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Research Article

A STUDY TO SCREEN CHILDREN FOR CELIAC DISEASE WITH A CLINICAL RISK-BASED APPROACH

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ABSTRACT

Aim: The aim of the present study was to screen children for Celiac Disease with a clinical risk-based approach.
Methods: The cross-sectional study was conducted in the Department of Paediatrics, NIMS Medical College and Hospital, Jaipur. 500 patients were recruited and data was statistically analysed. All children attending Paediatrics Department during the study period (January 2022 to April 2024). Written informed consent was obtained in every case.
Results: Out of total included children 302 (60.4 %) were male and 198 (39.6 %) were female. Total 279 (55.8 %) children were in age group of 12 months to 60 months, 195 (39 %) children were in age group between 61 months to 120 months, 26 (5.2 %) children were in age between 121 months to 192 months. Among 500 children, who attended hospital (OPD/IPD) during study period and were screened clinically using high risk approach, 105 (21%) had one or more risk features for celiac disease. Anti-tTgA was sent for all high-risk cases. Total numbers exceed 105 (cases with high risk factors) as many had more than one factors. Among biopsy proven 9 cases, most consistent feature was pallor which was present in 7 (77.7 %) patients followed by chronic diarrhoea in 4 (44.4%) and under nutrition in 4 (44.4 %).
Conclusion: The prevalence of celiac disease is very high (more than 1 %) in general population and has associated subclinical morbidities so it should always be suspected and screened for. Children who are attending hospital (OPD/IPD), should be screened for clinical features related to celiac disease, so we can pick up the cases before significant complications occur. Anti-tTgA is very sensitive and simple screening method to detect celiac disease, so this test should be better utilized for screening. Positive Anti-tTgA should be confirmed by small intestinal biopsy to confirm celiac disease.

Keywords*: children, Celiac Disease, clinical risk-based approach*

INTRODUCTION

Celiac disease was considered rare in India till 1980's. However, increased number of cases are being recognized in both children and adults. Recent data suggest that celiac disease affects more than 1 percent population in wheat eating part of our country specially in Punjab, Delhi, Haryana and Uttar Pradesh.[1]

Celiac disease commonly referred to as "wheat allergy" was long considered to be a hypersensitivity to Gluten, a protein contained in wheat. This resulted in intestinal damage causing enteropathy which caused diarrhoea, malnutrition and abdominal distension as clinical presentation. More recent data however show that it is actually an autoimmune disease where Gluten acts as trigger and tissue trans glutaminase is the auto antigen, reacting in a hereditary predisposed individuals (HLA DQ2, DQ 8 +ve) to cause intestinal damage.[2]

In earlier days the diagnosis was entirely dependent on demonstrating histopathological changes on small intestine biopsy. The procedure was not only invasive but also cumbersome and was done only when there was clear cut clinical indication. Availability of serological tests like Anti-tTgA and anti endomysial antibody as screening tests have made search of celiac disease much easier and more widely applicable.[3]

For early diagnosis utilizing serological tests many methodologies have been tried. Community based surveys have helped in diagnosing several undiagnosed cases. However, they are difficult to carry out and are not cost effective. Some other authors have tried clinical risk based approach[4] where subjects were screened clinically for presence of one or more clinical features of celiac disease and if clinical features are present, they were offered serological testing followed by duodenal biopsy if the same is positive.
The aim of the present study was to screen children for Celiac Disease with a clinical risk-based approach.

MATERIALS AND METHODS

The cross-sectional study was conducted in the Department of Paediatrics, NIMS Medical College and Hospital, Jaipur. 500 patients were recruited and data was statistically analysed. All children attending Paediatrics Department during the study period (January 2022 to April 2024). Written informed consent was obtained in every case.
The subjects were studied using a 3-tier approach.

1. Clinical screening

Detailed history and physical examination were done in each case with particular reference to find out features suggestive of celiac disease. The various demographic and clinical details pertaining to celiac disease were recorded for each individual.

