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RESEARCH ARTICLE

Comparison between the KARVI scale and the Child Development Evaluation test (EDI) as a screening tool for suspected neurodevelopmental delay

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Abstract

Background: *Early detection of suspected neurodevelopmental delay allows for timely diagnosis and appropriate intervention, for which numerous screening tests have been developed. However, most are complex and impractical for health-care workers at the community level.This study aimed to validate the KARVI scale in the neurodevelopment assessment of children under 1 year of age.* **Methods:** *We conducted an observational, longitudinal, comparative, inferential, and prospective study. Healthy children without risk factors for developing neurodevelopmental delay from 0 to 12 months of age were evaluated remotely using the Zoom® application. The Child Development Evaluation Test and the KARVI scale were applied once a month for four consecutive months.* **Results:** *Fifty individuals were analyzed, with a predominance of males in 52%. Adequate percentages for a screening test were obtained in the first evaluation with a sensitivity of 70% (confidence interval [CI] 95% 34.75-93.33) and a specificity of 75% (CI 95% 58.8-87.31), and in the fourth evaluation with a sensitivity of 100% (CI 95% 29.4-100) and a specificity of 78.72% (CI 95% 64.34-89.3), being significant in both evaluations (p = 0.007 and p = 0.001, respectively).* **Conclusions:** *The KARVI scale has the elements to be an effective screening test for suspected neurodevelopmental delay, but more extensive studies are needed to obtain more reliable results.*

Keywords: *Neurodevelopment. Screening. Growth. Development.*

Comparación entre la escala KARVI y la prueba de Evaluación del Desarrollo Infantil (EDI) como tamizaje para la sospecha de retraso en el neurodesarrollo

Resumen

Introducción: *La identificación temprana de retraso en el neurodesarrollo permite un diagnóstico oportuno y una intervención apropiada. Para ello, se han creado diversas pruebas de tamizaje; sin embargo, la mayoría son complejas y poco prácticas para el personal de la salud a nivel comunitario. El objetivo del estudio fue realizar la validación de la escala KARVI en la valoración del neurodesarrollo en niños menores de un año.* **Métodos:** *Se realizó un estudio observacional,*

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longitudinal, comparativo inferencial y prospectivo, en el cual se evaluaron, vía remota mediante la aplicación Zoom®, niños sanos de 0 a 12 meses de edad sin factores de riesgo para desarrollar retraso en el neurodesarrollo. Se aplicaron la prueba EDI (Evaluación del Desarrollo Infantil) y la escala KARVI una vez al mes por cuatro meses consecutivos. **Resultados:** *Se analizaron 50 individuos, con predominio del sexo masculino en el 52%. Se obtuvieron porcentajes adecuados para una prueba de tamizaje tanto en la primera evaluación, con sensibilidad de 70% (IC 95% 34.75-93.33) y especificidad de 75% (IC 95% 58.8-87.31), como en la cuarta, con sensibilidad de 100% (IC 95% 29.4-100) y especificidad de 78.72% (IC 95% 64.34-89.3), con significación estadística en ambas evaluaciones (p = 0.007 y p = 0.001, respectivamente).* **Conclusiones:** *Se considera que la escala KARVI cuenta con los elementos para considerarla como una prueba de tamizaje efectiva para detectar retraso del neurodesarrollo, sin embargo. Sin requieren estudios más extensos para obtener resultados más confiables.*

Palabras clave: *Neurodesarrollo. Tamizaje. Crecimiento. Desarrollo.*

Introduction

Growth and development begin during pregnancy and continue throughout the years[1]. Neurodevelopment is an interactive process between children and their environment[2], influenced by genetic, environmental, biochemical, and physical factors[3]. Its ultimate goal is the maturation of the nervous system, achieving the development of brain functions and personality formation[4]; there are critical periods with conditions for acquiring skills[5].

The World Health Organization (WHO) estimates that 10% of a country's population shows some form of developmental delay[2]. According to the Pan American Health Organization, approximately 250 million children (43%) under the age of five in developing countries are at greater risk of not reaching their full development due to poverty, constituting a public health problem[2]. In Mexico, a prevalence of 6% of children with disabilities has been reported, and approximately 25% of children under the age of five have a developmental delay[2].

