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Expert consensus validation of an instrument to improve the timely detection of developmental dysplasia of the hip in children

Validación por consenso de expertos de un instrumento para mejorar la detección oportuna de displasia del desarrollo de cadera en población infantil

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Abstract

Background: Developmental Dysplasia of the Hip (DDH) is the most common human congenital malformation. When diagnosed and treated before five months of age, it has a high cure rate. If not, surgical management is required with high economic costs, a great impact on morbidity and sequelae that can generate permanent disability.
Objective: To design and validate an instrument to timely detect DDH.
Material and methods: A systematic review of the current literature on the timely diagnosis of DDH was carried out using PRISMA methodology. An expert panel, with eight specialists from different public and private health institutions was formed to validate it.
Results: All participants in the expert panel agreed that DDH is a public health problem. They consider that there are many patients with late diagnosis and sequelae due to a lack of timely treatment. There was consensus on the feasibility of implementing the proposal. The expressed need to update the current regulations regarding diagnostic means was identified.
Conclusions: It is necessary to promote epidemiology, risk factors, correct physical examination, ideal imaging methods according to the patient's age, and timely referral pathways for patients. Add our DDH instrument to the section to the healthy child card. This should include risk factors: pelvic presentation, female sex, and family history of DDH. As well as the marking of a normal vs abnormal physical examination

Resumen

Introducción: la displasia del desarrollo de la cadera (DDC) es la malformación congénita más común en humanos. Si se diagnostica y trata antes de los cinco meses de edad presenta una alta tasa de curación; si no, requiere tratamiento quirúrgico con altos costos económicos, gran impacto en la morbilidad y secuelas que pueden generar discapacidad permanente.
Objetivo: diseñar y validar un instrumento para detectar tempranamente la DDC.
Material y métodos: instrumento elaborado a partir de una revisión de la literatura sobre el diagnóstico oportuno de DDC, utilizando la metodología PRISMA. Para validarlo se conformó un panel de expertos con especialistas de diferentes instituciones de salud.
Resultados: todos los participantes del panel de expertos coincidieron en que la DDC es un problema de salud pública. Consideran que existen muchos pacientes con diagnóstico tardío y secuelas debido a la falta de tratamiento oportuno. Hubo consenso sobre la viabilidad de implementar la propuesta. Se identificó la necesidad de actualizar la normativa vigente en materia de medios de diagnóstico.
Conclusiones: es necesario promover la exploración física correcta, los métodos de imagen ideales según la edad del paciente y las vías de derivación oportunas. Incluir nuestro instrumento de DDC en la sección de la tarjeta del niño sano. Se deben incluir factores de riesgo: presentación pélvica, sexo femenino y antecedentes familiares de DDC. Además, se debe marcar una exploración física normal frente a anormal.

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Background

Developmental dysplasia of the hip (DDH) is an alteration in the alignment between the femoral head and the acetabulum,[1] secondary to changes in its size, shape, and orientation, resulting in structural instability that causes mechanical overload on the outer edge of the acetabulum during normal activities.[2,3] It is the most common congenital malformation in humans,[4,5] with a worldwide incidence of between 1–34 cases per 1000 live births, and it is the most prevalent musculoskeletal pathology in children and young adults, as well as the leading cause of hip osteoarthritis in those under 65 years of age.[6,7]

If DDH is diagnosed and treated before five months of age, it has a cure rate of up to 99%.[8,9] When treatment begins after five months of age, surgical management is required, which translates into high economic costs for the patient and their families, as well as a great impact on morbidity at a physical, psychological, and social level, in addition to sequelae that can be greater and generate permanent disability.[10,11]

The international recommendation for the timely diagnosis of this pathology is not conclusive. While some countries advocate universal screening,[12,13] others suggest focusing on newborns with risk factors.[14,15] Furthermore, because of the use of imaging studies for diagnosis, physical examination is currently downplayed due to its low diagnostic value.[16,17] Hip ultrasound is the gold standard for detection, but due to the lack of infrastructure in the health system, some developing countries choose to use a simple hip X-ray as a screening method.[18,19]

The objective of this paper was to design and validate a tool to more promptly detect DDH in young infants. The design of the tool was carried out based on a bibliographic review and was validated with a panel of experts.