2. Serological screening

Those children who have one or more features of celiac disease was tested for presence of Anti-tTgA. The test for serum Anti-tTgA was done by using ELISA and standard kit.

3. Histological (duodenal biopsy)

Children found to be Anti-tTgA positive were offered an endoscopic duodenal biopsy. Biopsy was histologically examined and was graded as per Marsh criteria. Children whose duodenal biopsy show positive finding (Marsh 2 to 3c) was labelled as celiac disease. Other investigation like hemogram, serum iron, iron binding capacity and vitamin D levels etc was done as per indications.

Selection of individuals

All children (Both male & female) who were presented in paediatrics department (Both OPD & IPD) in between 1 to 16 years of age were included in study.

Testing strategy

This study was a cross-sectional study in which subjects underwent detailed history taking and examination regarding their current and any past illness and standard questionnaire was administered to all children. If screen positive (based on 1 or more symptoms in questionnaire) blood sampling for investigations relevant for their presenting illness and Anti-tTgA were sent. Anti-tTgA was estimated by ELISA. The cut off for a positive Anti-tTgA test was 15U/mL as per the manufacturer's guidelines. Children with positive Anti-tTgA test underwent endoscopic duodenal biopsy. The biopsy specimens were evaluated as per the modified Marsh's classification.

INCLUSION CRITERIA

- Children who has attended Paediatrics department in Max Super Speciality Hospital Vaishali Ghaziabad during the study period.

EXCLUSION CRITERIA

- Children whose parents were not willing to join the study.
- Already diagnosed as celiac disease.

STATISTICAL ANALYSIS

- All the collected data was entered in the Microsoft Word Excel Sheet 2007 version and the data obtained was analysed using the SPSS (Statistical Package for the Social Sciences) 20 Version for the descriptive analysis and statistical tests of significance.
- The mean, standard deviations and the proportions (% of subjects affected) were calculated for each clinical parameter and the various statistical test of significance were used.
- Chi-square is a statistical test commonly used to compare observed data with data we would expect to obtain according to a specific hypothesis.
- $\chi 2 = (O-E)2/E$
- Significance for all statistical tests was predetermined at a probability (p) value of 0.05 or less

RESULTS

Table 1: Age and Sex distribution of cases and high risk cases according to Age Group

Age group	**Male**	**Female**	**Total**
12 month to 60 month	172 (61.6%)	107(38.3%)	279
61 month to 120 month	117 (60%)	78 (40 %)	195
121 month to 192 month	13 (50%)	13 (50%)	26
Total	302 (60.4%)	198 (39.6%)	500
Age group	**High risk factors**	**No risk factor**	**Total no of cases**
12 month to 60 month	57 (20.5%)	222 (79.4%)	279
61 month to 120 month	38(19.3%)	157s (80.6%)	195
121 month to 192 month	10 (38.4%)	16 (61.6%)	26
Total	105 (21%)	395 (79%)	500

Out of total included children 302 (60.4 %) were male and 198 (39.6 %) were female. Total 279 (55.8 %) children were in age group of 12 months to 60 months, 195 (39 %) children were in age group between 61 months to 120 months, 26 (5.2 %) children were in age between 121 month to 192 months. Among 500 children, who attended hospital (OPD/IPD) during study period and were screened clinically using high risk approach, 105 (21%) had one or more risk features for celiac disease. Anti-tTgA was sent for all high risk cases. 38.4% of children above 10 years of age had high risk factors compared to only 19.3% and 20.5% of cases in the age groups 5 -10 years and 1 - 5 years respectively. Differences however were not significant (p value=0.083).

