

Validation of a screening tool for developmental problems in children 60-71 months in Mexico

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Abstract

Background: Early childhood is a critical period for child development. The Child Development Evaluation Test (EDI in Spanish), developed and validated in Mexico, is a screening tool for developmental problems in children from 1 month to 4 years and 11 months. **Objective:** To validate group 15 of the EDI test for children aged 60-71 months, comparing sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) using the Battelle Developmental Inventory 2nd edition (BDI-2) in Spanish as the gold standard. **Methods:** A cross-sectional analytic study with 46 children aged 60-71 months was conducted at the Hospital Infantil de México Federico Gómez. Children were evaluated using group 15 of the EDI test and BDI-2. The sample was non-probabilistic by convenience. Diagnostic metrics and comparisons were performed globally and in the developmental domain. **Results:** The sensitivity and specificity of group 15 for the EDI test were 93.8% (95% confidence interval [CI]: 81.8%-100%) and 73.3% (95% CI: 57.5%-89.1%), respectively. The PPV was 65.2%, and the NPV 95.5%. The highest percentage of false negatives was in the cognitive domain, followed by the adaptive domain. **Conclusion:** In this first study, group 15 of the EDI test shows high sensitivity and NPV, allowing early detection in an age group previously not covered, thus facilitating interventions in this group.

Keywords: Child Development. Infant health. Child care. Early intervention.

Validación diagnóstica de una herramienta para la detección oportuna de problemas en el desarrollo infantil de niños de 60-71 meses de edad en México

Resumen

Introducción: La Primera Infancia es un periodo crítico para el desarrollo infantil. La prueba Evaluación del Desarrollo Infantil (EDI), desarrollada y validada en México, es una herramienta de tamiz para detectar problemas del desarrollo en niños desde un mes de vida y hasta 4 años 11 meses. Esta investigación, realizada en 2019, tuvo como objetivo validar el grupo 15 de la prueba EDI y ampliar el rango de edad de evaluación hasta los 60 a 71 meses, comparando sus métricas de sensibilidad, especificidad, valor predictivo positivo (VPP) y valor predictivo negativo (VPN) con el Inventario de Desarrollo de Batelle, segunda edición (IDB-2), como estándar de referencia. **Métodos:** Se realizó un estudio transversal analítico prospectivo con 46 niños y niñas de 60 a 71 meses, evaluados mediante el grupo 15 de la prueba EDI y el IDB-2, en el Hospital Infantil de México Federico Gómez. Los participantes fueron seleccionados mediante muestro no probabilístico por

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conveniencia. Se analizaron las métricas diagnósticas y se compararon los resultados globales y por dominios. **Resultados:** La sensibilidad y especificidad del grupo 15 de la EDI fueron del 93.8% (IC 95%: 81.8%-100%), y 73.3% (IC 95%: 57.5%-89.1%), respectivamente. El VPP fue del 65.2% y VPN de 95.5%. El dominio cognitivo presentó el mayor porcentaje de falsos negativos, seguido del dominio adaptativo. **Conclusión:** El grupo 15 de la prueba EDI demostró alta sensibilidad y VPN, permitiendo la detección oportuna en un rango de edad previamente no cubierto, facilitando intervenciones tempranas en este grupo.

Palabras clave: Primera infancia. Prueba EDI. Desarrollo infantil. Tamiz.

Introduction

The National Strategy for Early Childhood Care (ENAPI, for its Spanish acronym), developed within the framework of the Early Childhood Commission of the National System for the Protection of Girls, Boys, and Adolescents (SIPINNA, for its Spanish acronym), establishes that early childhood spans from birth to 5 years and 11 months of age¹. This strategy, supported by the creation of a Comprehensive Early Childhood Policy approved on April 30, 2019, emphasizes the importance of this period as a foundation for building a better society and country².

