PFT [pulmonary capability tests], so conclusion is simply clinical. Thus, we are looking for a clever device for determination of asthma in this age bunch.

Our point behind planning of the ongoing review convention is to assess the serum hsCRP level as a symptomatic marker of asthma in pre-younger students.

2. Aims & Objectives

2.1. Research question

Is serum hsCRPa diagnostic marker among preschool asthmatics?

2.2. Null hypothesis

Serum hsCRP is not a diagnostic marker among pre-school asthmatics.

2.3. Objectives

To evaluate the efficacy of serum hsCRP as a diagnostic marker of asthma & correlation of serum hsCRP level among the different grades of severity of asthma in pre-school children.

3. Materials and Methods

After getting clearance from institutional ethical committee this observational cross-sectional diagnostic study was conducted in both out patient & indoor patient of Veer Surendra Sai Institute of Medical Sciences & Research (VIMSAR), Burla, Sambalpur from November2019 to October 2021. Each patient was enrolled in the study after taking informed consent from the parents & the legal guardian. Case Performa for each patient was filled & data was collected from the sheet regarding the baseline characteristics like gender, weight, BMI, age etc.

3.1. Study subjects

There are two groups of study population.

3.1.1. Asthmatic group

This group included subjects with the following inclusion criteria [all criteria inclusive];

1. (a) Age -1 to 5 yrs,
   (b) Both genders,
   (c) Acute Asthma diagnosis by GINA 2018 guideline.

   As per GINA guideline 2018, an asthma diagnosis in children 5 years & younger can often be based following features-

   i. Symptom patterns (wheeze, cough, breathlessness (typically manifested by activity limitation), & nocturnal symptoms or awakenings),
   ii. Presence of risk factors for development of asthma.
   iii. Therapeutic response to controller treatment

3.2. Exclusion criteria

The following subjects were excluded from the study:

1. The cohort of children with chronic asthma who are on regular treatment with controllers & rescuers are as such not included in the study,
2. Collagen Vascular Disease(By Documentation)
3. Chronic Skin Disease Like Epidermolysis Bullosa Simplex,
4. Acute Suppurative Conditions Like Abscess,
5. Malignancy,
6. Patients on Inhaled Corticosteroid,

7. Pneumonia,
8. Chronic disease like tuberculosis.

3.2.1. Preschool Non asthmatic healthy controls group

1. Non asthmatic preschool asymptomatic children with minor health ailments.,
2. Children who are not diagnosed as asthma & are not having any acute or chronic illness at the time of study,
3. Children who shall be accompanying the patients in indoor. e.g. relatives or siblings.

Sample size estimation was done based on diagnostic test confidence interval(CI) estimating sensitivity of a new test – absolute precision of 5% method by n master v2.0, BRTC, Vellore as there is no previous study. As per the rule of assumption, we have taken 50% sensitivity of hsCRP to detect asthma in preschool children. Taking CI to be 95%, minimum sample size was calculated to be 384 among cases & 384healthy controls.

From the start of our study we follow cases in our OPDs & IPDs of Dept. of Paediatrics VIMSAR, Burla. These patients were informed about our study through patient information sheet. 811 patients gave their consent by signing the consent form. These patients were passed through inclusion & exclusion criteria for both the group. There were a total of 402 subjects in the asthmatic group & 409 subjects in the healthy subject group.

3.3. Methods

Serum hsCRP is done in the department of biochemistry, VIMSAR by anephelometer of company Genrui PA50 marketed by Biogeny diagnostic Pvt Ltd.

3.3.1. Data analysis

hsCRP (High Sensitive C-Reactive Protein) & Severity of asthma (as per GINA 2018 guidelines) was considered as primary outcome variable.

Data collected from the study was processed, checked for internals errors, internal, & external validation were done using n Master version 2.0 software, SPSS v & STATA/IC v 16.1software. Data was analyzed in terms of independent t -test & chi square test & result was interpreted. P value less than 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

4. Results

A total of 811 participants were included in the final analysis with 402 participants in asthmatics category & 409 participants in healthy children category.

