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Research Article

The Use of Total Serum Immunoglobulin M in the Diagnosis of Congenital Infection: A Literature Review and Retrospective Cohort Study

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Abstract

Diagnosing congenital infections (CIs) poses challenges due to diverse clinical presentations. Total serum immunoglobulin M (IgM) has been used as a screening tool for CIs, but its efficacy remains uncertain. In this single-center retrospective cohort study conducted between April 2018 and April 2022 at a level III Neonatal Intensive Care Unit (NICU), we aimed to review the literature on and assess the utility of total serum IgM in diagnosing CIs in newborns. Among 53 infants with total serum IgM measurements, only one value was modestly elevated. Further testing for congenital pathogens was negative. The most frequently cited reason for obtaining total serum IgM was isolated small for gestational age (SGA) status; however, alternative explanations for SGA status were present in most cases. Considering no CIs were diagnosed in our cohort, and > 98% of total serum IgM values were normal, we conclude screening infants with isolated abnormalities is of low yield. If testing is pursued, targeted testing is recommended over broad screening.

Keywords

Congenital Infection, Immunoglobulin M, Small for Gestational Age (SGA), Neonatology, Thrombocytopenia, Cytomegalovirus (CMV)

1. Introduction

Diagnosing congenital infections (CIs) is challenging. CIs may cause protean clinical manifestations or no symptoms at all in the newborn period [1, 2]. When symptoms are present, they are often non-specific, with significant overlap between different infectious and non-infectious entities [1, 2]. Researchers and clinicians have long sought a biomarker to aid in diagnosing CIs.

In the 1960s, researchers showed elevated total serum immunoglobulin M (IgM) levels in neonates with CIs [3-5]. Subsequently, total serum IgM became a convenient and cost-effective way to screen newborns for CIs. Sixty years later, a survey of neonatal providers on their approach to diagnosing congenital and perinatal infections found that nearly 40% of respondents continue to use total IgG or IgM when seriously considering a CI diagnosis [6]. More recent research has questioned whether total serum IgM is sensitive enough to be an effective screening tool in diagnosing CIs [7-9].

Our Neonatal Intensive Care Unit (NICU) group has used total serum IgM in the workup of CIs. Here, we review the

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literature on total serum IgM as a screening tool for CIs and document our experience with its use over a five-year period to assess its utility in diagnosing CIs.

2. Materials and Methods

This is a single-center retrospective study of infants admitted to a level III NICU between April 2018 and July 2022. The study was approved by both the Louisiana State University Health New Orleans and site-specific Institutional Review Boards.

All infants admitted to the NICU during the study period were eligible for inclusion. The Slicer-Dicer tool, embedded within the electronic medical record (Epic), was used to identify all patients who had at least one total serum IgM measurement obtained during the first week of life during their NICU admission. All other infants were excluded.

Maternal and newborn data were obtained and recorded, including descriptive data on birth weight, growth status, estimated weeks of gestational age, sex, maternal race, mode of delivery, and maternal age. Clinical data were also obtained, including total serum IgM measurements, laboratory values, cranial ultrasounds, other tests to evaluate for infection, and the rationale behind obtaining a total serum IgM level. Deidentified data was recorded and stored in a REDCap database (UL1 TR000445 from NCATS/NIH) hosted at Louisiana State University Health New Orleans [10, 11]. The data obtained was summarized in descriptive terms using basic mathematical functions (means and percentages).

During the study period, no guidelines regarding testing for CIs were in place. Therefore, the decision to pursue a CI work-up was at the discretion of the medical team. Total serum IgM concentrations were obtained from patients directly (no samples were obtained from umbilical cord blood). Total serum IgM concentrations were measured using the Beckman Coulter AU5800 analyzer (Beckman Coulter Life Sciences, Indianapolis, IN, USA). Normal total serum IgM cut-offs were determined by the manufacturer and instrument used. During the study period, the threshold of detection changed three times: < 25 mg/dL (2018-2019), < 21 mg/dL (2019-2021), and < 20 mg/dL (2022). Unless values surpassed the threshold, results were reported as < 25, < 21, or < 20 mg/dL. Small for gestational age (SGA) was defined as a birthweight for gestational age < 10%. Thrombocytopenia was defined as a platelet count < 150,000/μL. Neutropenia was defined as an absolute neutrophil count (ANC) (mature neutrophils plus band neutrophils) < 1,500/μL, and neutrophilia was defined as an ANC > 15,000/μL. Anemia was defined as a hematocrit < 40%. Polycythemia was defined as a hematocrit> 65%.