Health care for children under 5 years of age in Mexico is regulated by NOM-031-SSA2-1999 for Child Health Care, which stipulates growth and development monitoring as basic health-care actions (section 9.16) and promotes community participation in these actions (section 12.2). In Appendix F, behaviors to be evaluated for child development were included through a technical guide³. In response to the need for a specific instrument for the timely detection of developmental problems in children under 5 years living in poverty, the Child Development Evaluation Test (EDI, for its Spanish acronym) was designed and validated with funding from the National Commission for Social Protection in Health (CNPSS, for its Spanish acronym), through PROSPERA, a social inclusion program⁴.

There are different developmental screening tests used internationally (Table 1), including Ages and Stages Questionnaires (USA)⁵, Bayley Infant Neurodevelopmental Screen (USA)⁶, Denver II (USA)⁷, Psychomotor Development Evaluation Scale (Chile)⁸, National Screening Test (PRUNAPE) (Argentina)⁹, and the EDI developed and validated in Mexico for the timely detection of developmental problems in children from 1 month of age up to 4 years and 11 months (Table 1)¹⁰.

In Mexico, the international panel of experts, "Validation of Diagnostic Instruments for Child Development Problems in Mexico," concluded that the EDI test is the most appropriate screening instrument in the context of the Mexican population. At the same time, the Battelle Developmental Inventory 2nd edition (BDI-2) is the

reference standard for diagnosing developmental delays. Since 2014, the EDI test has replaced the technical guide and, together with the BDI-2 and competency-based early stimulation, forms part of the technical guidelines for early child development that establish care for children under 5 years in this area⁴.

However, the EDI does not cover the age range from 5 years to 5 years and 11 months, leaving a diagnostic gap for this group. This situation is especially critical as it corresponds to the transition between preschool and primary education. The absence of a valid tool for this age range limits the possibility of timely identification and intervention¹¹.

A series of specific developmental milestones for this age range were developed and integrated as group 15 of the EDI test to address this gap. The present study aims to validate these milestones by comparing the sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) of group 15 against the gold standard, the BDI-2 in Spanish. The hypothesis proposes that these metrics will be > 70%.

Methods

This research was conducted in two phases, each utilizing a different methodology to achieve its objective. In the first phase, a review of national and international literature was undertaken to identify developmental milestones for children aged 5 years-5 years and 11 months. These milestones were incorporated as items in the formulation of group 15 of the EDI test, and areas to be evaluated through questioning and observation were established. In the second phase, a prospective analytical cross-sectional study was conducted. Participants were recruited through the study protocol announcement to the general population, primarily through the official social network of the neurodevelopment research unit at the *Hospital Infantil de México Federico Gómez* (HIMFG).

A non-probabilistic convenience sampling was used to select participants who met the following inclusion criteria: being between 5 years of age and 1 day before

Table 1. Developmental screening tests in the Americas

Developmental screening test	Language	Administration time (min)	Age range (months)	Sensitivity	Specificity
Ages and Stages Questionnaires (USA)	English and Spanish	10-15	4-60	0.70-0.90	0.76-0.91
Battelle developmental inventory screening 2 nd ed.. (USA)	English and Spanish	10-30	0-95	0.72-0.93	0.79-0.88
Bayley infant neurodevelopmental screen (USA)	English	10	3-24	0.75-0.86	0.75-0.86
Denver II	English and Spanish	20-30	0-71	0.56	0.80
Psychomotor development evaluation scale (<i>Escala de Evaluación del Desarrollo Psicomotor</i> , Chile)	Spanish	20	0-24	Not reported	Not reported
PRUNAPE National Screening Test (PRUNAPE <i>Prueba Nacional de Pesquisa</i> , Argentina)	Spanish	10-15	0-60	0.80	0.93
Child development evaluation test (EDI <i>Prueba de Evaluación del Desarrollo Infantil</i> , México)	Spanish	10-15	Total 0-15 16-59	80.5 76.1 88.5	60.5 59.1 62.3

turning 6 years (children 60-71 months of age), being presumably healthy, and having been evaluated at the neurodevelopment research unit of the HIMFG. In addition, parents were required to sign informed consent authorizing the application of the EDI test and the use of the obtained information. Children with any associated chronic disease were excluded.

