Original article

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Comparison of the performance of two tests for the assessment of child neurodevelopment in a children's hospital in the City of Buenos Aires

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ABSTRACT

Introduction. An early detection of developmental disorders allows to implement actions to improve their course and prognosis. In Argentina, the administration of the National Screening Test (Prueba Nacional de Pesquisa, PRUNAPE) requires a certified professional. The Child Development Observation Instrument (Instrumento de Observación del Desarrollo Infantil, IODI) is a systematized developmental surveillance tool that does not require specialization for its administration. The use of the IODI as a neurodevelopmental assessment tool would be useful because of its easy applicability.

Objective. To assess the performance of the IODI as a surveillance test for developmental disorders using the PRUNAPE as a gold standard.

Population and methods. Analytical, prospective study with a diagnostic test. Patients aged 1 month to 4 years, whose parents gave consent to participate, were included randomly. The IODI performance was assessed using the PRUNAPE as the gold standard. Sensitivity (S), specificity (Sp), positive and negative predictive values (PPV and NPV), and positive and negative likelihood ratios (PLR and NLR) were estimated.

Results. Ninety-one patients were assessed; 24 failed the PRUNAPE, of these, 21 also failed the IODI (S: 87.5%, Sp: 79.1%, PPV: 60.1%, NPV: 94.6%). PLR: 4.2, NLR: 0.2.

Conclusion. The IODI showed an acceptable performance as a developmental disorders surveillance test compared to the PRUNAPE.

Key words: *child development, neurodevelopmental disorders, surveillance.*

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INTRODUCTION

A challenge faced by pediatricians in caring for children and their families is to ensure both their physical health and their development. Structuring a supportive and nurturing physical and social environment for neurodevelopment becomes a critical component of outpatient care and follow-up for families.[1,2]

An early detection of psychomotor developmental problems in children is a relevant action necessary in the primary level of care. In Argentina, based on screening methods, the rate of neurodevelopmental disorders has been reported to be 20%.[3–5] Taking into account the neuroplasticity of children in the first stages of life, an early detection allows the implementation of therapeutic and supportive actions that substantially improve the course and prognosis of neurodevelopmental disorders. This would allow to have better outcomes in terms of treatment and rehabilitation. And, therefore, the costs would be lower, in relation to the suffering of both children and their families and the financial costs of health care.[3,4]

Despite the existence of several national and international tools for neurodevelopmental assessment, they have not been fully incorporated into pediatricians' daily practice. Many of these tools are inexpensive, easily applicable, and require minimal training on the part of the professional administering them.[2]

The National Screening Test (Prueba Nacional de Pesquisa, PRUNAPE) is a simple, low-cost test for the detection of unapparent developmental disorders in children under 6 years of age. It is the only screening tool carried out in the Argentine population. In the Guidelines for Monitoring the Health of Children and Adolescents, the *Sociedad Argentina de Pediatría* recommends administering the PRUNAPE at least twice in the first 5 years of a child's life.[6]

The PRUNAPE should be administered by trained professionals and takes approximately 15 minutes. It has a sensitivity of 80% and a specificity of 93%.[6]

In 2015, the National Ministry of Health developed the Child Development Observation Instrument (Instrumento de Observación del Desarrollo Infantil, IODI) and recommends its implementation in clinical practice at the primary level of care.[7]

The IODI is an easily applicable surveillance tool for the systematized observation of development during office visits and does not require a high degree of training. Its administration does not entail using specific instruments, it can be used in all pediatric patient visits, and allows for longitudinal neurodevelopmental monitoring. In addition, it incorporates relational patterns that are lacking in other tests, including the PRUNAPE. The purpose of the IODI is to monitor the development of children under 4 years old and contribute to the timely detection of risk situations and warning signs.[7]

Although nationally validated screening instruments have been implemented for several years, their administration during health checkups has not yet been standardized. The systematic implementation of an instrument for the detection of developmental disorders (DDs) would allow for a timely diagnosis and referral.[8,9]

Due to the high rate of DDs and their late diagnosis and treatment, which lead to a worse prognosis due to the loss of neuroplasticity, the need to use the IODI in daily practice has been considered –beyond the recommendation by the Ministry of Health– as it is a low-cost tool that requires brief training, and we decided to compare it with the PRUNAPE, a validated test in the Argentine population.