3. Results

During the study period, 53 patients had at least one total serum IgM level obtained in the first week of life. A single patient had a minimally elevated total serum IgM level of 27 mg/dL (normal < 20 mg/dL) obtained at 120 hours of life. Age at acquisition of total serum IgM levels ranged from 1 to 163 hours of life. Twenty measurements were obtained in the first 24 hours of life (37.7%), and 35 were obtained by 48 hours of life (66%). No patient had a repeat total serum IgM level during NICU admission.

The gestational age of study participants ranged from 27 to 40 weeks, with a mean of 36 weeks. The mean birthweight of the study subjects was 1923 g, with 10 subjects weighing < 1500 g and 43 subjects weighing < 2500 g. Forty of the fifty-three subjects (75.5%) were classified as SGA. Additional neonatal and maternal characteristics are shown in Table 1.

Table 1. *Demographics of total serum IgM group.*

	Total Serum IgM Group[a]
Female	29/53 (55)
African American	34/53 (64)
Gestational age, wks	36 (2.8)
Birth weight, g	1923 (607)
SGA[b]	44/53 (83)
Maternal age, yrs	28.9 (6.5)
Cesarian delivery	34/53 (64)
Median age at sIgM[c], hrs of life	28.2
Elevated sIgM[c]	1/53 (1.9)
CMV testing performed	23/53 (43)
Direct bilirubin > 1 mg/dL	19/47 (40)
First platelet count < 150,000/μL	24/52 (45)
First neutrophil count < 1,500/μL	4/52 (7.7)
First hematocrit < 40%	4/52 (7.7)
First hematocrit > 65%	5/52 (9.4)

[a]n (%); Mean (SD) | [b]*SGA* small for gestational age | [c]*sIgm* total serum IgM

CMV testing was performed on 23 subjects (43.4%, 14 polymerase chain reaction tests, nine viral cultures) within the first three weeks of life. All CMV tests were negative. Five of these patients had additional CI testing performed, including testing for *Toxoplasma gondii*, herpes simplex virus, human immunodeficiency virus (HIV), Zika virus, and rubella virus. All additional CI testing was negative.

Twenty-two of twenty-six subjects (84.6%) had normal cranial ultrasounds (CUS). The other four CUSs showed some degree of intracranial bleeding: two grade one interventricular hemorrhages (IVHs), one grade three IVH, and one subdural

hematoma. No intracranial calcifications were seen.

Hematological abnormalities were common. Of the 52 patients with a CBC in the first week of life, 31 (59.6%) had at least one hematological aberration. Thrombocytopenia was the most common anomaly (45.3%), followed by polycythemia (9.6%), neutropenia (7.7%), and anemia (7.7%). Additionally, 47 patients had at least one direct bilirubin obtained in the first week of life. Of those, 19 (40.4%) had a direct bilirubin ≥ 1.0 mg/dL.

The reasons for obtaining total serum IgM levels varied and are summarized in Table 2. SGA status, direct hyperbilirubinemia, anemia, hydrops, microcephaly, and multiple congenital anomalies were cited as reasons for total serum IgM acquisition. It could not be gleaned from the electronic medical record why total serum IgM levels were obtained in two subjects. Of the 44 SGA infants, 37 (84%) had an alternative explanation for their SGA status, most commonly maternal hypertension. Other alternative explanations for SGA status and their frequencies are shown in Table 3.

Table 2. *Documented reason(s) for obtaining total serum IgM levels.*

Reason	Total Serum IgM Group (n=53)[a,b]
SGA status	41 (77.4)
SGA status alone	32 (60.4)
SGA status + other feature(s)	9 (17)
Direct hyperbilirubinemia	11 (20.8)
Direct hyperbilirubinemia alone	3 (5.7)
Direct hyperbilirubinemia + other feature(s)	8 (15.1)
Thrombocytopenia	8 (15.1)
Thrombocytopenia alone	1 (1.9)
Thrombocytopenia with other feature(s)	7 (13.2)
Microcephaly	3 (5.7)
Multiple congenital anomalies	2 (3.8)
Hydrops	1 (1.9)
Anemia	1 (1.9)
Not specified	2 (3.8)

[a]n (%) | [b]percentages do not equal 100% as some subjects had multiple explanations for obtaining a total serum IgM level

