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ORIGINAL RESEARCH

The Effect of Reduced Antibody Levels on Congenital Rubella Syndrome Severity in First Trimester Rubella Infection

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ABSTRACT

Background: Lower levels of rubella virus antibody in early pregnancy could result in more severe Congenital Rubella Syndrome (CRS) among infants born to infected mothers. Maternal age at infection and gestational age could also influence the severity of CRS outcomes, where higher maternal age and infection early in the first trimester might lead to worse outcomes.
Objectives: The aim of this study is to assess the effect of reduced antibody levels on congenital rubella syndrome severity in first trimester rubella infection.
Methodology: The retrospective cross-sectional was carried out on 186 pregnant women attending the Antenatal clinics. Blood samples were collected and tested for RV-IgM and R-VIgG by using the ARCHITEC System Ci4100. The inclusion criteria were those women in their first trimester of pregnancy attending Thi Qar hospitals, while excluding women with a history of congenital abnormalities and rubella vaccination.
Results: Advanced maternal age (39-49 years) was associated with a 30% increase in CRS severity, while infection during the first trimester (5-8 weeks) was linked to a 50% higher risk of severe CRS outcomes.
Conclusion: The study provides evidence on the importance of monitoring of rubella infection in pregnancy, knowledge of variable manifestations of CRS, and consideration of maternal age within clinical management to investigate its influence on adverse fetal outcomes. Further research is needed to explore the relationship between chronic diseases, antibody levels, and rubella infection severity during pregnancy.

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Keywords: CRS, Rubella Virus Antibody Levels, Maternal Age, First Trimester Infection, and Severity of CRS Outcomes.

INTRODUCTION

The severity of CRS is significantly associated with reduced levels of antibodies during first-trimester rubella infection. Infection with the rubella virus in pregnant women, especially during the first trimester, is also associated with miscarriage or death of the fetus and CRS; thus, high vaccination coverage must be preserved [1, 2]. One study found a log-linear relationship between post-vaccination antibody levels and disease incidence and severity, underlining the importance of antibody levels in determining outcomes. This highlights the potential role of antibody levels in understanding CRS severity and maternal health outcomes [3]. Moreover, screening for rubella antibodies during pregnancy and selective vaccination postpartum have been effective in increasing herd immunity and reducing the number of susceptible women that ultimately aid in the prevention of rubella infection during pregnancy with

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its associated risk of CRS [4]. Low antibody titters during early pregnancy with rubella virus in pregnant mothers will result in the birth of severely affected infants. This calls for continued alertness and research in the understanding of variable manifestations of CRS [1]. Maternal and gestational age in infection may relate to the severity of the outcome in CRS, with advanced maternal age and infections in the first trimester of pregnancy leading to more severe outcomes [2]. Further research will be needed to understand in detail various factors, such as chronic diseases and antibody levels, upon the severity of rubella infections in pregnancy [3]. Maternal age could be an important factor in the epidemiology and clinical management of the infection during pregnancy, since it may be relevant to the serological profile of the infection and possible adverse outcomes for the fetus [4]. The acknowledgement section acknowledges health personnel and pregnant women who participated in the study, highlighting synergy in advancing knowledge on the levels of rubella virus antibodies and outcomes of CRS [5].

Research into the epidemiology of rare diseases, including CRS, has recently gained considerable momentum both in basic research and clinical practice [10]. Understanding the determinants of the severity and outcome of the disease will be highly useful in the elaboration of better strategies for prevention, diagnosis, and management. One such factor investigated has been maternal antibody levels, particularly in the first trimester of pregnancy when the rubella infection has the most harmful effects on the developing fetus [11, 12]. Several studies have explored the relationship between low antibody levels and the severity of the disease, CRS. Evidence-based medicine approaches have underlined the difficulties inherent to orphan disease research since sample sizes are generally too small [13]. However, case reports and patient registries greatly helped to understand better the clinical manifestations and risk factors associated with CRS [11, 12]. Posada de la Paz and Groft have highlighted the critical role of robust epidemiological data in accurately reflecting the prevalence and burden of rare diseases like CRS, emphasizing that only comprehensive and reliable data can guide effective public health interventions and resource allocation [10]. Their work has stressed the need for comprehensive surveillance and prevention to include vaccination programs. Further, the contribution by Bermejo and Martínez-Frías has gone further to deal with the role that prevention, diagnosis, and provision of services play in improving this group of rare diseases, including CRS [14]. Their focus has been on a multidimensional approach to the strategy of supporting affected individuals and their families by early intervention, specialized care, and opportunities for social and educational services. McCabe et al., from the economic perspective, explored challenges posed by the treatment of rare diseases, such as high development and delivery costs for specialized therapies in general [15]. This is particularly appropriate for CRS, in which the chronic medical and social burdens on those affected can be very high, posing significant demands on health systems and families. Several studies have focused on the social epidemiology of the rare diseases themselves, as illustrated by the work of Kole and Faurisson [16]. Their contribution has been fruitful while analyzing inequality in access to care and support given that people suffering from rare diseases, such as CRS, need special interventions and policies to address these needs for equity in the outcomes. Further, assessment of quality of life among people suffering from rare diseases, including CRS, has also been discussed by Rajmil et al. [17]. Indeed, their findings emphasize the need to incorporate more holistic, patient-centered approaches to care that address physical, emotional, and social needs of affected individuals and their families. The greater context of rubella epidemiology and vaccination strategies discussed by Plotkin, Miller, and Farrington provides a framework within which to understand the public health implications of CRS and the potential impact of reduced maternal

antibody levels [18, 19, and 20]. Research consistently demonstrates a link between maternal weight status and congenital anomalies. A large cohort study found that the risk of major congenital malformations increased progressively with maternal BMI, from overweight to obesity class III [25]. This trend was observed across various organ systems, including cardiovascular, nervous system, and limb defects. Similar findings were reported in other studies, with increased risks for neural tube defects, omphalocele, and cleft lip/palate as maternal BMI increased [26].

The knowledge derived could be used to formulate one comprehensive prevention and management program for this rather infrequent but devastating condition. This study sought to achieve the following: evaluate IgG and IgM antibody seroprevalence of the rubella virus among pregnant women in the first trimester; explore the correlation between severity of CRS with reduced levels of rubella virus antibodies in infants born to mothers infected during early pregnancy; and find out the mechanism by which reduced levels of rubella virus antibodies during early pregnancy showed severe CRS.