Methods

As a starting point for the design of the instrument, a systematic review of the current literature on the timely diagnosis of DDH was carried out, using the PRISMA methodology of COCHRANE.[20] The search was conducted for articles published from 2011 to 2021 in national and international databases such as PubMed, Cochrane, UpToDate, LILACS, and Artemisa, using the list of MeSH terms for the following words: "*developmental dysplasia of the hip*", "*timely diagnosis*", "*screening*", "*hip ultrasound*", "*timely detection*". The Boolean operators "*OR*" and "*AND*" were used.

Studies focused on the timely detection of DDH in the last 10 years, conducted in humans, including randomized clinical trials, descriptive studies, and systematic reviews. Studies that did not provide conclusive results, those with low significance, or those conducted in patients with other comorbidities were excluded. Duplicate studies were eliminated, and, of the remaining ones, the abstracts were read. The identification, screening, and eligibility assessment of the studies were conducted independently by two researchers. Discrepancies were resolved by consensus, and, when necessary, a third researcher participated in the discussion. Articles published after 2021 were not included because the systematic review was designed to cover the most recent decade of consolidated evidence available at the time the study protocol was defined, and data collection was completed. This time frame also aligns with the most recent national clinical practice guidelines and regulatory frameworks relevant to the Mexican health system. Those that did not meet any of the search or inclusion criteria were discarded (figure 1).

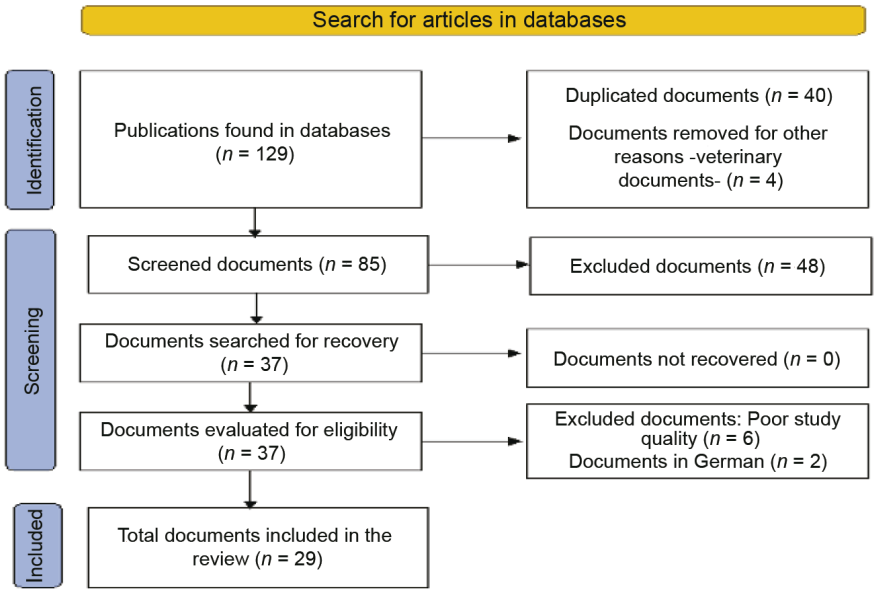
With the information obtained, a critical analysis of the studies was carried out, tabulating the checklist items: title, summary, introduction, methods, results, discussion, and funding. The objective was to evaluate the level of evidence provided by the results obtained using an evaluation template.

Subsequently, based on the analysis of the articles found, a synthesis was prepared to be shared with a group of experts in the management of DDH, subjecting it to discussion and the search for consensus using a modified nominal group to validate the results obtained. To carry out the modified nominal group, a coordination committee was first established, consisting of three reviewing researchers. With the evidence obtained, the factors with the strongest association for DDH were identified, and the instrument was designed based on them.

To validate the instrument, a panel was formed, selected by convenience sampling, with eight specialists from the following areas: public health, pediatric orthopedics, pediatric rehabilitation, medical imaging, pediatrics, neonatology, and maternal and child specialist nursing. Experts were selected based on their clinical or academic experience in DDH or related fields, representation from different disciplines involved in DDH care, and affiliation with public and private health institutions.