In the case group, the mean age was 32.06 ± 15.35 months for asthmatics & 34.82 ± 14.23 months for healthy children, the mean weight was 13.59 ± 3.49 kg for asthmatics & 14.37 ± 2.79 kg for healthy children, the mean BMI was 16.89 ± 2.20 kg/m^2 for asthmatics & 16.67 ± 1.66 kg/m^2 for healthy children. The difference in mean age, weight & BMI between study groups was statistically insignificant & it was a matched control on these parameters.Table 1

Out of 402 participants in asthmatics group, the gender was male for 279 (69.4%) participants & it was female for 123 (30.6%) participants. Out of 409 participants in Healthy Children group, the gender was male for 278 (67.9%) participants & it was female for 131 (32.1%) participants. The gender distribution was comparable & matched.Table 2

Out of 402 participants in asthmatics group, the Socioeconomic Status was Upper for 24 (5.97%) participants, Upper Middle for 108 (26.87%) participants, Lower Middle for 189 (47.01%) participants & Upper Lower for 65 (16.10%) participants & 16(3.98%). Out of 409 participants in Healthy Children group, the Socio-Economic Status was Upper for 13 (3.1%) participants, Upper Middle for 153 (37.4%) participants, Lower Middle for 152(37.1%) participants & Upper Lower for 89 (21.7%) participants & lower for 10(2.44%). The difference in the proportion of gender & socio-economic statusbetween study group was statistically not significant. The controls were matched on these parameters.Table 3

Among the study population, hsCRP level of patients was less than 3 mg/dl for 403 (49.69%) participants & more than 3 mg/dl for 408 (50.30%) participants.Table 4

Among the 811 subjects included in the study, 409 (50.43%) were healthy controls & hence were free of asthma. In the case group, Mild for 279 (34.40%) participants & Severe for 123 (15.16%) participants. The severity classification was according to GINA-2018 guideline criteria.Table 5

Out of 123 participants in severe asthmatic group, the hsCRP of patients was more than 3 mg/L for 111 (90.24%) participants & it was less than 3 mg/L for 12 (9.76%) participants. Out of 688 participants in non-severe asthmatic group, the hsCRP of patients was more than 3 mg/L for 287 (41.5%) participants & it was less than 3 mg/L for 401 (58.5%) participants. The difference in the proportion of hsCRP of patients between severe GINA category of patients was statistically significant.Table 6

The hsCRP of patients had sensitivity of 90.24% (95% CI 83.58% to 94.86%) in predicting presence of severe GINA category of patients. Specificity was 58.53% (95% CI 54.69% to 62.30%), false positive rate was 41.47% (95% CI 37.70% to 45.31%), false negative rate was 9.76% (95% CI 5.14% to 16.42%), positive predictive value was 28.61% (95% CI 24.16% to 33.39%), negative predictive value was 97.02% (95% CI 94.86% to 98.45%), & the total diagnostic accuracy was 63.46% (95% CI 60.00% to 66.83%).Table 7

Out of 279 participants in mild asthmatic group, the hsCRP was more than 3 mg/L for 251 (89.96%) participants & it was less than 3 mg/L for 28 (10.04%) participants. Out of 532 participants in others group, the hsCRP of patients

Table 1: Comparison of baseline parameters between cases & healthy controls (n=811)

Parameters	Asthmatics(n=402) Mean+SD	Healthy Children (n=409) Mean+SD	p value
Age(months)	32.06 ± 15.35	34.82 ± 14.23	0.101
Weight(kgs)	13.59 ± 3.49	14.37 ± 2.79	0.105
BMI (kg/m^2)	16.89 ± 2.20	16.67 ± 1.66	0.114

Table 2: Comparison of gender distribution between groups

Gender	Asthmatics No (%)	Healthy Children No (%)	Chi-square	p value
Male	279 (69.4%)	278 (67.9%)	28.275	0.101
Female	123 (30.6%)	131 (32.1%)		