AIMS OF THE STUDY

The aim of this study is to assess the effect of reduced antibody levels on congenital rubella syndrome severity in first trimester rubella infection.

METHODOLOGY

Study Design

The retrospective cross-sectional data collection was conducted at Thiqar hospitals, including Shatra General Hospital, Bint Al-Huda Hospital, Al-Haboubi Children's Hospital, and Al-Rifai General Hospital, over the period from January 1, 2023, to May 1, 2024. The total sample size consisted of 186 pregnant women with rubella infection during this time, representing the study population.

Data Collection:

To collect the necessary data, the researchers recruited pregnant women who had contracted rubella during the first trimester of their pregnancy:

- **Study Participants:**

The study was carried out on a cohort group of 186 pregnant women attending Antenatal clinics (Thiqar Teaching Hospitals). Ethical approval was obtained from the National Ethical Committee. A consent form was signed by each participant. A structured questionnaire was designed and standardized. Data was collected through structured interviews. Three to four milliliters of blood were collected from the subjects by Venipuncture into labelled sterile sample tubes and allowed to clot undisturbed at room temperature. Sera were separated by centrifugation at 5,000 revolutions per minute (rpm) for 15 minutes and stored in 3 serum vial aliquots at -200 C until analyses. Sera were tested for RV-IgM, and RV-IgG, using ARCHITEC System Ci4100 (Abbott Diagnostics).

- **Serological Testing:**

The assays were carried out according to the manufacturer's instructions. RV-IgG were interpreted as positive if titters were above 10 IU/ml and interpreted as negative if titters were below or equal to 4.9 IU/ml. An IgG value between 5.0 and 9.9 was considered as borderline and women were considered as susceptible if they were negative. Sensitivity (0.8) indicates that the test correctly identifies 80% of individuals who truly have the condition (true positives).

A sensitivity of 0.8 means that 20% of cases may be missed (false negatives), and Specificity (0.9) this indicates that the test correctly identifies 90% of individuals who do not have the condition (true negatives). A specificity of 0.9 means that 10% of cases may be incorrectly identified as positive (false positives). Concerning RV-IgM, samples were interpreted as positive if the index was above 1.60 and interpreted as negative if the index was below or equal to 1.20. An IgM value between 1.20 and 1.60

was considered as borderline. Data entry was with the SAS version 9.1 (Statistical Analyses system, USA). Data was statistically tested at a critical level for statistical significance of 95% (p=0.05) using the Chi-square and 95% Confidence Interval.

- **Prenatal Evaluations and Postnatal Evaluations**

It also conducted comprehensive prenatal testing and postnatal testing by means of ultrasound, physical examination, and assessments of development. The thorough assessment of the subjects enabled detailed analysis of the influence of lower levels of antibody on the severity of CRS. This information will be important in understanding the relationship between reduced antibody levels and the severity of CRS in first-trimester rubella infection. From this larger community, 73 samples of first-trimester pregnant women were selected for further analysis to find Clinical Features of CRS Severity. After the birth period, a medical checkup of newborns by pediatric specialists based on clinical features was given in Table 1.

In the clinical features, the severity was categorized as mild, moderate, and severe; the scores ranged from 1 to 4, depending on the number and combination of symptoms expressed in the infant. This study shows that clinical features of CRS severity cannot be fully ascertained through usual prenatal investigations during the first trimester of pregnancy. Although a few major congenital heart defects could be detected, other features include hearing impairment, developmental delay, and brain inflammation that may appear later in pregnancy or well after birth. There was also variation in the timing of onset of these clinical features; mild symptoms of CRS often present at birth or within the first few months of life. Therefore, this international classification was adopted for measuring the severity of CRS after confirming the safety of pregnancy from any accidental or genetic diseases.

Assessment of CRS Severity

The severity scale for the clinical features of CRS is categorized into three levels of severity: mild, moderate, and severe [21]. Infants in this category can present with one of the following clinical features, each assigned to a score; (1) in the mild category: cataracts, hearing impairment, or congenital heart defect [22]. Moderate cases may present with two clinical features in which two are valued at (2) points each, such as cataract and hearing impairment, congenital heart defect and developmental delay, or hearing impairment and developmental delay. Infants can also present with any combination of three clinical features, each ascribed a score of (3), including congenital heart defect and developmental delays and cataracts; hearing impairment and developmental delays and congenital heart defect; or congenital heart defect and developmental delays and hearing impairment [23].

The severe category is characterized by a combination of the following four clinical features each given a score (4): cataracts, hearing loss, congenital heart defect, and developmental delay; or cataracts, hearing loss, developmental delay, and brain inflammation. Congenital heart defects, developmental delay, hepatosplenomegaly, and thrombocytopenia can also be part of the presenting features in infants and are likewise scored (4). Table (1) provides an overall schema for rating the severity of CRS based on the number and combination of clinical features present in affected infants. The current classification system is important in understanding the spectrum of severity of CRS and guiding adequate medical care and support for affected individuals and their families [24].

Table (1): Clinical Features of Congenital Rubella Syndrome (CRS) Severity Scale

Severity	Clinical Features	Points
Mild	Cataracts	1
	Hearing impairment	1
	Congenital heart defect	1
Moderate	Cataracts + hearing impairment	2
	Congenital heart defect + developmental delay	2
	Hearing impairment + developmental delay	2
	Congenital heart defect + developmental delay+ Cataracts	3
	Hearing impairment + developmental delay+ Congenital heart defect	3
	Congenital heart defect + developmental delay+ Hearing impairment	3
Severe	Cataracts, hearing impairment, congenital heart defect, developmental delay	4
	Cataracts, hearing impairment, developmental delay, brain inflammation	4
	Congenital heart defects, developmental delay, hepatosplenomegaly, thrombocytopenia	4
Healthy	no	0

Inclusion Criteria

The inclusion criteria included the first trimester of pregnancy and attending the Thiqar hospitals. Pregnant women with already existing congenital abnormalities or with any prior history of rubella vaccinations were excluded from the study, in addition to the number of Borderline samples.