The American Academy of Pediatrics recommends neurodevelopmental evaluations at 9, 18, 30 months, and 4-5 years of age in the absence of risk factors[6]. This assessment evaluates developmental milestones[7] and identifies warning signs such as regression or persistence of patterns that should have disappeared[8]. As the pediatrician's clinical judgment is not sufficient, it is necessary to use screening tools that assess different areas of development[9]. Several international screening tests are described below (Table 1)[8,10-14].

The available screening tests are very complex and lengthy, making them impractical for health workers at the community level. Therefore, neurodevelopmental assessment is often omitted from the well-child visit[15]; a standardized clinical test is needed to make a timely diagnosis[4]. A screening test identifies individuals with suspected disease in an apparently healthy population[16]; it should have a sensitivity and specificity >70%[16]. In the review of the literature, we found tests developed and validated in Mexico, highlighting the *Evaluación del Desarrollo Infantil* (EDI), with the lowest bias, and the *Valoración Neuroconductual del Desarrollo del Lactante* (VANEDELA), with the most documented validation process[9]; the EDI is the most widely used[16] (sensitivity 76.1% and specificity 59.1%)[17] (Table 2)[15,17-19].

This study aimed to provide a screening tool for detecting suspected neurodevelopmental delay in children under 1 year of age that is practical and can be used by health professionals and caregivers. It is not intended to replace the existing ones but to be a filter that easily identifies those patients at risk who require more extensive and detailed evaluation.

The test is the KARVI scale, created by Dr. Miguel Angel Karlis Rangel, which evaluates children from 0 to 12 months in five areas: sensory (proprioceptive and fine motor), auditory, visual, emotional (socio-affective), and motor (gross motor). It has two achievements per area per month, which are scored as "Yes" (achieved) or "No" (not achieved), leaving a total of 10 items for each month. The test is composed of observational and verbal items. Each domain is scored individually, resulting in a total score that is classified into four categories: optimal development (two achievements reached), standard development (one achievement reached), lack of developmental stimulation (no achievement reached in 1 month of evaluation in a single domain), and developmental delay (none of the achievements reached in at least 2 consecutive months of evaluation). If no achievement is reached in a certain area, the evaluation of the previous and current month of that individual activity is repeated the following month. The results are color coded (traffic lights) to highlight their importance (blue = optimal, green = standard, yellow = lack of stimulation, and red = developmental delay) (Table 3). Among the advantages of

Table 1. Characteristics of existing screening tests at international level

Test	Battelle developmental inventory	Bayley scales of infant and toddler development III	Denver scale II	Milani comparetti test	Ages and stages questionnaire 3
Areas evaluated	Cognitive, adaptive, motor, communication and socio-personal development	Cognitive, language, motor, social-emotional, and adaptive	Personal social, adaptive fine motor, gross motor, and language	Postural behavior, spontaneous motor, and stimulation-induced movement patterns	Communication, fine and gross motor, problem-solving, and social-personal
Ages evaluated	0-96 months	1-42 months	0-72 months	0-24 months	1-66 months
Items	100 items	91 items	125 items	27 items	30 items
Application time	30-90 minutes	50-90 minutes	20-25 minutes	15-25 minutes	10-15 minutes
Special material	Yes	Yes	Yes	Yes	No
Previous training	Yes	Yes	Yes	Yes	No

Table 2. Characteristics of the tests developed and validated in Mexico

Test	EDI	VANEDELA
Areas evaluated	Gross motor, fine motor, language, social development, and cognition	Cognitive, language, motor, socio-emotional, and adaptive
Ages evaluated	1-60 months (14 groups)	1-24 months (6 groups)
Formats	Areas of development, warning and alarm signs	Somatometry, developmental behaviors, developmental reactions, and warning signs
Application time	10-15 min	10-15 min
Special material	Yes	Yes
Previous training	Yes	Yes

EDI: Child Development Evaluation; VANEDELA: Neurobehavioral Assessment of Infant Development.