It was ensured that the group included representatives from different Mexican public health institutions (IMSS, ISSSTE, Ministry of Health), as well as private institutions. It was explained to all participants what their participation would consist of, and their informed consent was requested.[21,22] Prior to the validation meeting, the results of the bibliographic review were shared via email, classifying the information based on level of evidence, timely diagno-

Figure 1 Search results (PRISMA)



Source: prepared by the authors based on the results obtained from the bibliographic review

sis, imaging methods, types of screening, and timely clinical diagnosis, as well as a questionnaire with five open-ended questions.

To carry out the validation session, a date and time were agreed upon to hold a videoconference using a technological platform. Each expert was assigned a user number (omitting personal data) to enter the session, and they were asked to keep the camera off to preserve anonymity and reduce information bias. The discussion was organized around the application of the question guide, which contained open-ended questions to obtain qualitative information and closed-ended questions to obtain statistical data. The videoconference lasted a total of 2 hours and consisted of three rounds of discussion. The modified nominal group was used in real time to conduct the meeting, and the following points were addressed: 1) DDH as a public health problem in Mexico; 2) usefulness of the instrument for the timely detection of DDH; and 3) barriers/obstacles to implementation.

Based on the arguments presented by the members of the expert panel, consensus was sought for each question in the questionnaire, including the proposal of an instrument to contribute to solving the problem of lack of timely detection of DDH in the Mexican context. With the information obtained, integration and ranking were carried out to obtain the general conclusion of the expert group through the final report of results, which was sent by email to the participants.

Ethical considerations

Our work is considered a low-risk study because no personal data, biological samples, or confidentiality agreements were used. To carry out the expert panel, informed consent was requested from all participants. Due to the current pandemic and in compliance with social distancing measures, the sessions were held through an internet platform (Zoom), and informed consent was obtained verbally. The research project was evaluated and approved by the ethics committee of the National Institute of Public Health with CI: 695, Folio Identifier: D42.

Results

Systematic review of literature

The systematic review of the literature identified 29 publications that met the selection criteria. The main risk factors associated with DDH were: being first-born, female sex, breech presentation at birth, a history of DDH in first-degree relatives, and some musculoskeletal anomalies (e.g., torticollis or metatarsus adductus) or clinical syndromes (e.g., trisomy 21).[23] Cephalic presentation was a protective factor for both hips (right, $p = 0.045$ and left, $p = 0.001$), while high gestational age and macrosomia were factors associated with DDH.[24]

The clinical signs assessed in the physical examination proved to have poor diagnostic value on their own; for example, the positive predictive value of an orthopedic surgeon for detecting DDH was low (PPV = 33.3%).[25]

It is known that ultrasound is the method of choice to diagnose DDH in patients younger than four months and anteroposterior pelvis (AP) radiography in patients between 4–6 months.[17] These recommendations agree with other published reviews.[26,27] Magnetic resonance imaging (MRI) has some advantages, such as better soft tissue resolution without radiation exposure; however, it is not routinely recommended for DDH screening.[28] In contrast, it has been documented that radiography is not useful in patients younger than 6 months due to the presence of cartilaginous tissue (radiolucency) in the femoral head.[29]

With the information obtained from the literature review, the screening proposal for the detection of DDH in Mexico was developed, which allows newborns to be classified into two groups: those who have a low risk of DDH and those who present characteristics to be considered high risk (table I). A graphic element was also designed that can be included on page 21 of the current well-child booklet used in Mexico (figure 2).

Instrument validation

All participants in the expert panel agreed that DDH is a public health problem.[21] They perceived that the incidence is higher than previously thought and that there are many patients with late diagnoses and sequelae due to the lack of timely treatment. They considered that late diagnosis is due to poor training or lack of updating among health personnel on the subject, the absence of population studies, and long waiting times for patient referral.

The low level of training of health personnel is a problem present at all levels of care. "*As neonatologists or pediatricians in first contact, we have very little information regarding timely diagnosis*" (participant 4).