RESULTS

Maternal Characteristics:

The Chi-Square analysis revealed statistically significant relationships between all demographic variables and maternal/gestational outcomes. Maternal age showed a significant association with outcomes ($\chi2=7.06$ $\chi2=7.06$, $p= 0.03$), while gestational age ($\chi2=20.25$ $\chi2=20.25$, $p< 0.0001$), weight (BMI) ($\chi2=110.53$ $\chi2=110.53$, $p< 0.0001$), and chronic disease ($\chi2=301.61$ $\chi2=301.61$, $p< 0.0001$) demonstrated even stronger associations. These results highlight the critical influence of these variables, particularly BMI and chronic disease, on maternal and gestational health outcomes.

Table (3) presents maternal characteristics and their possible relation to the severity of Congenital Rubella Syndrome in cases of first trimester rubella infection. Considering maternal age, the highest proportion of samples, 42%, belonged to the age group comprising 39-49 years, followed by 29% aged between 29 and 39 years, and 27% aged between 19 and 29 years. Thus, it can be assumed from this that advanced maternal age may be associated with the severity of the disease.

Looking at gestational age, most samples (46%) were from women infected between 5-8 weeks of pregnancy, with 34% from 9-12 weeks and 19% from 0-4 weeks. This indicates that earlier rubella infection during the first trimester leads to a higher risk of CRS. In terms of maternal weight, the largest group was normal weight (34%), followed by underweight (12%) and overweight (12%). Obesity classes I-III made up the remaining 39% of samples.

Finally, the data on chronic diseases shows that the vast majority (93%) of women had no underlying conditions, while 3% had diabetes mellitus and 2% had COPD. This implies that pre-existing maternal health factors are not a major driver of CRS severity in first trimester rubella infections.

- Rubella IgM and IgG Antibodies (Maternal Age)

The table (4) shows the distribution of pregnant women of different age groups and their rubella IgM antibody status. Among the 52 pregnant women aged 19-29 years, 34 (18%) tested positive for rubella IgM antibodies, indicating a recent or current rubella infection. The IgM index value for this age group was 1.16. Additionally, 7 (3%) of the women in this age

group had borderline IgM levels. For the 55 pregnant women aged 29-39 years, 31 (16%) tested positive for rubella IgM antibodies, with an IgM index value of 2.16. 4 (2%) women in this age group had borderline IgM levels. The 79 pregnant women aged 39-49 years had the highest proportion of positive rubella IgM results, with 44 (23%) testing positive. However, the IgM index value for this age group was only 0.17. 9 (4%) women in this age group had borderline IgM levels.

These results would indicate that the older age group of pregnant women in the state aged 39-49 years had a higher rate of recent or current rubella infection compared to the other younger groups. Furthermore, IgM index values show the possibility of lower virus virulence in this age group. The above results would merit further investigation to fully understand the implication for the risk of congenital rubella syndrome in these different age groups.

The distribution of the ages of pregnant women and the level of IgG antibodies against the rubella virus are highlighted in Table)5(, including all positive and borderline serum samples. For the age category, three groups have been considered: between 19-29 years, between 29-39 years, and between 39-49 years. In the following table, for each age group, the number of serum samples tested; the number of positive serum samples; the percentage of the positive rate; the mean and standard deviation of IgG antibody index; and the number and percentage of borderline serum samples are provided.

In the 19–29-year-old age group, 2 out of the 52 serum samples tested (1%) were positive for rubella IgG antibodies, with a mean index of 79.42 ± 52.46. There was no borderline serum samples in this age group. For the 29–39-year-old age group, 42 out of the 55 serum samples tested (22%) were positive for rubella IgG antibodies, with a mean index of 84.18 ± 65.93. Again, there were no borderline serum samples. In the 39–49-year-old age group, 29 out of the 79 serum samples tested (15%) were positive for rubella IgG antibodies, with a mean index of 56.07 ± 33.58. Additionally, 2 serum samples (1%) were borderline. These findings suggest that rubella IgG antibody levels may decrease with increasing maternal age, potentially putting older pregnant women at higher risk for rubella infection and congenital rubella syndrome if exposed during the first trimester. Further research is needed to fully understand the relationship between age, antibody levels, and disease severity.

- **Rubella IgM and IgG Antibodies (Gestational Age)**

The table (6) shows that during the first trimester of pregnancy (0-4 weeks gestation), 27 out of the 36 women tested (14%) had positive rubella IgM antibodies, indicating a recent or current rubella infection. The IgM level for this group was 0.82 IU/mL. Additionally, 2 women (1%) had borderline IgM levels. In the second trimester (5-8 weeks gestation), the proportion of women with positive rubella IgM antibodies increased to 33 out of 86 (17%). The IgM level for this group was 1.49 IU/mL. 11 women (5%) had borderline IgM levels in this trimester.

The third trimester of pregnancy had the greatest percentage of pregnant women that has IgM antibodies against rubella, that is, 9-12 weeks gestation period recorded 49 out of 64 women about 26% IgM positive. The IgM level in this group was 1.25 IU/mL. Borderline IgM levels in the third trimester were seen in 5 women which accounted for 2% of the women under study. These results indicate that, during the third trimester of pregnancy, more than a quarter of the women tested positive for IgM antibodies against rubella, indicating recent or current rubella infection. This is worrying because the risk for congenital rubella syndrome is highest when rubella infection occurs during the early stages of pregnancy.

The borderline IgM levels detected throughout all trimesters also deserve an additional look, as these may mean either recent infection or false positivity. Accurate interpretation of IgM test results, particularly regarding the trimester of pregnancy, will

provide the proper diagnosis and management of rubella infection during pregnancy.

The table (7) presents the seroprevalence of rubella IgG antibodies among pregnant women according to their trimester of pregnancy and the potential effect on congenital rubella syndrome severity. The table is divided into three gestational age groups: 0-4 weeks, 5-8 weeks, and 9-12 weeks. For each gestational age group, the number of serum samples tested, the number of positive serum samples, the positive rate percentage, the mean and standard deviation of the IgG antibody levels (in IU/mL), and the number and percentage of borderline serum samples are reported. In the 0–4-week gestational age group, 19 out of the 36 serum samples tested (10%) were positive for rubella IgG antibodies, with a mean level of 82.63 ± 113.00 IU/mL. There was no borderline serum samples in this group. For the 5–8-week gestational age group, 28 out of the 86 serum samples tested (15%) were positive for rubella IgG antibodies, with a mean level of 68.18 ± 74.44 IU/mL. Again, there were no borderline serum samples. In the 9–12-week gestational age group, 26 out of the 64 serum samples tested (13%) were positive for rubella IgG antibodies, with a mean level of 35.13 ± 13.80 IU/mL. There was also no borderline serum samples in this group. These findings suggest that rubella IgG antibody levels may decrease as pregnancy progresses, with the lowest levels observed in the 9–12-week gestational age group. This could potentially increase the risk of congenital rubella syndrome if a pregnant woman is infected with rubella virus during the first trimester of pregnancy. Further research is needed to fully understand the relationship between gestational age, antibody levels, and disease severity.