Table 3. Interpretation of results obtained on the KARVI scale

Achievements	1 month	2 consecutive months
0 achievements per area	Delayed stimulation (yellow)	Developmental delay (red)
1 achievement per area	Standard development (green)	-
2 achievements per area	Optimal development (blue)	-

this test are its duration of 5-10 min, its straightforward language, and the fact that it does not require any special material but uses objects that are familiar to the child. A limitation is that it is only used in children under 12 months of age.

During our study, we faced several problems, including that in March 2020, the WHO declared a severe acute respiratory syndrome coronavirus 2 pandemic, which triggered an epidemiological emergency that forced governments to take measures such as social isolation[20]. As a result, face-to-face consultations were reduced, pathology checks were postponed, treatments were interrupted, and social activities were restricted, increasing problems in early childhood development[21]. Studies that analyze the impact of the pandemic on neurodevelopment have emerged. In Spain, a decrease of up to 15% in neurodevelopmental consultations has been reported[22]; in Italy, it is mentioned that paying more attention to children with risk factors for developing neurodevelopmental delays is important[23]. This information represents a major challenge for physicians, who must focus on early detection[24].

Studies of remote neurological assessment using telemedicine, defined by the WHO as "The delivery of health services using information and communication technologies for the exchange of information for the diagnosis, treatment, and prevention of disease," were identified in the literature[25]. Telemedicine removes the barriers of time and distance by reaching remote locations and reducing waiting times[26]. The Internet and electronic devices are helpful in monitoring and diagnosing clinical conditions[27]; thus, the evaluations performed by telemedicine are not inferior to those performed in person in terms of patient and health professional satisfaction[28]. There have been publications in which telemedicine has been used to evaluate neurological disorders, and this field of telemedicine has been called "teleneurology"[29]. In Australia in 2016, a study was conducted to determine whether a mobile phone application could identify the risk of neurodevelopmental delay using the General Movements Assessment scale and concluded that the application facilitated identification[30]. In Iowa in 2014, parents of children with neurological conditions concluded that telemedicine consultations were as effective as in-person consultations[31]. The world has seen the current situation as an opportunity to develop an alternative to continue neurodevelopmental assessment[32]. In Spain, a 63% increase in pediatric consultations through telemedicine was demonstrated from March to June 2020, maintaining the follow-up of patients with neurodevelopmental disorders and minimizing the risk of contagion[22]. After reviewing these studies, we developed the idea of continuing our project through teleneurology.

Methods

We conducted an observational, longitudinal, comparative, inferential, and prospective study to determine the sensitivity of the screening test (KARVI scale) in the neurodevelopment assessment in children under 1 year of age. We decided to compare our KARVI scale (screening test) with the EDI test (gold standard), a test developed and validated in Mexico for detecting neurodevelopmental problems[33]. The study hypothesis (alternative) was "The screening tool (KARVI scale) is as sensitive as the EDI test for the timely detection of suspected neurodevelopmental delay in children under 1 year of age," while the null hypothesis was "The screening tool (KARVI scale) is not as sensitive as the EDI test for the timely detection of suspected neurodevelopmental delay in children under 1 year of age."

The study was approved by the Research Ethics Committee of the ITESM School of Medicine (No. P000253-EKARVI2019-CEIC-CR003). Pediatricians and neonatologists in the metropolitan area of Monterrey, Nuevo León, were informed of the project; individuals who met the inclusion criteria were identified and, with prior authorization from the physician, were invited to participate. Informed consent was given to each caregiver, and a signed consent form was obtained before the assessments. Participants were recruited between October 2020 and October 2021.