Table 2: Distribution of risk factors among High-Risk Cases (single or more than one)

Risk factors	**Anti-tTgA sent**	**Anti-tTgA positive**	**Biopsy positive**
Constipation	45	6 (13.3%)	3 (6.6%)
Abdominal pain	32	4(12.5%)	3 (9.3%)
Chronic diarrhoea	17	5 (29.4%)	4 (23.5%)
Abdominal distension	12	2(16.6%)	2 (16.6%)
Pallor	66	10 (15.2%)	7 (10.6%)
Family history of celiac disease	2	2(100%)	2 (100%)
Clubbing	0	0(0%)	0 (0)
Wrist widening	2	0(0%)	0 (0%)
Under nutrition (<3rd Percentile)	9	4 (44.4%)	4 (44.4%)
Short stature (<3rd Percentile)	24	4 (16.6%)	3 (12.5%)

Total numbers exceed 105 (cases with high risk factors) as many had more than one factors.

Table 3: Presenting features of biopsy proven celiac disease

Risk factors associated with celiac cases	**Percentage**
Constipation	3 (33.3%)
Abdominal pain	3 (33.3%)
Chronic diarrhoea	4 (44.4%)
Abdominal distension	2 (22.2%)
Pallor	7 (77.7%)
Family history of celiac disease	2 (22.2%)
Clubbing	0 (0)
Wrist widening	0 (0%)
Under nutrition (<3rd Percentile)	4 (44.4%)
Short stature(<3rd Percentile)	3 (33.3%)

Among biopsy proven 9 cases, most consistent feature was pallor which was present in 7 (77.7 %) patients followed by chronic diarrhoea in 4 (44.4%) and under nutrition in 4 (44.4 %).

Table 4: Distribution of weight among male and female

Weight interpretation	**Male**	**Female**	**Total no of cases**
< 3rd centile	4 (44.4%)	5 (55.6%)	9 (1.8%)
3rd – 50th centile	203 (66.3%)	103 (33.7%)	306 (61.2%)
50th – 97th centile	95 (51.6%)	89 (48.4%)	184 (36.8%)

>97th centile	0 (0%)	1 (100%)	1 (0.2%)
Total	**302 (60.4%)**	**198 (39.6%)**	**500**

Among 500 cases, Weight of 9 (1.8%) children were below 3rd centile, 306 (61.2%) were between 3rd and 50th centile and 184 (36.8%) were between 50th - 97th centile. Among 9 cases who were below 3rd centile 4 (44.4%) were males and 5 (55.6%) were females.

Table 5: Distribution of weight among different age group

Age Group	< 3rd centile	3rd -50th centile	50th – 97th centile	> 97 th centile	Total
< 5 years	4(1.4%)	154(55.2%)	121(43.4%)	0(0%)	279
5– 10 years	4(2.05%)	133(68.2%)	58(29.7%)	0(0%)	195
>10 years	1(3.84%)	19(73%)	5(19.20%)	1 (3.84%)	26
Total	**9 (1.8%)**	**306(61.2%)**	**184 (36.8%)**	**1 (0.2%)**	**500**

Among 279 children of below 5 years, 4(1.4%) had weight below 3rd centile. Among 195 children of age group between 5-10 year 4 (2.05%) and among 26 children of above 10-year age 1 (3.84%) had weight below 3rd centile. Although more percentage of children who were below 3rd centile were in age group of more than 10 years compared to other age group which was statistically significant (p value =0.0000).

Table 6: Distribution of Height among male and female

Height interpretation	Male	Female	Total no of cases
< 3rd centile	12(50%)	12(50%)	24(4.8%)
3rd – 50th centile	113(60.4%)	74(39.6%)	187(37.5%)
50th – 97th centile	176(61.1%)	112(38.9%)	288(57.6%)
>97th centile	1(100%)	0(0%)	1(0.2%)
Total	**302 (60.4%)**	**198 (39.6%)**	**500**

Among 500 cases, 24 (4.8%) had height/length below 3rd centile, 187 (37.5 %) were between 3rd and 50th centile and 288 (57.6 %) were between 50th - 97th centile. Among 24 cases who were below 3rd centile 12 (50%) were males and 12 (50%) were females.