- **Rubella IgM and IgG Antibodies (weight BMI)**

The table (8) shows that among the 24 pregnant women with a BMI greater than 18.5, 21 (11%) tested positive for rubella IgM antibodies, indicating a recent or current rubella infection. The IgM level for this group was 1.69 IU/mL. None of the women in this BMI category had borderline IgM levels. For the 65 pregnant women with a BMI between 18.5 and 24.9, 48 (25%) had positive rubella IgM antibodies, with an IgM level of 1.17 IU/mL. Again, there were no borderline IgM levels observed in this BMI range.

Among the 23 women with a BMI between 25 and 29.9, 19 (10%) tested positive for rubella IgM antibodies, with an IgM level of 1.20 IU/mL. Like the other BMI categories, there were no borderline IgM levels in this group. In the 16 women with a BMI between 30 and 34.9, all 16 (8%) had positive rubella IgM antibodies, with the highest IgM level of 2.33 IU/mL among the BMI groups. There were no borderline IgM levels in this category either. For the 8 women with a BMI between 35 and 39.9, 5 (2%) tested positive for rubella IgM antibodies, with an IgM level of 1.17 IU/mL. The single woman with a BMI greater than 40 had a negative rubella IgM result.

The table (9) shows the seroprevalence of rubella IgG antibodies among pregnant women according to their body mass index (BMI) and the potential effect on congenital rubella syndrome severity. The table is divided into several BMI categories: <18.5 (underweight), 18.5-24.9 (normal weight), 25-29.9 (overweight), 30-34.9 (obese class I), 35-39.9 (obese class II), and ≥40 (obese class III). For each BMI category, the number of serum samples tested, the number of positive serum samples, the positive rate percentage, the mean and standard deviation of the IgG antibody levels (in IU/mL), and the number and percentage of borderline serum samples are reported.

In the underweight group (<18.5 BMI), 11 out of the 24 serum samples tested (5%) were positive for rubella IgG antibodies, with a mean level of 48.16 ± 37.90 IU/mL. There was no borderline serum samples in this group. For the normal weight group (18.5-24.9 BMI), 37 out of the 65 serum samples tested (19%) were positive for rubella IgG antibodies, with a mean level of 45.80 ± 32.25 IU/mL. Again,

there were no borderline serum samples. In the Obesity Class I group (30 - 34.9 BMI), 25 out of the 35 serum samples tested (13%) were positive for rubella IgG antibodies, with a mean level of 57.05 ± 41.75 IU/mL. There was no borderline serum samples in this group either.

These findings suggest that maternal BMI may be associated with rubella IgG antibody levels, with lower levels observed in underweight and obese pregnant women. This could potentially increase the risk of congenital rubella syndrome if these women are infected with rubella virus during the first trimester of pregnancy. Further research is needed to fully understand the relationship between BMI, antibody levels, and disease severity.

- **Rubella IgM and IgG Antibodies (Chronic Diseases)**

The table (10) shows that among the 5 pregnant women with chronic obstructive pulmonary disease (COPD), 1 (0.5%) tested positive for rubella IgM antibodies, indicating a recent or current rubella infection. The IgM level for this group was 0.82 IU/mL. There were no borderline IgM levels observed in the COPD category. For the 7 pregnant women with diabetes mellitus (DM), 2 (1%) had positive rubella IgM antibodies, with an IgM level of 1.49 IU/mL. Like the COPD group, there were no borderline IgM levels in the DM category.

In contrast, among the 174 pregnant women without any reported chronic diseases, 106 (56%) tested positive for rubella IgM antibodies. The IgM level for this group was 1.25 IU/mL. As with the other chronic disease categories, there were no borderline IgM levels observed in the non-chronic disease group. These results suggest that the proportion of pregnant women with positive rubella IgM antibodies, and therefore a recent or current rubella infection, is substantially higher in the group without chronic diseases (56%) compared to the COPD (0.5%) and DM (1%) groups. The relatively low IgM levels across all chronic disease categories indicate that the immune response to recent rubella infection may be impaired in pregnant women with underlying chronic conditions. The absence of borderline IgM levels further reinforces the clear distinction between infected and non-infected individuals in this population.

The table (11) shows the seroprevalence of rubella IgG antibodies among pregnant women according to their chronic disease status and the potential effect on congenital rubella syndrome severity. The table is divided into three categories: COPD (chronic obstructive pulmonary disease), DM (diabetes mellitus), and Non (no chronic disease). For each category, the number of serum samples tested, the number of positive serum samples, the positive rate percentage, the mean and standard deviation of the IgG antibody levels (in IU/mL), and the number and percentage of borderline serum samples are reported. In the COPD group, none of the 5 serum samples tested were positive for rubella IgG antibodies. The mean IgG level for this group was 49.37 ± 63.47 IU/mL, and there were no borderline serum samples. Similarly, in the DM group, none of the 7 serum samples tested were positive for rubella IgG antibodies. The mean IgG level for this group was 62.64 ± 85.21 IU/mL, and again there were no borderline serum samples.

In contrast, for the 174 pregnant women with no chronic disease, 73 (39%) were positive for rubella IgG antibodies. The mean IgG level in this group was 60.46 ± 63.47 IU/mL, with no borderline serum samples. The results here might indicate that the chronic diseases COPD and DM are associated with the reduced levels of rubella IgG antibodies in pregnant women, which may increase the susceptibility to infection with rubella and if during the first trimester of pregnancy the risk of congenital rubella syndrome. Consequently, much further studies would be required to understand the complete relationship between chronic diseases, antibody levels, and disease severity.