Inclusion criteria were individuals aged 0-12 months, born at term, previously healthy, without apparent risk factors for neurodevelopmental delay (metabolic or genetic diseases, tumors, cranioencephalic trauma, or neurological infections with sequelae), attending well-child visits and referred by their physicians, whose caregivers and physicians agreed to participate in the evaluation, and who had the means to conduct sessions remotely. Exclusion criteria were individuals older than 12 months, pre-mature births, caregivers who did not wish to participate in the study, children with a previously diagnosed disease associated with any neurodevelopmental delay (metabolic and genetic diseases), healthy children whose neurodevelopment could be affected by a previous disease (tumors, cranioencephalic trauma, and neurological infections with sequelae), incomplete evaluations, and children who did not come for follow-up or who did not have the means to conduct sessions through remote access.

We worked with qualitative variables grouped as positive test (abnormal) or negative test (normal) to obtain dichotomous variables. Optimal development (blue) in the KARVI test and normal development (green) in the EDI test were identified as equivalent variables and were considered negative. Standard development (green), delayed stimulation (yellow), and developmental delay (red) in the KARVI test and developmental delay (yellow) and risk of developmental delay (red) in the EDI test were considered positive.

The following formula was used to calculate the sample size:

$$n = \frac{z^2 PQ}{d^2}$$

$$n = \frac{(1.98)^2 (0.20)(1-0.20)}{(0.05)^2} = 250$$

Legend: z = 1.98, d = 0.05, P = prevalence of neurodevelopmental problems, Q = 1-p

The following parameters were used:

Table 4. Demographic variables for each application

Evaluation	Age (months)	Weight (kg)	Length (cm)	HC (cm)	BMI (kg/m^2)
Evaluation 1					
Range	1-9	3.8-10.6	51-74	36-46	12.18-20.54
Mean (SD)	4.7 (2.4)	7.08 (1.5)	64 (5.5)	41.68 (2.22)	17.1 (1.65)
Median	5	6.9	64	42	17.12
Mode	5	5.3	62	42	15.86
Variance	5.7	2.2	30.76	5.07	2.7
Evaluation 2					
Range	2-10	5-10.6	55-74	37-47	13.87-20.11
Mean (SD)	5.7 (2.4)	7.7 (1.36)	67.17 (4.8)	43.01 (2.01)	17.11 (1.62)
Median	6	7.7	68	43	17.12
Mode	6	7	68	43	16.56
Variance	5.7	1.8	23.77	4.07	2.64
Evaluation 3					
Range	3-11	5.6-10.8	57-77	38-48	14.28-20.26
Mean (SD)	6.7 (2.4)	8.33 (1.28)	68.95 (4.48)	44 (1.99)	17.45 (1.48)
Median	7	8.32	70	44	17.59
Mode	7	7.2	67	44	17.59
Variance	5.7	1.66	20.07	3.97	2.21
Evaluation 4					
Range	4-12	6.3-11.4	60-79	40-48	14.91-20.15
Mean (SD)	7.7 (2.4)	8.87 (1.21)	71.21 (4.54)	44.89 (1.84)	17.45 (1.43)
Median	8	8.85	72	45	17.39
Mode	8	9	70	44	18
Variance	5.7	1.47	20.68	3.42	2.05

BMI: body mass index; HC: head circumference; SD: standard deviation.

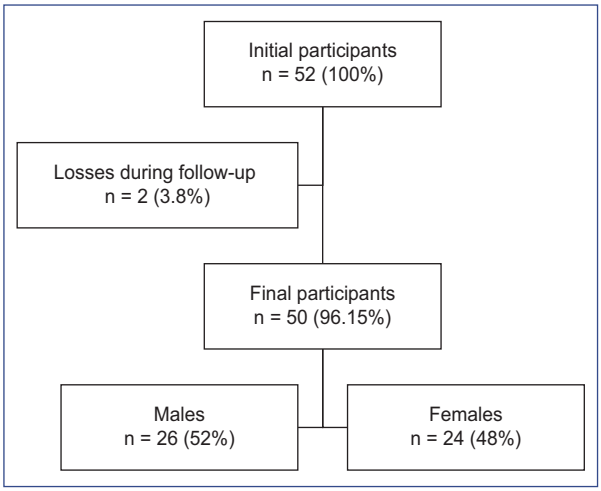

Figure 1. Total number of participants during the study.