Data were collected through clinical history, physical examination, the version for group 15 of the EDI test, and the BDI-2 Spanish version.

The EDI test is a screening tool developed and validated in Mexico for the timely detection of child development problems. The 20 items for this group are answered by primary caregivers or are scored through observation of behaviors grouped into five axes: (a) biological risk factors; (b) warning signs; (c) developmental areas (fine motor, gross motor, language, social, and knowledge); (d) alarm signs; and (e) neurological examination (Table 2). Possible results are normal development (green), developmental lag (yellow), or risk of delay (red). Classification in red can be based on results obtained in one or more of the following axes: developmental areas, neurological examination, or alarm signs. Results are classified as red based on results obtained in one or more axes. Tests reported as either yellow or red are considered abnormal¹⁰.

The BDI-2 Spanish version identifies developmental delays in children from birth to 7 years and 11 months. It consists of 341 items applied according to age and corresponding developmental area. These areas are personal-social, adaptive, motor, communication, and cognitive.

The Inventory uses a traffic light system to interpret results, as well as standardized scores and a global measure called Total Developmental Quotient (TDQ). This quotient classifies developmental level in ranges from a score below 70, indicating significant delay, to values of 130, interpreted as accelerated development.

The EDI test and BDI-2 test were administered and reviewed by trained personnel from the HIMFG neurodevelopment research unit. Personnel who reviewed the tests did not participate in their administration.

The study was approved by the Research, Ethics, and Biosafety Committees of the HIMFG, file number HIM-AE-02-2019.

Statistical analysis

A descriptive statistical analysis of participants was conducted, using means for normally distributed numerical variables and absolute frequencies and percentages for categorical variables. Sensitivity, specificity, and predictive values were calculated with 95% confidence intervals (CIs) to obtain diagnostic validation metrics. Statistical analyses were performed using IBM SPSS software version 25.

Results

A total of 46 participants who met the inclusion criteria were included from Mexico City, State of Mexico, and Nuevo León. Of the total, 32 (69.6%) were male. The mean age was 64.39 months (Fig. 1).

Table 2. Developmental areas items for children 60-71 months in the child development evaluation test (EDI)