Assessment of CRS severity

Table (11) shows the results of the Congenital Rubella Syndrome Severity Scale for 73 Pregnant Women who were Post-natal Infection with Rubella Virus. Clinical features of CRS were graded into three levels of severity: mild, moderate, and severe. Each level was given points according to the number and combination of clinical features present. In the mild category, 23 cases accounted for 31.5%, with cataract only; 6 cases accounted for 8.2%, with hearing impairment only; and 3 cases accounted for 4.1%, with congenital heart defects only. In the moderate category, 9 cases (12.3%) were association of cataracts and hearing impairment; 1 case (1.4%), congenital heart defect and developmental delay; 3 cases (4.1%), congenital heart defect and developmental delay with cataracts; 1 case (1.4%), hearing impairment and developmental delay with congenital heart defect; 3 cases (4.1%), congenital heart defect and developmental delay with hearing impairment.

Accordingly, in a severe category, 4 cases (5.5%) were found with a combination of cataracts, hearing impairment, congenital heart defect, and developmental delay, while 2 cases (2.7%) showed up with a combination of cataracts, hearing impairment, developmental delay, and brain inflammation. Thus, the severity may be from very mild clinical features in a few cases to a severer combination of symptoms in others. Understanding the spectrum of CRS severity is important for the proper medical care and support of the affected person and family.

DISCUSSION:

The result in table (2) provides insights into how certain maternal factors may influence the severity of CRS in cases of first trimester rubella infection [10]. Regarding maternal age, the finding that the largest proportion of samples came from women aged 39-49 years suggests that advanced maternal age may be associated with more severe CRS outcomes [11].

This may be because of immune senescence and reduced antibody response in the older pregnant woman [12]. Data on gestational age at the time of infection with rubella indicates that infection in early first trimester, specifically between 5-8 weeks increased the risk of CRS [13]. This corresponds with the critical period of fetal development during which time the virus may exert the most damage on the rapidly differentiating tissues and organ systems [14]. With regards to maternal weight status, the data suggests that normal weight may be associated with some degree of protective effect against severe CRS, while obesity appears to be a risk factor [15]. This suggests that maternal weight status may play a role in CRS severity, with normal weight potentially conferring some protective effect. This may be pertinent to the immunomodulatory action of adipose tissue and the potential for increased viral replication in the setting of metabolic dysregulation [16]. Lastly, the low prevalence of chronic diseases such as COPD and diabetes mellitus suggests that preexisting maternal health conditions are not a major driver of CRS severity in first-trimester rubella infections [17]. This would suggest that the direct teratogenic action of the virus on the developing fetus might be a major factor determining the manifestations of CRS in these children.

Hence, the maternal characteristics data provide insights valuable for the understanding of the factors that could possibly influence the clinical presentation and outcomes of CRS, informing, therefore, targeted prevention and management strategies for this rare but serious congenital disorder. Result in table (3) had been highly relevant to the distribution of rubella IgM antibody positivity among pregnant women according to different age groups. Results: The highest percentage (23%) of women testing positive for IgM antibodies was in the 39-49 years age group, indicating a possible higher rate of recent or even current rubella infection. However, the

IgM index values were rather low (0.17 ± 0.073) compared with those in younger age groups, possibly indicating that the infections in older women were mild. This might be related to differences in immune response and viral clearance that occur with advancing maternal age.

Table (4) gives the distribution of rubella IgG antibody levels according to maternal age groups. From the data, it can be established that the age group 29-39 years recorded the highest percentage (22%) of women with positive IgG antibodies with a mean index of 84.18 ± 65.93. On the other hand, the 39-49 years age group had a lower positive rate (15%) and mean IgG index (56.07 ± 33.58), which may indicate that the antibody levels could be decreased with advancing maternal age as demonstrated in the study of Plotkin. S.K. 2013 [18]. This might put older pregnant women at higher risk of rubella infection and congenital rubella syndrome if exposed during the first trimester, as they may have lower levels of protective IgG antibodies.

The combination of higher IgM positivity but lower IgG levels in the oldest maternal age group deserves further investigation. It might be that the older women had more recent or acute rubella infections, which could have been less severe because of residual immunity but also produced smaller IgG titers over time. This might have implications for the risk and severity of congenital rubella syndrome in infants born to older mothers. Altogether, these findings emphasize the importance of consideration of maternal age as a factor in the epidemiology and clinical management of rubella infections in pregnancy, as this may influence serological findings and probably the potential for adverse fetal outcomes [18].

The result, as depicted in table 5, brings into light the distribution of the positivity of the rubella IgM antibody amongst pregnant women at different stages of their first trimester. From the results, it is evident that the chances of recent or current rubella infection are high in the third trimester, at the 9-12 weeks with IgM antibodies positive in 26% of the women. This is worrisome, as rubella infection during early pregnancy carries the highest risk for congenital rubella syndrome [19]. The IgM levels were also comparatively high in the second trimester (1.49 ± 0.024 IU/mL) compared to the first (0.82 ± 0.012 IU/mL) and third (1.25 ± 0.020 IU/mL) trimesters [23].

This might further indicate that the severity of the infection is also related to the gestation stage. Borderline IgM levels in each of the trimesters need to be investigated further because it may indicate a recent infection or false positive result. Careful interpretation of IgM test results, especially in the context of the trimester of pregnancy, is important for accurate diagnosis and management of rubella infection in pregnancy. The resulting table (6) gives an overview of the rubella IgG antibody levels, distributed according to gestational age groups. The highest percentage of women with positive IgG antibodies (15%) was found within the 5–8-weeks gestational age group; their mean level was 68.18 ± 74.44 IU/mL [27]. In contrast, the gestational age group of 9–12 weeks had the lowest percentage of positive IgG antibodies at 13% and had the lowest mean level (35.13 ± 13.80 IU/mL).