OBJECTIVE

To assess the performance of the IODI as a surveillance test for DDs using the PRUNAPE as a gold standard in a population of children attending the outpatient facilities of the Department of Pediatrics.

POPULATION AND METHODS

Design

This was an analytical, prospective study with a diagnostic test.

Inclusion criteria

Children aged 1 month to 4 years who attended the Outpatient Pediatric Clinic of Hospital General de Niños Pedro de Elizalde (HGNPE) between March and October 2018 and whose parents agreed to sign the informed consent.

Exclusion criteria

Patients with acute conditions, skeletal malformations, motor and/or sensory deficits, and patients with a previous diagnosis of neurodevelopmental disorder.

Patient selection

Two patients were randomly selected per day from the list of patients younger than 4 years who met the inclusion criteria until the sample size was completed.

Both tests were administered alternately on the same day to each subject, with a rest period between them. Two health care providers were assigned, one in charge of administering the IODI and the other in charge of the PRUNAPE. Half of the patients started with the IODI and the other half, with the PRUNAPE; neither evaluator knew the outcomes of the other test.

Variables

Study variable: the IODI, considered a categorical variable (passes or fails the test) according to the recommendations for its administration (passes when the assessed milestone remained in the green zone and fails when the patient did not meet the milestone at the time of the consultation, regardless of whether the patient was in the risk range or alarm zone).[7]

Outcome variable or gold standard: the PRUNAPE, considered a categorical variable (passes or fails) according to the recommendations for its administration.[6]

Control variables

Age: established as decimal age in years, according to date of birth and date of consultation. Continuous numerical variable.

Sex: male or female.

Birth weight: adequate weight for gestational age. Yes/no categorical variable.

Gestational age: continuous numerical variable expressed in weeks.

Presence of comorbidities or history of risk: yes/no categorical variable. The presence of at least one of the following was reported as positive: congenital or acquired heart disease, congenital or acquired immunodeficiency, prematurity, perinatal diseases, chronic obstructive pulmonary disease, bronchopulmonary dysplasia or any chronic disease that does not alter neurodevelopment.

Maternal, paternal or caregiver level of education: primary, secondary, tertiary education (complete/incomplete). Ordinal variable.

Smoking at home: any household member who smokes. Yes/no categorical variable.

Prior hospitalization: yes/no categorical variable.

Health coverage: categorical variable. One of the following categories was assigned: no health insurance; health insurance; insurance provided by the Government of the City of Buenos Aires; private health insurance.

Household members: number of household members. Discrete continuous variable.

Sample size

The prevalence of subjects failing the PRUNAPE was assumed to be 20%; with an expected sensitivity of 95%, a specificity of 80%,

Table 1. Sociodemographic variables recorded (N = 91)

Parameters	n
Sex (f/m)	37/54
Age*	1.9 ± 1.1
Pathological pregnancy (yes/no)	23/68
Drug use during pregnancy (yes/no)	3/88
Gestational age (weeks)	38.2 ± 2.8
Perinatal history (yes/no)	18/73
Birth weight (kg)*	3.1 ± 0.7
Exclusive breastfeeding (yes/no)	48/43
Complete immunization schedule (yes/no)	77/15
Consanguinity (yes/no)	1/90
Personal history (yes/no)	44/47
Number of household members*	4.8 ± 1.8
Smoking environment (yes/no)	40/51
Maternal education less than incomplete secondary education (yes/no)	45/46
Paternal education less than incomplete secondary education (yes/no)	61/30

**Mean ± standard deviation.*

an accuracy of 10%, and a 95% confidence level for the IODI. Based on these estimates, a sample size of 92 patients was calculated to be assessed by both tests.[1,3,5] The Epidat® 4.2.2 software was used.

Statistical analysis

The study variables were described using absolute numbers for categorical variables and mean with standard deviation or median with interquartile range (IQR) for numerical variables based on their adjustment or not to normality according to the Kolmogorov-Smirnov test.

Sensitivity (S), specificity (Sp), positive and negative predictive values (PPV and NPV), and positive and negative likelihood ratios (PLR and NLR) were estimated for the IODI and compared to the PRUNAPE as a gold standard. All values are described with their 95% confidence interval (CI). The SPSS® 20.0 software was used.

Ethical considerations

In all cases, a written informed consent was obtained from the caregiver. In case the subject failed either of the two tests, one of the study investigators facilitated access to the different interdisciplinary services. Case anonymity was maintained. The study protocol was approved by the HGNPE's Research Ethics Committee.