Table 7: Distribution of Height among different age group

Age group	< 3rd centile	3rd -50th centile	50th–97th centile	> 97 th centile	Total
< 5 years	14(5.01%)	81(29.0%)	184(65.9%)	0(0%)	**279**
5– 10 years	8(4.10%)	91(46.7%)	95(48.7%)	1(0.5%)	**195**
>10 years	2(7.69%)	15(57.7%)	9(34.6%)	0(0%)	**26**
Total	**24 (4.8%)**	**187 (37.4%)**	**288 (57.6%)**	**1 (0.2%)**	**500**

Among 279 children of below 5 years, 14(5.01 %) had height below 3rd centile compared to 8 (4.1 %) out of 195 and among 2 (7.69 %) out of 26 children in 5-10 year and >10 years respectively. Although more children were below 3rd centile in above 10 years group compared to other age groups but it was not statistically significant. (P value= 0.620).

Table 8: Screening for celiac disease by Anti-tTgA in different Weight and Age group

Age groups	Weight	No. Of cases	Anti-tTgA sent	Anti-tTgA positive
≤5 years	≤3rd centile	4	4	2 (50%)
	3- 50th centile	154	36	5 (13.8%)
	50-97th centile	121	17	2 (11.7%)
	≥97th centile	0	0	0
	Total	**279**	**57**	**9**
5-10 years	≤3rd centile	8	4	2 (50%)
	3- 50th centile	91	24	3 (12.5%)
	50-97th centile	95	10	0
	≥97th centile	1	0	0
	Total	**195**	**36**	**5**
≥10 years	≤3rd centile	2	1	0
	3- 50th centile	15	5	0
	50-97th centile	9	3	0
	≥97th centile	0	1	0
	Total	**26**	**10**	**0**
TOTAL		**500**	**105**	**14 (13.3%)**

Out of 279 children below 5 years age, Anti-tTgA was sent for 57 (20.4%) children and it was positive in 9 (3.2%) In below 5 years age group 4 children had weight below 3rd centile and out of them 2 were Anti-tTgA positive. Out of 195 children

between 5- 10 years age, Anti-tTgA was sent for 38 (19.4 %) children and it was positive in 5 (2.56%). Among 5-10 year age group 4 children had weight below 3rd centile and out of them 2 were Anti-tTgA positive. Out of 26 children above 10 years age, Anti-tTgA was sent for 10 (38.4 %) children and it was negative in all. Among 5–10-year age group 1 child had weight below 3rd centile and Anti-tTgA was negative.

Table 9: Diagnostic evaluation of celiac disease based on ≥ 3 risk factors

Multiple risk factors (≥ 3 risk factor)	**No of patients**	**Anti-tTgA sent**	**Anti-tTgA positive**	**Biopsy positive**
Abdominal pain+ Chronic diarrhoea+ Pallor	1	1	0	-
Constipation+ Abdominal distension+ Pallor	2	2	0	-
Constipation+ Abdominal pain + Pallor	6	6	1	1
Constipation+ Abdominal pain+ Abdominal distension	1	1	0	-
Constipation+ Abdominal pain+ Pallor + family history of celiac disease	1	1	1	1
Chronic diarrhoea+ Abdominal distension+ Pallor + Wrist Widening	1	1	0	-
Chronic diarrhoea+ Abdominal distension+ Pallor	1	1	1	1
Abdominal pain + Pallor + Under Nutrition	1	1	1	1
Abdominal distension+ Pallor+ Under Nutrition	1	1	0	-
Chronic diarrhoea+ Abdominal distension+ Under Nutrition	2	2	0	-
Chronic diarrhoea+ Family history of celiac disease+ short stature	1	1	1	1
Constipation+ Pallor+ Under Nutrition	1	1	1	1
Constipation+ Pallor+ short stature	2	2	0	-
Constipation+ Wrist widening + Under Nutrition	1	1	0	-
Pallor+ short stature+ Under Nutrition	1	1	0	-
Chronic diarrhoea+ Pallor+ short stature+ Under Nutrition	1	1	1	1
Chronic diarrhoea+ short stature+ Under Nutrition	1	1	1	1
Abdominal distension+ Pallor+ short stature	1	1	0	
Abdominal pain + Pallor +short stature	1	1	0	
TOTAL	**27**	**27**	**8 (29.6%)**	**8 (29.6%)**

There were total 27 children out of 500, who had any 3 or more specified risk factors. Anti-tTgA was sent for all 27 patients and report was positive in 8 (29.6%) patients. Biopsy was done in all sero-positive patients, which was consistent with celiac disease in all. This shows chances of picking up cases celiac disease are more if more than one risk factor is present.