Table 3: Comparison of socioeconomic distribution in subjects & control groups

Socio Economic Status	Asthmatics (n=402)	Healthy children (n=409)	Chi-square	p value
Upper	24 (5,7%)	13 (3.4%)	15.16	0.102
Upper Middle	108 (26.87%)	153 (37.40%)	15.29	0.120
Lower Middle	189 (47.01%)	152 (37.1%)	14.19	0.114
Upper Lower	65 (16.10%)	85 (21.83%)	14.3	0.102
Lower	16 (3.98%)	6 (1.54%)	13.7	0.101

Table 4: Analysis of hsCRP in the study subjects in both groups (N=811)

hsCRP (mg/dl)	Frequency	Percentages
< 3 mg/dl	403	49.69%
> 3 mg/dl	408	50.30%

Table 5: Asthma severity category in study subjects in both cases & controls (n=811)

Asthma Severity		Frequency	Percentages
1.Non-asthmatics		409	50.43%
2.Asthmatics	a. Mild	279	34.40%
	b. Severe	123	15.16%

Table 6: hsCRP levels & asthma severity categories (n=811)

hsCRP	Severe (n=123)	Non-Severe (n=688)	Chi square	p value
> 3 mg/dl	111 (90.24%)	287 (41.5%)	98.8	0.001
< 3 mg/dl	12 (9.76%)	401 (58.5%)		

Table 7: Predictive diagnostic validity of hsCRP for severe asthma (n=811)

Parameter	Value	95% CI	
		Lower	Upper
Sensitivity	90.24%	83.58%	94.86%
Specificity	58.53%	54.69%	62.30%
False positive rate	41.47%	37.70%	45.31%
False negative rate	9.76%	5.14%	16.42%
Positive predictive value	28.61%	24.16%	33.39%
Negative predictive value	97.02%	94.86%	98.45%
Diagnostic accuracy	63.46%	60.00%	66.83%
Positive likelihood ratio	2.18	1.73	3.739
Negative likelihood ratio	0.17	0	0.286

Table 8: Comparison of hsCRP of mild asthmatics with hsCRP of others (N=811)

hsCRP	Mild asthma (n=279)	Others (n=532)	Chi square	p value
> 3 mg/dl	251 (89.96%)	147 (27.63%)	288.692	0.002
< 3 mg/dl	28 (10.04%)	385 (72.37%)		

was more than 3 mg/L for 147 (27.63%) participants & it was less than 3 mg/L for 385 (72.37%) participants. The difference in the proportion of hsCRP of patients between mild GINA Category of patientswas statistically significant (p value less than 0.05).Table 8

The hsCRP of patients had sensitivity of 89.96%(95% CI 85.82% to 93.23%) in predicting presence of mild GINA category of patients. Specificity was 73.24%(95% CI 69.18% to 77.03%), false positive rate was 26.76% (95% CI 22.97% to 30.82%), false negative rate was 10.04% (95% CI 6.77% to 14.18%), positive predictive value was 64.69% (95% CI 59.71% to 69.45%), negative predictive value was 93.05% (95% CI 90.11% to 95.33%), & the total diagnostic accuracy was 79.14% (95% CI 76.14% to 81.92%).Table 9

Out of 402 participants in asthmatic group, the hsCRP of patients was more than 3 mg/L for 362 (90.05%) participants & it was less than 3 mg/L for 40 (9.95%) participants. Out of 389 participants in Healthy Children group, the hsCRP of patients was more than 3 mg/L for 26 (6.68%) participants & it was less than 3 mg/L for 363 (93.32%) participants. The difference in the proportion of hsCRP of patients between asthmatics was statistically significant.Table 10

The hsCRP of patients had sensitivity of 90.05% (95% CI 86.70% to 92.80%) in predicting presence of mild GINA category of patients. Specificity was 93.32%(95% CI 90.36% to 95.59%), false positive rate was 6.68% (95% CI 4.41% to 9.64%), false negative rate was 9.95% (95% CI 7.20% to 13.30%), positive predictive value was 93.30% (95% CI 90.34% to 95.58%), negative predictive value was 90.07% (95% CI 86.73% to 92.81%), & the total diagnostic accuracy was 91.66% (95% CI 89.51% to 93.49%).Table 11

5. Discussion

The present study was undertaken to estimate serum hsCRP levels indiagnosed cases of asthma in children below 5 years of age & to correlate the clinicaldiagnosis of asthma to the estimated hsCRP levels & its grading.