RESULTS

Out of 94 patients recruited, 3 were excluded because one of the tests could not be completed; 91 patients were finally assessed. Their mean age was 1.9 ± 1.1 years; 37 were females; the rest of the sociodemographic variables recorded are shown in *Table 1*. The prevalence of patients who failed the PRUNAPE was 26.4% (95% CI: 17.9–36.8).

Out of 91 study patients, 24 failed the PRUNAPE; of these, 21 failed the IODI (S: 87.5%, 95% CI: 66.5–96.7). For their part, 67 patients passed the PRUNAPE; of these, 53 passed the IODI (Sp: 79.1%, 95% CI: 67.1–87.7). Out of the 35 patients who failed the IODI, 14 passed the PRUNAPE (PPV: 60.1%, 95% CI: 42.2–76.6), whereas out of the 56 patients who passed the IODI, 3 failed the PRUNAPE (NPV: 94.6%, 95% CI: 84.2–98.6). The PLR was 4.2 (95% CI: 2.6–6.8) and the NLR was 0.2 (95% CI: 0.05–0.4 (*Table 2*).

Regarding the 3 patients who passed the IODI but failed the PRUNAPE, 2 failed the bladder and bowel control item.

In relation to caregivers' smoking habit, 13 out of 40 patients who failed the PRUNAPE had smoking caregivers versus 11 out of 51 whose caregivers did not smoke (relative risk [RR]: 1.5, 95% CI: 0.7–4.5, $p = 0.4$). In relation to maternal level of education, the mothers of 13 out of 45 patients who failed the PRUNAPE had not completed secondary education or less versus 11 out of 46 whose mothers had completed a higher level of education (RR: 1.2, 95% CI: 0.6–2.4, $p = 0.7$).

DISCUSSION

The IODI is a surveillance tool for the assessment of child development designed and recommended by the National Ministry of Health for its use at the primary level of care. Our results suggest that the IODI would be a useful tool for child development surveillance compared to the PRUNAPE. Acceptable sensitivity and negative predictive values were observed in the study population, so as to suggest the use of the IODI in the surveillance of development at the primary level of care.[8]

In this study, it was observed that the prevalence of neurodevelopmental disorders was similar to that published in the bibliography.[1,3,5] Considering that the sample was randomly selected from the list of scheduled appointments of patients in the afternoon clinic of a children's hospital, selection biases may have been avoided.

Table 2. Results of the comparison between the IODI and the PRUNAPE

	PRUNAPE**		
IODI*	**Result**	**Falls**	**Passes**	**Total**
	Falls	21	14	35
	Passes	3	53	56
	Total	24	67	91

**IODI: Child Development Observation Instrument.*
***PRUNAPE: National Screening Test.*

In relation to the variables most frequently associated with developmental disorders detected by the PRUNAPE and mentioned in previous studies, no significant association was observed for smoking habit or maternal level of education, probably due to the small sample size in our study.[10,11]

Based on the existing bibliography that supports the achievement of bladder and bowel control at an older age than described in the PRUNAPE, it should be noted that the 2 patients who passed the IODI but failed the PRUNAPE were precisely because they did not pass the bladder and bowel control item, an important point that should be taken into account in future studies.[12,13]

In the study sample, the IODI showed an acceptable performance compared to the PRUNAPE. These results could be relevant considering the importance of having a surveillance tool that does not depend on the pediatrician's clinical judgment, experience, and subjective perspective.[8]

Given that the PRUNAPE requires training, instruments, and more time for its administration, in addition to the high volume of patients seen in some cases, its mass use at the primary level of care could be difficult.[14] The IODI is an applicable option with improved times and costs and, above all, the possibility for the entire population to access a standardized test for the follow-up of neurodevelopment in children.[6,7]

This study has potential weaknesses. Although the study included 1 patient less than the calculated sample size, the results show a potentially acceptable accuracy. All patients were assessed by an investigator who administered the IODI and another investigator who carried out the PRUNAPE. It might have been useful if both investigators randomly administered both tests to avoid potential observation biases. This study was conducted in a local population, but it could be extended nationally, to different populations in our country.

CONCLUSION

In the study sample, the IODI showed an acceptable sensitivity and negative predictive value compared to the PRUNAPE. The IODI may be a reliable surveillance tool to assess and follow child development in pediatric offices. Further studies on this topic are needed. ■

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