Table 3. *Alternative explanations for SGA status in total serum IgM Group.*

Alternative explanation	SGA[a] infants (n=44)[b,c]
Maternal hypertension	22 (50)
Maternal substance use (tobacco, alcohol, opioids)	6 (13.7)
Multiple congenital anomalies more consistent with chromosomal/genetic disorder	3 (6.8)
Maternal diabetes	3 (6.8)
Advanced maternal age	3 (6.8)
Twin gestation	2 (4.5)
Maternal chronic anemia	1 (2.3)
Uterine anomaly	1 (2.3)

[a]*SGA* small for gestional age | [b]n (%) | [c]percentages do not equal 100% as some mother-infant dyad had multiple alternative explanations

4. Discussion

Total serum IgM is an attractive CI screening tool: IgM does not usually cross from maternal to fetal circulation, the fetus can make its own IgM starting in the first trimester [12], and total serum IgM levels increase in acute infection [13]. Additionally, the test is inexpensive and widely available with a quick turnaround time. Conversely, pathogen-specific tests often must be sent to reference laboratories, are relatively expensive, and may take weeks to return. For these reasons, total serum IgM continues to be used today, as evidenced by a 2019 survey of US-based neonatal providers conducted by Hwang and colleagues [6]. The authors noted that 39% of respondents utilized total IgG or IgM (not pathogen-specific) when seriously considering a CI diagnosis.

The history of total serum IgM as a marker of CI began in 1964 when Weller and colleagues discovered rubella-neutralizing antibodies in the amniotic fluid and serum of term newborns following maternal infection during pregnancy [14]. Subsequent research by Bellanti et al. confirmed these fetal and neonatal antibodies were IgM [15].

Beginning in 1965, authors began describing elevated total serum IgM levels in infected neonates. McCracken and Shinefield reported significantly increased levels of total serum IgM in eight symptomatic newborns with CMV compared to healthy controls [3]. Building on this, Stiehm et al. found elevated total serum IgM results (as high as 165 mg/dL) in eight of 13 infants with congenital rubella, which was especially pronounced when the infection occurred during the first trimester of pregnancy [4]. Alford et al. further supported these findings, identifying elevated total IgM levels in the serum of 39 of 46 infected newborns [5]. Two years later, Alford et al. again observed a high correlation between elevated total serum IgM levels and infection [16]. In this cohort, 45 newborns had elevated total serum IgM levels, 42 of whom were infected.

Khan et al. reported elevated total serum IgM levels in a significant proportion of ill neonates within the first two days and the first two weeks of life [17]. Additionally, Cederqvist et al. investigated toxoplasmosis during pregnancy, finding elevated total serum IgM levels in three of four infected infants but not in uninfected infants [18].

While initial studies suggested total serum IgM was a promising diagnostic tool for CI, subsequent research has raised doubts. For example, McCracken et al. found that only 18% of newborns with congenital rubella had total serum IgM values exceeding 20 mg/dL, with 10% of non-infected controls also exhibiting elevated levels [19]. Similarly, Miller et al. screened over 5,000 newborns for elevated total serum IgM levels. They found minimal association with neonatal disease, with only one case of confirmed CI among infants with elevated total serum IgM levels [20]. Gotoff et al. reported that < 2% of umbilical cord IgM levels surpassed 17 mg/dL, with a small fraction of those cases correlating with confirmed CIs [21]. Matthews and O'Herlihy observed elevated total serum IgM levels in greater than 10% of SGA infants, but only a fraction of these cases were associated with CI [7].

Subsequent studies continued to demonstrate challenges in utilizing total serum IgM as an effective screening tool for CI. Motoyama et al. reported a poor correlation between total serum IgM levels and infection, with mean IgM levels higher in uninfected, control infants [8]. Similarly, Mahon et al. found only one confirmed case of CI out of 163 newborns screened using total serum IgM measurements, suggesting a negligible yield for screening purposes [9]. Collectively, these studies challenge the utility of total serum IgM as a reliable screening tool for CI, highlighting limitations in both sensitivity and specificity.

No patients in our cohort had a confirmed CI. Two patients admitted to the NICU during the study period were diagnosed with congenital CMV. Unfortunately, total serum IgM levels were not obtained on either patient. Nearly all total serum IgM measurements obtained were normal. A single patient had a slightly elevated level obtained on the fifth day of life. This female infant was born at 36 weeks gestation via Caesarean section. Apgar scores were 8 and 9 at 1 and 5 minutes respectively. The infant was SGA with a weight for gestational age <1%. An IgM value was obtained at 120 hours due to her SGA status. The infant was otherwise well appearing without physical or laboratory abnormalities (normal hematocrit, platelet count, and ANC). A CMV PCR test was obtained and was negative. In the absence of infection, the precise cause of this infant's slightly elevated IgM value is unclear; however, the value may have been within the normal reference range initially and subsequently followed the expected increase in total serum IgM over the first weeks of life [22]. A repeat level was not obtained, so it is unclear if the IgM value returned to normal.