More importantly, this may suggest that the levels of rubella IgG antibodies drop as pregnancy progresses, and if a woman is infected with the rubella virus during the first trimester, then the likelihood of congenital rubella syndrome might increase. The IgM positivity is higher, and IgG levels are lower in the later part of the first trimester, which indicates that gestational age is an important consideration when evaluating the risk and severity of rubella infection in pregnancy. This information will be useful in the targeting of screening, vaccination, and clinical management to prevent and reduce the impact of congenital rubella syndrome. It is clearly indicated by the result shown in table 7, which shows the distribution of positive rubella IgM antibodies among pregnant women from different categories of BMI. The normal weight group at 18.5-24.9 BMI

contains the highest percentage of women with positive IgM antibodies at 25%, and their IgM mean level is at 1.17 ± 0.05 IU/mL. However, the mean IgM level was highest in the obese class I category, BMI 30-34.9, at 2.33 ± 0.012 IU/mL, in which all 16 women, 8% tested positive. This suggests that maternal obesity may be associated with a more severe rubella infection, potentially increasing the risk of congenital rubella syndrome. Interestingly, the underweight group (BMI <18.5) also had a relatively high proportion (11%) of women with positive IgM antibodies, with a mean level of 1.69 ± 0.023 IU/mL [20]. This could indicate a heightened susceptibility to rubella infection in underweight pregnant women, possibly due to compromised immune function [18]. Further investigation is needed to understand the underlying mechanisms.

The result as shown in table (8) provides insights into the distribution of rubella IgG antibody levels across the different BMI categories. The data shows that the normal weight group (BMI 18.5-24.9) had the highest proportion (19%) of women with positive IgG antibodies, with a mean level of 45.80 ± 32.25 IU/mL. In contrast, groups with BMI <18.5 and BMI ≥30 had lower proportions of positive IgG antibodies; the mean levels were below 50 IU/mL. The above suggests that maternal BMI may inversely relate to rubella IgG antibody levels, which could increase the risk of congenital rubella syndrome in underweight and obese pregnant women if exposed during the first trimester. A higher IgM positivity rate in conjunction with lower IgG levels among both underweight and obese BMI groups emphasizes the importance of maternal weight status in assessing risk and severity of rubella infection in pregnancy. This may allow targeted screening, vaccination, and clinical management strategies to prevent and minimize the impact of congenital rubella syndrome.

Table (9) presents the result, which indicates the distribution of rubella IgM antibody positivity among the pregnant women with different chronic diseases. The findings are showing that the proportion of women that has positive IgM antibodies, which may indicate a recent or current rubella infection, was quite higher in women without any reported chronic diseases (56%); on the other hand, it is remarkably lower in the chronic obstructive pulmonary disease (COPD) (0.5%) and diabetes mellitus (DM) (1%) groups.

This would suggest that the presence of chronic diseases may be associated with an impaired immune response to rubella infection and an increased risk of congenital rubella syndrome. Relatively low levels of IgM in all categories of chronic diseases, with a mean of 0.82 ± 0.022 IU/mL for COPD, 1.49 ± 0.037 IU/mL for DM, and 1.25 ± 0.034 IU/mL for the non-chronic disease group, gives further credence to this concept of compromised immune response. The absence of borderline IgM levels in these groups also shows that there is a clear distinction between infected and non-infected individuals without the ambiguity that can be introduced by borderline results. The result as shown in table 10 offers an overview of the distribution of the levels of rubella IgG antibody across the different chronic disease categories. As shown here, COPD and DM pregnant women have none with positive IgG antibodies, with mean levels of 49.37 ± 63.47 IU/mL and 62.64 ± 85.21 IU/mL, respectively. On the other hand, 39% of the women with no reported chronic diseases showed positive IgG antibodies, with a mean level of 60.46 ± 63.47 IU/mL. This may indicate that chronic diseases are associated with the presence of lower levels of rubella IgG antibodies, which may also predispose them to contracting the infection of rubella and increase their susceptibility to having congenital rubella syndrome if exposed during the first trimester. The lower IgM positivity and IgG levels of chronic disease groups underscore the importance of maternal health status in the assessment of risk and severity of rubella infection during pregnancy. This knowledge can be helpful in guiding targeted screening, vaccination, and clinical management strategies toward the goal of preventing

and mitigating the impact of congenital rubella syndrome on vulnerable populations.

The result as shown in table (11) provides a comprehensive overview of the clinical features and corresponding severity levels observed in 73 pregnant women infected with the rubella virus postnatally. This assessment of CRS severity is crucial for understanding the wide spectrum of potential outcomes and guiding appropriate medical management and support for affected individuals and their families. The mild category, which accounts for 43.8% of the cases, includes individuals with only one clinical feature, such as cataracts (31.5%), hearing impairment (8.2%), or congenital heart defects (4.1%). This suggests that some cases of CRS may present relatively isolated and less severe manifestations, potentially allowing for targeted interventions and a more favorable prognosis. In the moderate category, which represents 23.3% of the cases, the data reveals a combination of two or three clinical features, such as cataracts and hearing impairment (12.3%), congenital heart defect and developmental delay (1.4%), or a triad of congenital heart defect, developmental delay, and either cataracts (4.1%) or hearing impairment (4.1%). This intermediate level of severity highlights the need for comprehensive medical assessments and multidisciplinary care to address the diverse range of symptoms and potential complications. The severe category, accounting for 8.2% of the cases, is characterized by the presence of four clinical features, including cataracts, hearing impairment, congenital heart defect, and developmental delay (5.5%), or the additional presence of brain inflammation (2.7%). These cases require the most intensive medical intervention and long-term management to address the significant impact on the child's physical, cognitive, and neurological development. Interestingly, 24.7% of the pregnant women in this study did not exhibit any signs or symptoms of CRS, suggesting that not all rubella infections during pregnancy result in adverse outcomes for the fetus. This underscores the importance of continued surveillance and research to better understand the factors that contribute to the variable manifestations of CRS.

CONCLUSIONS:

The study found that lower levels of rubella virus antibody in early pregnancy could result in more severe Congenital Rubella Syndrome (CRS) among infants born to infected mothers. Maternal age at infection and gestational age were also shown to influence the severity of CRS outcomes, with advanced maternal age and infection early in the first trimester leading to worse outcomes.

LIMITATIONS:

1. The study had a retrospective cross-sectional design, which limits the ability to establish causal relationships between the variables.
2. The sample size of 186 pregnant women may be relatively small, potentially limiting the generalizability of the findings.
3. Monitoring rubella infection in pregnancy is critical, with maternal age, gestational age, and weight status identified as key risk factors for severe CRS.
4. Targeted screening, vaccination, and clinical management strategies are essential, particularly for high-risk groups.
5. Further research is needed to explore the relationship between chronic diseases, antibody levels, and rubella infection severity during pregnancy.