Developmental area	Item
Gross motor	1. Can hop forward on one foot 7 times landing on the same foot? (<i>¿Puede brincar con un solo pie hacia adelante siete veces cayendo con el mismo pie?</i>)
	2. Can jump backward with feet together? (<i>¿Puede brincar hacia atrás con los pies juntos?</i>)
	3. Can walk in a straight line, touching heel to toe, for at least 5 steps? (<i>¿Camina siguiendo una línea recta, juntando el talón de un pie con la punta del otro pie, por lo menos 5 pasos?</i>)
Fine motor	1. Can draw a triangle by copying it? (<i>¿Puede dibujar un triángulo copiándolo?</i>)
	2. Can touch the tip of the thumb with the tip of each finger of the same hand consecutively? (<i>¿Puede tocar la punta de su dedo pulgar con la punta de cada dedo de la misma mano consecutivamente?</i>)
	3. Can cut paper with round-tipped scissors following a straight line, with 1 cm margin of error? (<i>¿Puede cortar el papel con tijeras de punta redonda siguiendo una línea recta, teniendo 1 cm de margen de error?</i>)
Language	1. Speaks clearly enough for others to understand? (<i>¿Habla con suficiente claridad para que otros lo entiendan?</i>)
	2. Communicates emotions using words such as: "happy," "sad," "angry?" (if you receive gifts, how do you feel?) (<i>¿Comunica sus emociones diciendo palabras como: "feliz", "triste", "enojado"? [si recibes regalos, ¿cómo te sientes?].</i>)
	3. Can follow three-step verbal commands, for example: "clap, give me the pencil, and stand up?" (<i>¿Puede seguir ordenes verbales de tres pasos, por ejemplo: "aplaude, dame el lápiz y ponte de pie"?</i>)
Social	1. Most of the time easily shares things with other children? (<i>¿La mayoría de las veces comparte fácilmente sus cosas con otros niños?</i>)
	2. Enjoys going to school? (<i>¿Le gusta ir a la escuela?</i>)
	3. Easily waits their turn when interacting with peers, teachers, or primary caregivers? (<i>¿Espera su turno con facilidad cuando interactúa con sus compañeros, maestros o cuidadores primarios?</i>)
Knowledge	1. When asked to write two numbers or two letters, can do it? (<i>Cuando le pides que escriba 2 números o 2 letras, ¿lo hace?</i>)
	2. Can complete sentences with words that mean the opposite? For example: "the rabbit is fast, the turtle is." (<i>¿Puede completar oraciones con la palabra que significa lo opuesto? Por ejemplo: "el conejo es rápido, la tortuga es."</i>)
	3. Can identify the value of two or more coins or bills? (<i>¿Identifica el valor de dos o más monedas o billetes?</i>)
Warning signs	1. Has persistent headaches, blurred vision, or dizziness? (<i>¿Presenta dolores de cabeza persistentes, visión borrosa o mareo?</i>)
	2. Has difficulty brushing teeth, washing and drying hands, or undressing without help? (<i>¿Presenta dificultad para cepillarse los dientes, lavarse y secarse las manos o desvestirse sin ayuda?</i>)
	3. For more than 3 days a week, does the child show fear, aggression, shyness, or sadness with greater intensity than children of their age? (<i>¿Durante más de tres días a la semana el niño presenta miedo, agresión, timidez o tristeza en mayor intensidad que los niños de su edad?</i>)
Neurological examination	1. Shows altered mobility in any part of the body? (<i>¿Presenta alteración en la movilidad de alguna parte del cuerpo?</i>)
	2. Shows alteration or asymmetry in eye movement or facial expression? (<i>¿Presenta alteración o asimetría en la movilidad de ojos o expresión facial?</i>)

Source: Child Development Evaluation Manual (EDI), July 2021.

It was found that 50% (n = 23) of participants obtained an abnormal test result (14 red and nine yellow), with the remaining patients having a normal test (23 green).

Of the 46 participants in the sample, 16 (34.7%) presented a TDQ below 90. According to the Battelle Developmental Inventory, a TDQ score below 80 is considered a developmental delay. However, in this study, a

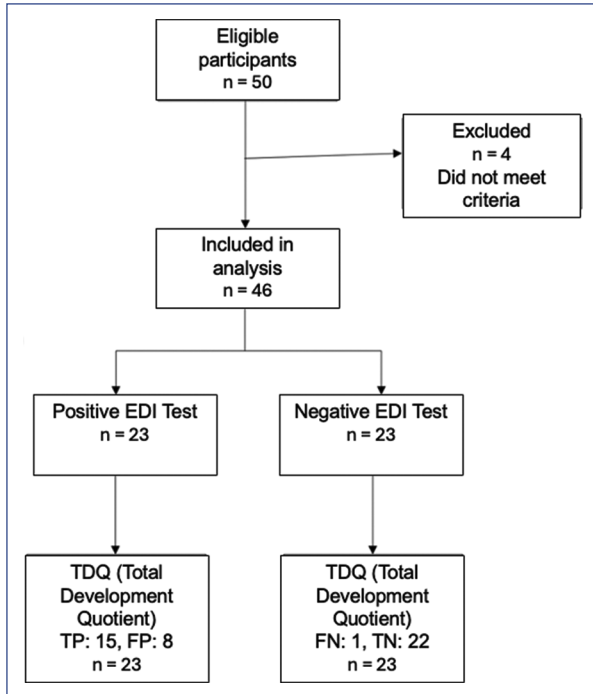


Figure 1. Study participant flow diagram. Results of the index test (EDI) and its comparison with the reference standard (Battelle Developmental Inventory, 2nd edition in Spanish). TDQ: total developmental quotient; TP: true positives; FP: false positives; FN: false negatives; TN: true negatives.