Total of 811 children under the age group of 5 years were enrolled. Of them, 402 children were diagnosed as asthma based on GINA guidelines 2018, for asthmatic children under 5 years of age after stringent inclusion & exclusion criteria. These children were graded based on severity of asthma into mild & severe asthma.Another409 children were studied as healthy controls as per the specified exclusion & inclusion criteria to have a well matched control group. A single sample serum hsCRP was estimated in both the groups. Statistical analysis were applied to the observations.

In our study the meanage among the asthmatic children was 32 months with a standard deviation of 15 months. Paramesh H had a result where the cohort of asthmatic children between 3-5 years.[7]

Out of the 402 participants in the asthmatics group, there were 279(69.4%) males & 173(30%) females. This shows the male preponderance of the disease in this age group. This finding of our study is in accordance with study conducted by Kuehni et al which stated that there is a male preponderance of asthma till puberty after which there is a slight female dominance.[8]

While previous study by H. Paramesh,[7] has shown that there is higher incidence of asthma among low socioeconomic status, our study has also shown similar outcomes depicting 36.5% of cases belonging to low socioeconomic status.

The BMI was within normal limits amongst the asthmatics. In the contrary BMI has been established as a risk factor in a previous study by Bor S & Erdogan A.[9] This might be ascribed to the preschool age group & in our study subjects which mostly belongs to low socioeconomic status, there are very few obese children due to poverty & malnutrition.

We have undergone testing of hsCRP in both the groups after taking due consent from the parents. Out of the 402 asthmatics, 362 (90.05%) subjects tested to be positive & only 40 subjects (9.95%) were negative. Similarly, out of 409 healthy subjects, only 36 (6.68%) were positive while majority i.e. 373(93%) were found to be negative. As per the above data the sensitivity was found to be 90.05% while specificity was 93.32% with a diagnostic accuracy of 91.66%. Hence, it is evident from our study that hsCRP is clearly found to be raised in children having asthma as compared to healthy non asthmatics.

Previous study conducted by shimoda et al, in adults distinguished asthmatics from healthy controls at a sensitivity of 69% & specificity of 70%.[10] It shows that hsCRP may be a strong predictor of asthma in children as compared to adults.

The present study revealed that diagnostic accuracy of hsCRP in severe asthma was 63%, & the specificity was 58%, whereas in case of mild asthma it was79% & 73% respectively with statistical significance. This implies hsCRP can be a predictor in the assessment of the severity of asthma but the strength is better in case of mild variety which indicates that it can be used as a screening modality for diagnosing asthma.

Takemura et al. studied & compared the hsCRP levels among adult steroid naïve (n=22) & patients on inhaled corticosteroids (n=23) with healthy controls (n=14).[11] Their study concluded that increase in serum hsCRP may be associated with increased airway inflammation & obstruction.

Study conducted by Razi et al. compared 108 adult asthmatics with93 healthy controls & corelated the results of hsCRP to find that mean hsCRP was significantly elevated in asthmatic group hence they concluded that hsCRP could be used as a diagnostic marker in asthmatics.[12]

Table 9: Predictive validity of hsCRP of patients in predicting mild asthmatics (n=811)

Parameter	Value	95%C I	
		Lower	Upper
Sensitivity	89.96%	85.82%	93.23%
Specificity	73.24%	69.18%	77.03%
False positive rate	26.76%	22.97%	30.82%
False negative rate	10.04%	6.77%	14.18%
Positive predictive value	64.69%	59.71%	69.45%
Negative predictive value	93.05%	90.11%	95.33%
Diagnostic accuracy	79.14%	76.14%	81.92%
Positive likelihood ratio	3.36	2.73	4.796
Negative likelihood ratio	0.14	0	0.195