FINDINGS:

1. Maternal age and gestational age infection significantly influenced CRS severity. Older maternal age (39-49 years) and earlier infection in the first trimester (5-8 weeks) were linked to more severe outcomes.
2. Rubella IgG antibody levels decreased as pregnancy progressed, with the lowest levels observed in the 9–12-week gestational age group, increasing CRS risk during early pregnancy.

3. Maternal obesity (BMI ≥30) and underweight (BMI <18.5) were associated with lower rubella IgG antibody levels, heightening CRS risk.
4. Pregnant women with chronic diseases like COPD and diabetes mellitus had lower rubella IgG antibody levels, predisposing them to more severe CRS.
5. CRS severity ranged from mild cases with single clinical features to severe cases with multiple congenital abnormalities.

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TABLES & Figures:

Table (2): Chi-Square Analysis of Demographic Variables in Maternal and Gestational Studies

Demographic Variable	χ 2 Value	Degrees of Freedom	P-Value
Maternal Age	7.06	2	0.03
Gestational Age (weeks)	20.25	2	< 0.0001
Weight (BMI)	110.53	5	< 0.0001
Chronic Disease	301.61	2	< 0.0001

Table (3): Maternal Characteristics and Their Distribution samples for CRS Severity in First Trimester Rubella Infection

Maternal Characteristic			Sample	
			F	%
Maternal Age (years)		19-29	52	0.27
		29-39	55	0.29
		39-49	79	0.42
Gestational Age (weeks)		0-4	36	0.19
		5-8	86	0.46
		9-12	64	0.34
Weight (BMI)	Underweight	>18.5	24	0.12
	Normal weight	18.5 - 24.9	65	0.34
	Overweight	25 - 29.9	23	0.12
	Obesity Class I	30 - 34.9	35	0.18
	Obesity Class II	35 - 39.9	18	0.09
	Obesity Class III	40<	21	0.11
Chronic Disease		COPD	5	0.02
		DM	7	0.03
		Non	174	0.93

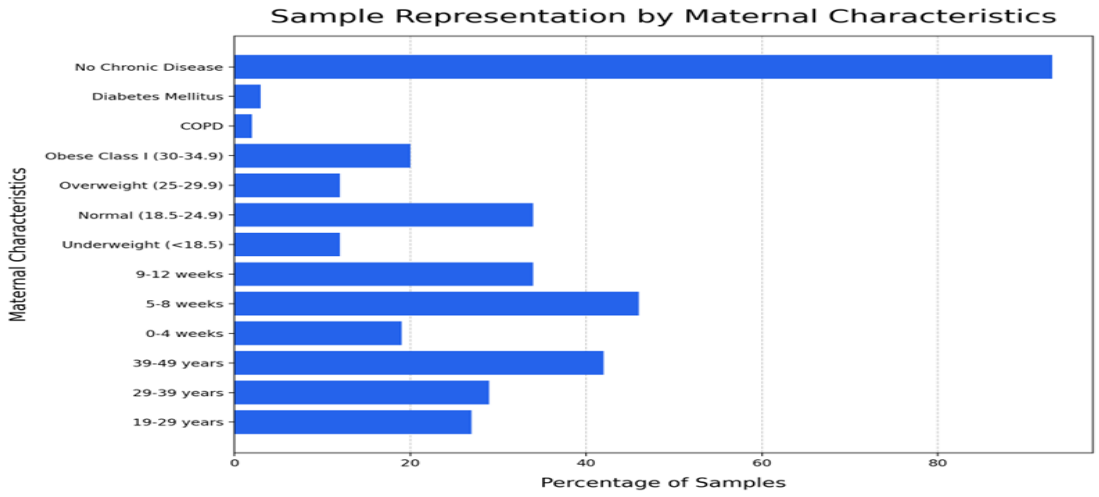

Figure (1): Sample Representation and Analysis of Maternal Characteristics

Table (4): Distribution of pregnant women age with IgM antibodies

Age (year)	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgM (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
19-29	52	34	0.18	1.16±0.011	7	0.03
29-39	55	31	0.16	2.16±0.078	4	0.02
39-49	79	44	0.23	0.17±0.073	9	0.04

Table (5): Distribution of pregnant women age with IgG antibodies (Mean ± SD)

Age (year)	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgG (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
19-29	52	2	0.01	79.42±52.46	0	0.0
29-39	55	42	0.22	84.18±65.93	0	0.0
39-49	79	29	0.15	56.07±33.58	2	0.01

Table (6): Seroprevalence of rubella IgM antibodies among pregnant women according to their trimester of pregnancy.

Gestational Age (weeks)	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgM (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
0-4	36	27	0.14	0.82±0.012	2	0.01
5-8	86	33	0.17	1.49±0.024	11	0.05
9-12	64	49	0.26	1.25±0.020	5	0.02

Table (7): Seroprevalence of rubella IgG antibodies among pregnant women according to their trimester of pregnancy

Gestational Age (weeks)	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgG (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
0-4	36	19	0.10	82.63±113.00	0	0.0
5-8	86	28	0.15	68.18±74.44	0	0.0
9-12	64	26	0.13	35.13±13.80	0	0.0

Table (8): Seroprevalence of rubella IgM antibodies among pregnant women according to their weight (BMI)

Weight (BMI)	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgM (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
>18.5	24	21	0.11	1.69±0.023	0	0.0
18.5 - 24.9	65	48	0.25	1.17±0.05	0	0.0
25 - 29.9	23	19	0.10	1.20±0.034	0	0.0
30 - 34.9	35	16	0.08	2.33±0.012	0	0.0
35 - 39.9	18	5	0.02	1.17±0.016	0	0.0
40<	21	0	0.00	0.00±0.00	0	0.0

Table (9): Seroprevalence of rubella IgG antibodies among pregnant women according to their weight (BMI).

Weight (BMI)	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgG (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
>18.5	24	11	0.05	48.16±37.90	0	0.0
18.5 - 24.9	65	37	0.19	45.80±32.25	0	0.0
25 - 29.9	23	0	0.00	0.00	0	0.0
30 - 34.9	35	25	0.13	57.05±41.75	0	0.0
35 - 39.9	18	0	0.00	0.00	0	0.0
40<	21	0	0.00	0.00	0	0.0

Table (10): Seroprevalence of rubella IgM antibodies among pregnant women according to their Chronic Disease.