Our cohort of patients tended to be around term gestation but small, with a mean birthweight less than two kg. Three-quarters of the cohort were SGA, and two-thirds had at least one laboratory abnormality. This is unsurprising since these are signs and symptoms often attributed to CIs. The most cited reason for obtaining a total serum IgM measurement was isolated SGA status. Evaluating all SGA infants for CI has been shown to be low yield, often < 1% [7, 23-26]. This is especially true when alternative diagnoses are present to explain an infant's small size. In our cohort, almost 90% of SGA infants had an alternative explanation for their SGA status, most commonly maternal hypertension.

A more nuanced approach to CI testing will likely be more successful when evaluating newborns for CIs than testing all SGA infants for CI. Maternal history (disease exposure, travel history, and preexisting medical conditions), local disease incidence patterns, and the full spectrum of clinical manifestations in the newborn are all pertinent when deciding which infants to evaluate. If a patient's symptoms cannot be reasonably attributed to other factors or are unusually severe, or a mother's travel or exposure histories warrant concern, it may

be reasonable to test for CIs. The American Academy of Pediatrics Committee on Infectious Diseases recommends pathogen-specific testing (PCR or immunoglobulins) if CI testing is pursued [27].

Local incidences of SGA status will influence the yield of CI testing in SGA infants. For example, between 2012 and 2022, 15.5% of infants admitted to our NICU were classified as SGA. This is significantly higher than the incidence of CIs. For example, CMV, the most commonly acquired congenital viral infection in the United States, has an estimated incidence of 1/200 live births, and the overwhelming majority of these infants are initially asymptomatic [27]. Given the discrepancy in the incidences of SGA and CIs, testing all SGA infants for CMV, at least in our population, would likely be low yield. This yield would further decline when screening for other infectious entities associated with growth restriction, which are even less common (*Toxoplasma gondii* or Rubella, for example).

Our study has limitations. We only examined a single population of patients with a relatively high incidence of SGA-status infants; therefore, our findings may have limited generalizability. Our study was retrospective, which introduced certain biases. Finally, no CIs were diagnosed in our cohort of patients; therefore, we cannot comment on total serum IgM's effectiveness as a screening tool for CI.

5. Conclusion

Our cohort of patients had many signs and symptoms classically associated with CIs [2]; however, no CIs were diagnosed. Greater than 98% of total serum IgM values fell within the normal reference range, with just a single elevated value. While we cannot assess total serum IgM's utility as a screening tool, we can report that it did not aid in diagnosing any CIs.

Screening infants with a single lab abnormality or clinical manifestation, such as isolated SGA status, for CIs is likely to be low yield, especially when alternative explanations for any abnormalities exist. Based on expert opinion, pathogen-specific testing should be used if CI testing is performed [27].

Diagnosing CIs is challenging yet worthwhile, as early diagnosis and treatment may improve clinical outcomes [1]; however, discretion must be used when deciding which patients to screen for CIs, as testing can result in higher healthcare costs and unnecessary familial anxiety. Maternal history, local disease incidence patterns, and clinical manifestations should be considered before pursuing CI testing.

Charles Alford, who published some of the original research on total serum IgM as a CI screening tool, stated it well in 1971—"…it must be emphasized that IgM determination is only a nonspecific indicator of infection and that it must always be supplemented with tests for specific pathogens…In time, of course, tests for specific IgM immunoglobulins…may become so reliable for the various pathogens known to produce intrauterine and perinatal infection that the need for preliminary, nonspecific screening will be eliminated" [28]. We believe that time has arrived.

Abbreviations

CI	Congenital Infection
IgM	Immunoglobulin M
NICU	Neonatal Intensive Care Unit
SGA	Small for Gestational Age
CMV	Cytomegalovirus
ANC	Absolute Neutrophil Count
HIV	Human Immunodeficiency Virus
IVH	Intraventricular hemorrhage
CUS	Cranial Ultrasound
PCR	Polymerase Chain Reaction

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Jeffrey Surcouf: Methodology, Writing-review and editing

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Conflicts of Interest

The authors declare no conflicts of interest.

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