Table 10: Comparative hsCRP in asthmatics & non-asthmatics (n=811)

hsCRP	Asthmatics (n=402)	Healthy Children (n=409)	Chi square	p value
> 3 mg/L	362 (90.05%)	36 (6.68%)	549.78	0.002
< 3 mg/L	40 (9.95%)	373 (93.32%)		

Table 11: Predictive validity of hsCRP for asthma (n=811)

Parameter	Value	95%C I	
		Lower	Upper
Sensitivity	90.05%	86.70%	92.80%
Specificity	93.32%	90.36%	95.59%
False positive rate	6.68%	4.41%	9.64%
False negative rate	9.95%	7.20%	13.30%
Positive predictive value	93.30%	90.34%	95.58%
Negative predictive value	90.07%	86.73%	92.81%
Diagnostic accuracy	91.66%	89.51%	93.49%
Positive likelihood ratio	13.47	9.15	18.101
Negative likelihood ratio	0.11	0.02	0.143

An Indian study conducted by Ramesh et al in Karnataka, evaluated the hsCRP levels in adult patients with asthma & he compared the hsCRP among atopic & non-atopic patients.[7] His study concluded that there exists a certain degree of low-grade systemic inflammation in addition to bronchial inflammation in nonatopic asthmatics. Hence hsCRP being a marker could be used as a surrogate marker of airway inflammation in non-atopic asthmatics.

A study in South Korea in the paediatric found strong positive correlation between the hsCRP levels & spirometry results.[13]

Similarly, Deraz et al.in a cross-sectional study to evaluate hsCRP in asthmatic children (n=60) with different grades of severity & control (n=60). They found that hsCRP concentrations were significantly higher in asthmatics than in controls with a sensitivity of 72%and specificity of 93%.[8]

Like other studies, the current study is also not devoid of limitations. As it is a hospital based study in a tertiary care centre with limited resources, the results could not be generalized. It is a single centre study, so the results are not devoid of confounders, diagnosis bias & information bias could not be avoided. The cohort of children with chronic asthma who are on regular treatment with controllers & rescuers are as such not included in the study. Still, there is a paucity of studies which relates hsCRP to diagnose asthma in the preschool age group. It. Seemed, the current study is one of the maiden efforts with that objective.

Despite the limitations, these data provide insights into the relationship between hsCRP & bronchial asthma. Our study is easy & economical to conduct. It has provided us with important information on the distribution & burden of asthma in preschool children attending the IPD & OPD of VIMSAR, Burla. In addition, we have found that serum hsCRP test can be a valuable marker of asthma in this age group. Future studies with a better study design & broad based larger sample size with multicentric approach can yield more reliable results.

6. Conclusion

Asthma being one of the most common chronic disorder of childhood, & given the impact of asthma in preschool age group & in the quality of life of the children, it is imperative to diagnose it as early as possible. Early diagnosis of asthma & a vivid knowledge about its natural history as well as

the risk factors can help us to control the progression of the disease & reduction in acute exacerbations. As standard diagnostic modalities like PFT & spirometry are not useful in the preschool age group, so the diagnosis is purely clinical. Hence, it is essential for devising a new diagnostic modality which can help us identify & diagnose the disease early. hsCRP has been studied in our tertiary care centre & has produced promising results in diagnosing asthma in our centre. It is cheap, easily available across India in various government & private healthcare facilities produces results in a quick span of time, & a reliable marker allowing early diagnosis & screening for mild variety of the disease. Though spirometry & clinical classification are the gold standards for grading of asthma, hsCRP can be considered as a new marker for assessment of different grades of asthma severity & control especially in the preschool age group.

7. Authors Contribution

All authors were involved in research design, data analysis, & manuscript preparation & editing.

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