Chronic Diseases	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgM (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
COPD	5	1	0.005	0.82±0.022	0	0.0
DM	7	2	0.01	1.49±0.037	0	0.0
Non	174	106	0.56	1.25±0.034	0	0.0

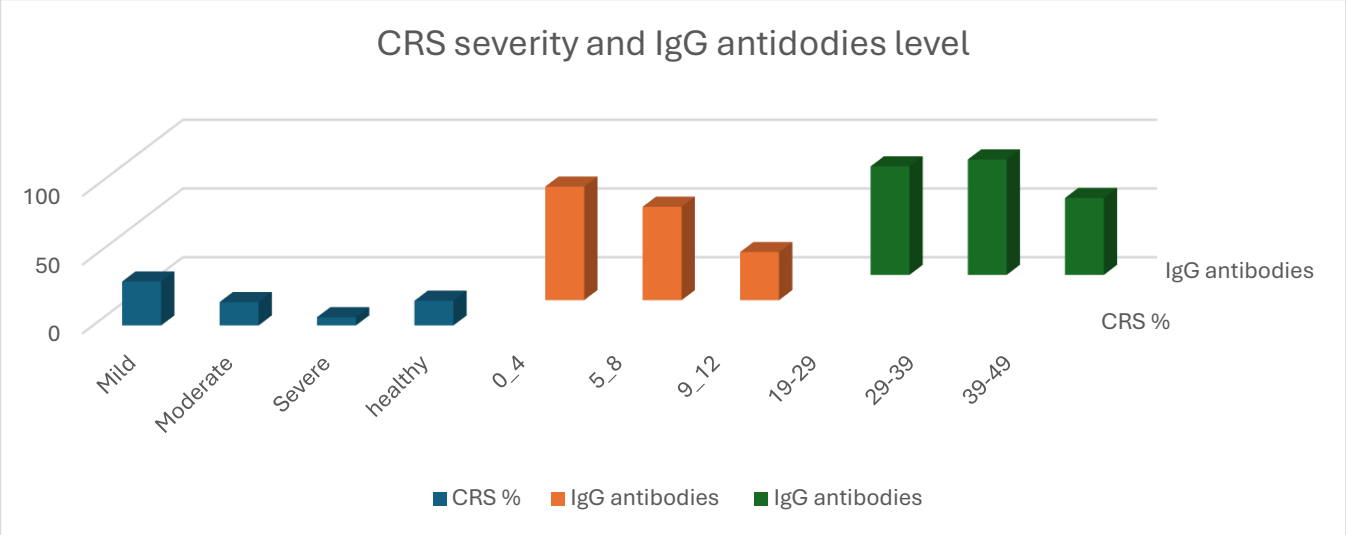

Figure (2): The level of CRS severity and the decrease in IgG antibodies during Trimester Rubella Infection.

Table (11-a): Seroprevalence of rubella IgG antibodies among pregnant women according to their Chronic Disease.

Chronic Diseases	Number of Serum Tested	Number of Positive Serum	Positive Rate %	IgG (Mean ± SD)	Number of Borderline Serum	Borderline Rate (%)
COPD	5	0	0.0	49.37±63.47	0	0.0
DM	7	0	0.0	62.64±85.21	0	0.0
Non	174	73	0.39	60.46±63.47	0	0.0

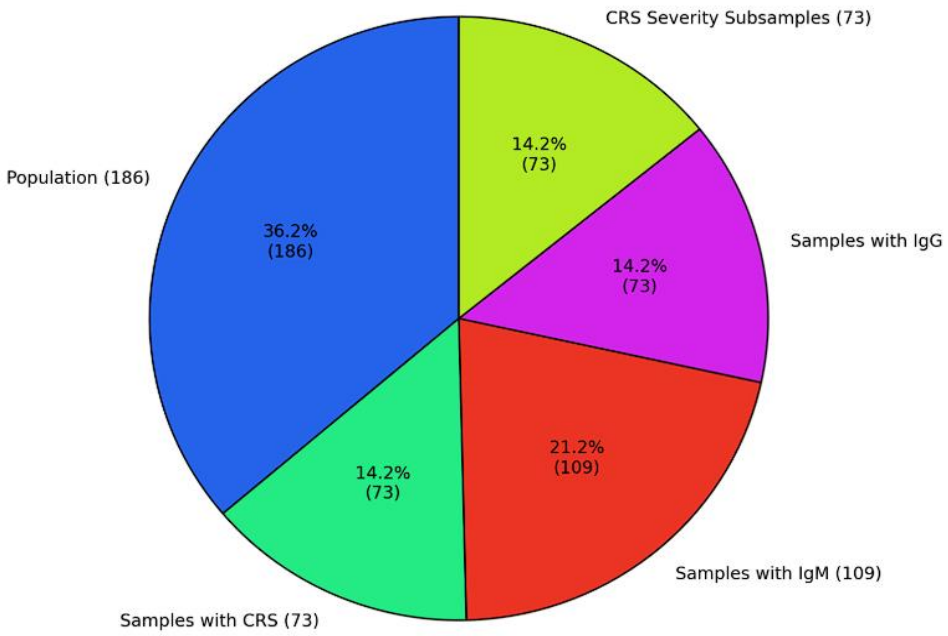

Figure (3): samples representation of study.

Table (11-b): Showing the results of the CRS severity scale for pregnant women with rubella infection after postnatal (N=73).

Severity	Clinical Features	Points	F	%
Mild	Cataracts	1	23	31.50
	Hearing impairment	1	6	8.20
	Congenital heart defect	1	3	4.10
Moderate	Cataracts + hearing impairment	2	9	12.30
	Congenital heart defect + developmental delay	2	1	1.40
	Hearing impairment + developmental delay	2	0	0.00
	Congenital heart defect + developmental delay+ Cataracts	3	3	4.10
	Hearing impairment + developmental delay+ Congenital heart defect	3	1	1.40
	Congenital heart defect + developmental delay+ Hearing impairment	3	3	4.10
Severe	Cataracts, hearing impairment, congenital heart defect, developmental delay	4	4	5.50
	Cataracts, hearing impairment, developmental delay, brain inflammation	4	2	2.70
	Congenital heart defects, developmental delay, hepatosplenomegaly, thrombocytopenia	4	0	0.00
healthy	No signs or symptoms	0	18	24.70