Table I Screening criteria for the detection of developmental dysplasia of the hip (DDH)

Low risk	High Risk
Male sex	Female sex
No family members with DDC	Relatives with DDC
Cephalic presentation	Pelvic presentation
Normal physical examination	Abnormal physical examination

Source: prepared by the authors based on the results obtained from the bibliographic review

It was reported that among first-contact personnel there is little knowledge regarding the risk factors for DDH, the correct performance of the Ortolani and Barlow maneuvers, and the imaging studies required to make the diagnosis according to age, with the consequent late diagnosis. Non-recommended actions, such as placing more than one diaper, are still indicated as treatment.

On the other hand, the medical imaging staff recognized the shortage of radiologists trained to correctly perform hip screening studies using ultrasound.

The absence of population studies in Mexico for the diagnosis of DDH was identified as a problem. Despite being the most common musculoskeletal condition in humans, its incidence and prevalence are unknown. It was also mentioned that the prevalence of adults with DDH is unknown and is relevant to understanding the burden of late diagnosis of this disease.

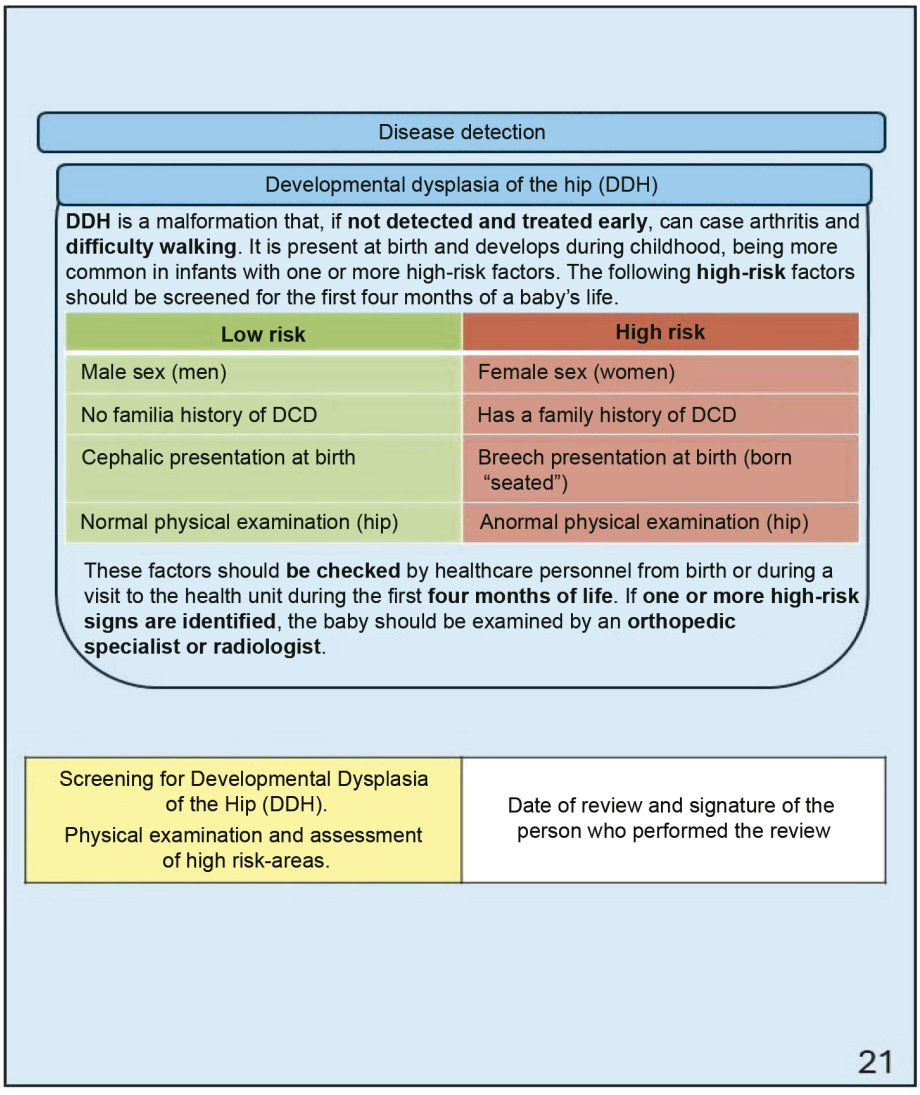
The cost of care was a relevant issue regarding the problem that late diagnosis of DDH generates for the health system. These are not only direct costs but also indirect costs that fall on the patient's family. "*Not only do the costs to the health sector increase, but also the costs generated for the family; the impact on the quality of life of both the patient and the family decreases*" (participant 8).