Table 10: Risk factor based evaluation for Celiac Disease

Risk factors	**Anti-tTgA sent**	**Anti-tTgA - positive**	**Biopsy positive**	**Incidence of Celiac disease among patients attending hospital (Total -500 patients)**
Single Risk factors	31	1 (3.12%)	0	-
Two Risk factors	47	5 (10.6%)	1(2.12)	0.2%
≥Three Risk factors	27	8 (29.6%)	8(29.6%)	1.6%
Total	**105**	**14 (13.33%)**	**9 (8.5%)**	**9 (1.8%)**

Anti-tTgA was sent for all children who had one or more risk factors. Out of 500 children 31 children had one risk factor, 47 and 27 children had 2 and ≥3 risk factors respectively. Children who had single risk factor 1 (3.12%) was seropositive but among children who had 2 risk factors Anti-tTgA was positive in 5 (10.6%) out of 47 and 8 (29.6%) out of 27 children in whom ≥3 risk factors were present. Among seropositive patients, who had 2 risk factors, only 1 (2.12%) out of 5 was biopsy positive for celiac disease compared to all 8 (29.6%) who had ≥3 risk factors. It shows more chances of celiac disease, if risk factors are more.

DISCUSSION

This is the hospital-based screening study for Celiac Disease in children from1 year to 16 years of age in North India. The prevalence of Celiac Disease varies in different parts of the world. Initially, it was thought to be a rare disease affecting predominantly Caucasians. The disease was initially presumed to be less common in Asian and African populations but recent reports show rising trend due to better availability of diagnostic modalities. The clinical presentation of celiac disease varies considerably from full blown malabsorption syndrome to subtle and atypical symptomatology. Younger children

present with typical features like diarrhoea, vomiting and failure to thrive. Older patients usually have atypical presentations like anemia, abdominal pain and osteoporosis.[5,6]

The epidemiological changes of Celiac Disease is explained by the iceberg model.[7] A substantial number of cases of CD are timely diagnosed due to the suggestive complaints (e.g chronic diarrhoea, unexplained iron deficiency) or other reasons (e.g. family history of Celiac Disease). These cases make up the visible part of the celiac iceberg, in quantitative terms expressed by the prevalence of the disease. However, it has been reported that for each diagnosed case of CD, an average of 5 to 10 cases remain undiagnosed, particularly in India it is due to lack of awareness and atypical presentation of celiac disease.[8] Undiagnosed celiac may cause morbidity like anaemia, osteoporosis and may result in decreased productivity and even possible risk of GI cancers. It is therefore important to diagnose celiac disease at the earliest to prevent these future complications.

Study by Sood et al[9] in 2006 at Punjab on total of 4347 school children in age group between 3 years to 17 years were screened for celiac disease, out of which 198 suspected children were identified for further evaluation. Twenty-one children tested positive Anti-tTgA assay and 17 of these 21 children agreed to undergo biopsy, of which 14 had histological changes consistent with celiac disease. In the final analysis the disease prevalence was 1 in 310 children but it is very less compared to our study which showed occurrence of 1.8% (9 in 500). Lal et al[10] in another study from Chandigarh (northern part of India) reported prevalence of celiac disease to be 1 in 120 in healthy school children which is very less than our risk-based screening which has occurrence of 1.8 % (9 in 500). Similarly, Makharia et al[1] reported overall sero-prevalence of celiac disease was 1.44% and overall prevalence of celiac disease was 1.04%. In other regions worldwide, the CD sero prevalence, assessed by Anti-tTgA antibody, was registered in children and adolescents that were previously healthy, like in studies carried out in Libya (0.82%), Belgium (0.86%) and Italy (1.5%).