cutoff point below 90 was established because a significant number of patients who showed a delay in some developmental domain or subdomain could achieve an average TDQ score.

From the comparison between EDI test results and BDI-2 TDQ (TDQ < 90), a sensitivity of 93.8% (95% CI: 81.8%-100%), specificity of 73.3% (95% CI: 57.5%-89.1%), PPV of 65.2% (95% CI: 45.7%-84.7%), and NPV of 95.5% (95% CI: 87.2%-100%) were obtained (Table 3).

According to the abnormal global result of the EDI test in relation to the developmental domains of the BDI-2 test, the cognitive domain was found to be the most frequently affected (Table 4).

The highest percentages of false negatives were identified in the cognitive domain (in the perception and concepts, reasoning, and academic skills subdomains) and the adaptive domain (personal responsibility subdomain) (Table 5).

Discussion

The sensitivity (93.8%) and specificity (73.3%) of group 15 of the EDI test, compared with the gold standard

Table 3. Abnormal EDI Test and TDQ < 90 in Battelle Test

EDI test result	TDQ < 90	TDQ ≥ 90	Total
Abnormal (yellow and red)	15 (93.8%)	8 (26.7%)	23 (50%)
Normal (green)	1 (6.3%)	22 (73.3)	23 (50%)
Total	16	30	46

TDQ: total developmental quotient.

for developmental assessment (BDI-2), confirmed the proposed hypothesis, exceeding the 70% established as validation criterion. These results indicate the potential of this tool as a valid option for evaluating development in children aged 60-71 months, a previously uncovered age group.

When comparing this EDI group with other screening tools, such as Denver II, the EDI showed superior sensitivity (93.8% vs. 56%), although its specificity was lower (73.3% vs. 80%)⁷.

It is worth mentioning that this test adhered to the previously established guidelines in the remaining 14 groups of the EDI test, and the sensitivity and specificity of group 15 achieved in this study are superior to those reported for the EDI test in general (sensitivity 80.5% and specificity 60.5%)¹⁰.

Early identification of developmental delays enables referral to therapeutic services, and children referred for early intervention are more likely to achieve progress in developmental milestones¹¹. The American Academy of Pediatrics recommends formal developmental evaluation for all children during well-child visits at 9, 18, 24, and/or 30 months. In addition, formal screening tests are recommended, considering administration time and cost, as well as reliability, sensitivity, and specificity¹².

Developmental screening involves using validated tools to identify children at high risk of developmental delay in an apparently normal population, whereas surveillance is the process of monitoring children identified as high-risk through screening¹³.

Like the current version for the 14 groups of the EDI test, this study used the same scoring system consisting of green (normal development), yellow (developmental lag), and red (risk of developmental delay).

Regarding the NPV, a green EDI test result indicates that the probability of all BDI-2 areas reporting an average result is 95.7%, reinforcing EDI's utility as a tool for ruling out developmental risks. However, the PPV of 65.2% indicates the need to interpret abnormal results with caution, as an abnormal result does not necessarily

Table 4. Sensitivity and specificity by domain

Battelle developmental inventory 2 nd edition	Total development quotient < 90	EDI test sensitivity (%)	EDI test specificity (%)
Adaptive	13	11 (84.6)	21 (63.6)
Personal-social	8	7 (87.5)	22 (57.8)
Communication	11	9 (81.8)	21 (18.6)
Motor	9	8 (88.9)	22 (59.4)
Cognitive	26	19 (73.1)	16 (80)