There was consensus on the feasibility of implementing the proposal. The need to update current regulations regarding diagnostic methods was identified: "*I would start with a modification to the NOM (Norma Oficial Mexicana, Mexican Official Standard), because although it is already described that only the Ortolani and Barlow maneuvers should be performed, there are divergences in the assessment*" (participant 5). "*It could be added to the timely screening strategy along with metabolic, cardiac, and auditory screening to make it comprehensive*" (participant 5).

The need to raise awareness among decision-makers about the economic repercussions of not addressing DDH was also mentioned.

Two areas of opportunity were identified to improve timely diagnosis: 1) first contact and 2) training of medical personnel in training: "T*he first contact with newborns is the area of greatest weakness; the diagnosis is often missed, and the child is not referred for an ultrasound initially, and the mistake of taking an X-ray is made*" (participant 1). "*Undergraduate teaching is important; it is where we must focus, because as doctors we are not really taught what hip dysplasia is, how it is diagnosed, nor the relevance or impact it has on society. Once doctors are sensitized, they would actively look for this condition*" (participant 1).

Figure 2 Instrument for the timely diagnosis of developmental dysplasia of the hip



Source: prepared by the authors based on the results obtained from the bibliographic review

Barriers to Instrument Implementation

Regarding the barriers identified for implementation, the cost of adding a section to the card was mentioned, as well as the workload in public health institutions due to the addition of another variable to be recorded, poor completion of information, the difficulty of achieving formal changes in legislation, the centralization of health services (since implementation and training should not be concentrated only in large cities and among specialist physicians), and the general lack of understanding of the disease among health personnel.

"*In our health system, it can take months to start treatment, even if a timely diagnosis has been made, which results in sequelae*" (participant 1).

One important barrier detected is how complicated and time-consuming it is to make the necessary modifications to the current NOM. Several participants highlighted this issue, including one who noted: "*The biggest problem I would identify is making the formal change to the NOM; legislation is an important limitation since the best health proposals get stuck there*" (participant 4).

Furthermore, it was suggested to overcome this barrier by emphasizing the potential cost savings of preventing the consequences of late diagnosis: "*Governments must be made aware of the cost of not addressing DDH; they must demonstrate how much is spent on prostheses and clearly show the economic repercussions*" (participant 3).

After conducting the intervention with the modified nominal group, the panel developed a series of affirmative statements based on the results obtained. A Likert-scale questionnaire was developed to measure the level of agreement among participants (table II).

The following results were obtained from the questionnaire used to measure the level of agreement among participants: for the first question, regarding whether they considered there to be a high incidence of undiagnosed DDH, the highest variability among responses was found: 50% neither agreed nor disagreed, 13% partially disagreed, and 38% strongly disagreed. Regarding the remaining questions, consensus was found on all statements, ranging from 75% to 100% (figure 3).