95% confidence level (C), prevalence of neurodevelopmental problems of 20% (P), and absolute precision of 5% (d).

This gave us a total sample of 250 individuals. However, this sample was modified by the pandemic, making it impossible to conduct the sessions in person. Therefore, it was decided to conduct them remotely using the Zoom® application, avoiding any physical exposure. A total of 52 children were recruited, two of whom dropped out of the protocol, leaving us with 50 individuals who were evaluated remotely using the Zoom® application by physicians (pediatric residents and interns) who had been previously trained in using both tests. Four monthly Zoom sessions were conducted to obtain age and anthropometric data; the WHO charts were used to obtain percentiles of weight, height, head circumference (HC), and body mass index. The KARVI scale and the EDI test were then applied, and the results were registered into the database.

Results

Fifty-two children were recruited, of which 3.8% (2/52) dropped out of the study due to lack of time to attend the sessions. In the end, the remaining 96.15% (50/52) constituted our final sample for analysis. Participants were 52% male (26/50) and 48% female (24/50) (Fig. 1).

Results were analyzed using IBM SPSS Statistics® version 28 software. Descriptive statistics were used to

Table 5. Results of the four evaluations performed with the KARVI test

Evaluation	P	Se (95%CI)	Sp (95%CI)	PPV (95%CI)	NPV (95%CI)	FP (95%CI)	FN (95%CI)
1	0.007	70% (34.75-93.33)	75% (58.8-87.31)	41% (18.44-67.08)	90% (75.67-98.08)	25%	30%
2	0.091	57.1% (18.41-90.1)	74.4% (58.83-86.48)	26% (7.79-55.1)	91% (76.94-98.2)	25.6%	42.9%
3	0.063	62.5% (24.49-91.48)	71.4% (55.42-84.28)	29.4% (16.88-46.09)	90.9% (80.02-96.15)	28.6%	37.5%
4	0.001	100% (29.4-100)	78.7% (64.34-89.3)	23.08% (14.76-34.21)	100% (0-0)	21.3%	0%

CI: confidence interval; FN: false negative; FP: false positives; NPV: negative predictive value; P: significance; PPV: positive predictive value; Se: sensitivity; Sp: specificity.

analyze demographic variables and obtain measures of central tendency (Table 4), followed by 2 × 2 and Pearson's χ^2 tables to compare the degree to which a test can discriminate between individuals with and without neurodevelopment problems. Inferential or comparative statistics were used for parameter estimation and hypothesis testing.

Four consecutive monthly evaluations of the EDI standard test and the KARVI test were performed using digital media: Zoom®, Skype®, and Whatsapp®, by one of the doctors in the study, with a duration of approximately 15-20 min, in which the EDI test was applied through the electronic platform and the KARVI test through Google® forms. Sensitivity, specificity, false negative/type II error, false positive/type I error, positive predictive value, and negative predictive value of both tests were determined in each evaluation. In evaluation 1, sensitivity was 70% (confidence interval [CI] 95% 34.75-93.33) and specificity was 75% (CI 95% 58.8-87.31); in evaluation 4, sensitivity was 100% (CI 95% 29.4-100) and specificity was 78.72% (CI 95% 64.34-89.3), both of which were significant (p = 0.007 and p = 0.001, respectively). A sensitivity of 57.1% (CI 95% 18.41-90.1) and a specificity of 74.4% (CI 95% 58.83-86.48) were obtained in evaluation 2 and a sensitivity of 62.5% (CI 95% 24.49-91.48) and a specificity of 71.4% (CI 95% 55.42-84.28) were obtained in evaluation 3, without being significant (p = 0.091 and p = 0.063, respectively) (Table 5).