Table 5. Sensitivity and specificity by subdomain

Battelle developmental inventory 2 nd edition Domains and subdomains	Scalar score < 8	EDI test sensitivity (%)	EDI test specificity (%)
Adaptive (ADP):			
Personal care (SC)	7	5 (71.4)	21 (53.8)
Personal responsibility (PR)	23	17 (73.9)	6 (65.3)
Personal-social (P-S):			
Adult interaction (AI)	11	10 (90.9)	1 (62.8)
Peer interaction (PI)	14	11 (78.6)	3 (62.5)
Self-concept and social role (RS)	7	6 (85.7)	1 (56.4)
Communication (COM):			
Receptive communication (RC)	12	10 (83.3)	2 (61.7)
Expressive communication (EC)	10	9 (90)	1 (61.1)
Motor (MOT):			
Gross motor (GM)	7	5 (71.4)	2 (53.8)
Fine motor (FM)	11	10 (90.9)	1 (62.8)
Perceptual motor (PM)	11	8 (72.7)	3 (57.1)
Cognitive (COG):			
Attention and memory (AM)	24	19 (79.2)	5 (81.8)
Reasoning and academic skills (RA)	21	17 (80.9)	4 (76)
Perception and concepts (PC)	25	19 (76)	6 (80.9)

imply generalized developmental delay. During this study, it was observed that patients could present areas of development with below-average results (TDQ < 90) and others with above-average results (TDQ ≥ 90) in the same diagnostic test (BDI-2), so when considering both scores, the global test result, that is the TDQ, results in average or even above average. The false-positive rate for red results in group 15 was 7.3%, so clinical interpretation should be cautious. In addition, the small sample size (46 participants) and the use of non-probabilistic sampling may limit the generalization of these findings.

Parents' concerns regarding development should be addressed through structured developmental assessment¹³. For many families, especially those with young children, pediatric care providers function as gatekeepers for mental health and developmental services; however, providers often fail to identify children with developmental

disorders, making it essential to find feasible methods to improve identification for effective treatment¹⁴.

This study provides initial evidence to consider implementing EDI group 15 in national programs. Its high sensitivity and NPV (95.5%) make it an effective screening tool for detecting children without risk. The rationale for conducting developmental assessments is based on the premise that health and development are interrelated¹⁵.

Early intervention is effective in high-risk children and is associated with cognitive and academic performance improvements¹⁶.

Conclusion

Solid foundations establish the importance of timely intervention in early childhood to stimulate development and thus achieve each person's maximum potential.

This intervention must occur as soon as any developmental delay is detected and, even more importantly, it must begin as soon as risk factors are identified that could convert a developmental lag into a delay.

It is known that health-care personnel's clinical judgment alone is not sufficient to conduct an evaluation that identifies patients at risk of developmental delay, so using standardized tools offers an opportunity for timely detection.

EDI test group 15, evaluated in this study as a screening test, offers important advantages for implementation, as the application time, required materials, and necessary training are very accessible. This could benefit the population of children over 5 years (60-71 months of age) who still belong to the early childhood range, for whom no Mexican tool exists to evaluate them adequately at the preschool education boundary and thus prepare their entry into primary education.

Implementing this new group in national programs such as developmental surveillance could close the existing gap in child development evaluation for this age group. However, studies with larger and more representative samples are needed to confirm these findings.

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Conflicts of interest

The authors declare no conflicts of interest.

Ethical considerations

Protection of humans and animals. The authors declare that no experiments involving humans or animals were conducted for this research.

Confidentiality, informed consent, and ethical approval. The authors have followed their institution's confidentiality protocols, obtained informed consent from patients, and received approval from the Ethics

Committee. The SAGER guidelines were followed according to the nature of the study.

Declaration on the use of artificial intelligence. The authors declare that no generative artificial intelligence was used in the writing of this manuscript.

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