Diagnosis of celiac disease has been done by previous studies in general population by using community-based survey by Sood et al[9], Bhatacharya M et al[11], Lal et al.[10] However community-based screening will require large sample size, is both time consuming and costly. Hence cost effectiveness of screening of large community has been questioned. Due to the above concerns, another method of screening in children by using risk-based approach has been employed. Makharia et al[1] in a community-based study, did this screening by a clinical risk-based approach, adopting a three-tier approach of clinical, serological and biopsy screening. However, this study had included large number of adult populations. Till date there is no study done exclusively in Indian children by using risk-based approach. In our study we have included children in age group of 1 year to 16 years of age by using risk-based questionnaire with three tier approach (clinical risk features, positive Anti-tTgA followed by duodenal biopsy). In our study we observed that the occurrence of celiac disease on the basis of ESPGHAN[12] Criteria is 1.8% (9 in 500) in the studied population. Additionally, 5 children had serology positive (in the presence of suggestive clinical feature) but had normal intestinal biopsy so may be said to be having latent celiac disease. Thus, overall occurrence of celiac disease (manifest and latent) was 2.8% (14 in 500) in this clinical risk-based approach. Finding in our study was compared with study conducted by Makharia et al[1] who had included both adults and children in his study. In their study clinical features (risk factors) were different in adults and children. In adult's chronic diarrhea or pallor were included as criteria for screening of celiac disease and failure to thrive or short stature were included in children. In their study, prevalence of celiac disease among risk group was 1.49% and overall prevalence was 1.04%. In present study occurrence among risk group was 8% and overall occurrence was 1.8%. Occurrence of celiac disease among risk group was very high compared to previous study and probable cause for this was the fact that present study was hospital based, which can reflect the effect of selection of patients since this segment of population can seek medical services due to co-morbidities associated with Celiac Disease. Hence chances of getting risk factors for celiac disease was also more compared to general population.

Other cause for this can be inclusion of a greater number of adults in Makharia et al[1] study (as the prevalence of celiac disease among adults was 0.85 % which is much less compared to children 1.41 %) so inclusion of adults decreased overall prevalence in their study. Higher occurrence of celiac disease in our study was because of age group differences 1 year to 16 years than study by Makharia et al[1] who had included children of age group between 5 – 17 years. In our study maximum number of children who had celiac disease were in age group of less than 5 years (66.6%) which age group was not included in study by Makharia et al.[1] Subjects with multiple risk factors (≥ 2 risk factors) in our study were diagnosed more as celiac disease, which were not included in study done by Makharia et al. We had screened all children who had attended our hospital during study period but investigation was sent only for those children who had one or more than one risk factor, which is more cost effective than studies done in general population without risk-based screening. Celiac disease has strong familial association among first degree relatives as in our study 2 children had family history of celiac disease along with other clinical feature, which were screened and came out to be positive for celiac disease.

In our study incidence of serological and biopsy proven celiac disease was more in patients who had ≥ 2 clinical features compared to single feature. If combination of clinical features (signs or symptoms) related to celiac disease are present, we should have strong suspicion of celiac disease and should screen accordingly.

CONCLUSION

The prevalence of celiac disease is very high (more than 1 %) in general population and has associated subclinical morbidities so it should always be suspected and screened for. Children who are attending hospital (OPD/IPD), should be screened for clinical features related to celiac disease, so we can pick up the cases before significant complications occur. Anti-tTgA is very sensitive and simple screening method to detect celiac disease, so this test should be better utilized for screening. Positive Anti-tTgA should be confirmed by small intestinal biopsy to confirm celiac disease. Screening children on the basis of clinical risk-based features is better than community-based screening, because it avoids screening of large population, is less time consuming, has better yield and is more cost effective. Multiple clinical risk factors are more in favour of celiac disease as compared to single risk factor as demonstrated by our study.

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