Table 6. Sample size and gender distribution of the validated tests in Mexico compared to the KARVI test

Test	n	Age	Female (%)	Male (%)
KARVI	50	1-12 months	24 (48)	26 (52)
EDI	438	1-60 months	190 (43)	248 (57)
VANEDELA	379	1-24 months	183 (48)	196 (52)

Discussion

Neurodevelopmental disorders are a major problem in developing countries, affecting child morbidity and public health. Their assessment at the point of care is essential but is not always possible due to factors such as the complexity of existing screening tests and, more recently, the isolation caused by the pandemic. Therefore, simpler tests are needed. During our study, we confirmed that the screening tool KARVI scale is as sensitive as the EDI test for timely detection of suspected neurodevelopmental delay in children under 1 year of age, as we obtained sensitivity percentages > 70% in scores 1 and 4, and specificity percentages > 70% in all 4 scores. However, we recognize that our study did not reach the ideal sample size for this type of scale, resulting in an inability to perform psychometric analysis and obtain wide CIs adequately. In addition, although Pearson's χ^2 test was performed with significant results in evaluations 1 and 4, given that it is very sensitive to the sample size, we could face errors in its interpretation, overestimating the test's usefulness. Therefore, it is recommended that the study should be reproduced in a larger population.

Among our limitations are the age of the patients, since only patients from 0 to 12 months were included; the recruitment process, referred by physicians from the metropolitan area of Monterrey; the follow-up of the patients, because it was only carried out for 4 months; the interpretation of the results, since the EDI test has three groups, while KARVI scale has four, which made it difficult to compare the results. Lastly, the application, since the same person performed both tests, which could lead to bias when knowing the result of the other test. In addition, it is necessary to consider the limitations resulting from the pandemic since the isolation prevented to conduct a face-to-face assessment of the patients, which affected the size of the sample and

Table 7. Comparison of results of the EDI test validation process in 2013 with that of the KARVI test in 2020

Test	Se (95%CI)	Sp (95%CI)	PPV (95%CI)	NPV (95%CI)
EDI modified	74% (65-82)	60% (51-68)	61% (53-70)	72% (63-81)
KARVI Evaluation 1	70% (34.75-93.33)	75% (58.8-87.31)	41% (18.44-67.08)	90% (75.67-98.08)
KARVI Evaluation 2	57.1% (18.41-90.1)	74.4% (58.83-86.48)	26% (7.79-55.1)	91% (76.94-98.2)
KARVI Evaluation 3	62.5% (24.49-91.48)	71.4% (55.42-84.28)	29.4% (16.88-46.09)	90.9% (80.02-96.15)
KARVI Evaluation 4	100% (29.4-100)	78.7% (64.34-89.3)	23.08% (14.76-34.21)	100% (0-0)

EDI: Child Development Evaluation; NPV: negative predictive value; PPV: positive predictive value; Se: sensitivity; Sp: specificity.

made it difficult to find caregivers willing to conduct sessions through remote access to electronic media and privacy issues, as well as communication problems and lack of understanding of the items by the child's caregivers.

In the literature, we found several validation studies of neurodevelopmental screening tests, highlighting the EDI test conducted in 2013 by Rizzoli et al. and the VANEDELA test conducted in 2011-2012 by Sanchez et al. their sample sizes and distribution by gender are shown in Table 6[17,19].

Our results were compared with those obtained with the modified version of the EDI test in children under 16 months of age during its validation process. In conclusion, KARVI is more specific than EDI, i.e., it is better at obtaining a negative result in healthy patients (Table 7). Despite the conditions, we had a diverse sample in terms of age and sex, representative of the general population; however, it is suggested to expand the sample to obtain more significant results.

The KARVI scale has the elements to be an effective screening test to detect suspected neurodevelopmental delay since it has adequate sensitivity and specificity (> 70%). In addition, it does not require special materials, caregivers can use it without prior training, and its use requires less time than other tests. However, we faced some limitations in the present study, such as the sample size. therefore, a study with a larger number of patients and recruitment sites should be conducted. Both tests should be administered in person, and more personnel should be available to administer the tests separately and minimize bias. Finally, the results are satisfactory under the circumstances in which this study was conducted. We will continue the validation process and implement the electronic scale project.

Ethical disclosures

Protection of human and animal subjects. The authors declare that no experiments were performed on humans or animals for this study.

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author has this document.

Conflicts of interest

The authors declare no conflicts of interest.

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