Discussion

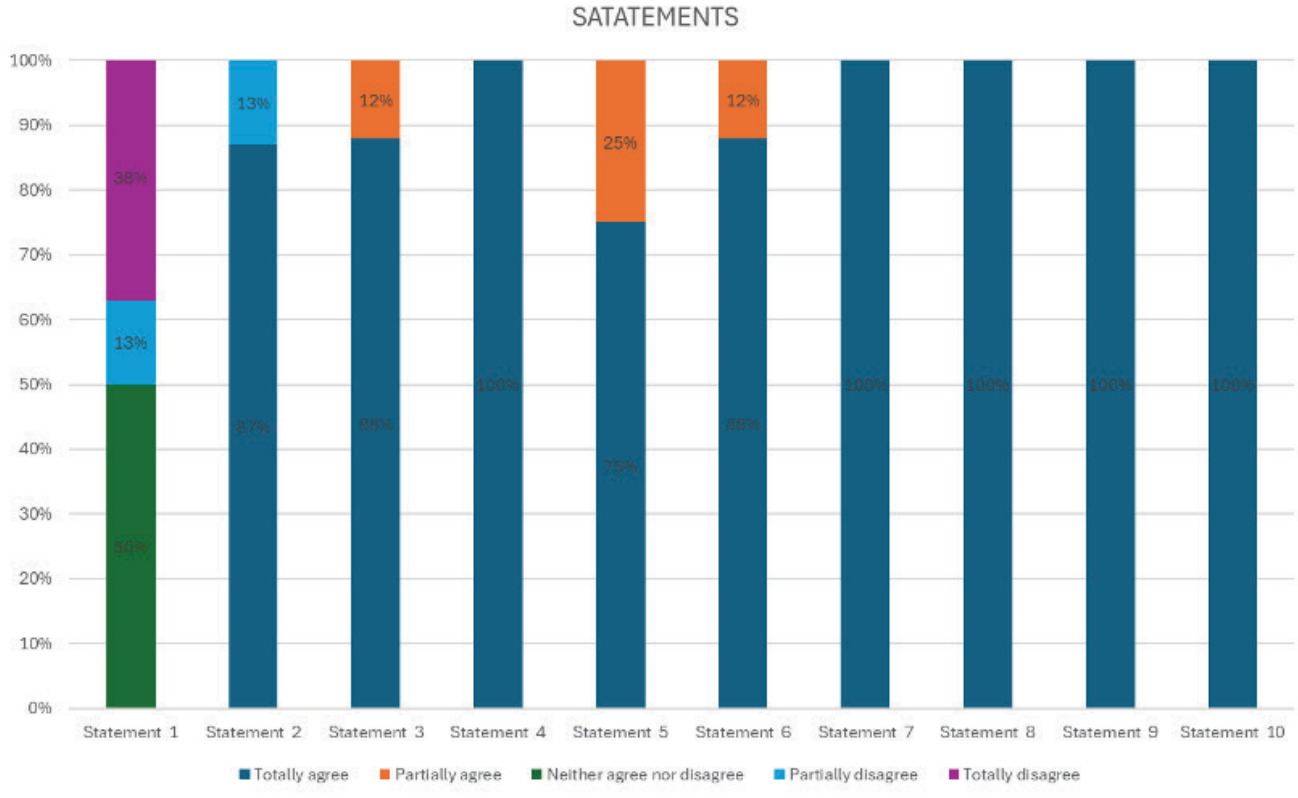
After carrying out the systematic review of the current literature (2011 to 2021), no clinical or epidemiological evidence was found that establishes a clear guideline to follow.

Table II Questionnaire to measure the level of agreement among participants

#	Statement
1	In Mexico, there is a high incidence of DDH without timely diagnosis
2	Training is needed to improve the timely diagnosis of DDH in Mexico
3	Late diagnosis of DDH diminishes the quality of life of those who suffer from it
4	Timely detection of DDH, in addition to improving the patient's quality of life, can reduce care costs for the Mexican healthcare system
5	Adding a space for DDH to the well-child record is a useful and easy-to-use tool.
6	The difficulty in making modifications to current official regulations (NOM) is an obstacle to the timely diagnosis of DDH
7	The current referral and counter-referral system is an obstacle to the timely diagnosis and care of DDH
8	It is necessary to raise awareness among decision-makers about the importance of DDH and the consequences of late diagnosis
9	The costs associated with a late diagnosis of DDH are a relevant issue about which decision-makers should be informed
10	The referral and counter-referral system of the Mexican health system need to be improved

Source: prepared by the authors

Figure 3 Results of the measurement of the level of agreement between participants



Source: prepared by the authors based on the results obtained from questionnaire to measure the level of agreement among participants

The literature varies according to the resources available in each country. In Austria, there are permanent campaigns with universal hip ultrasound;[13] however, this requires a comprehensive health system with considerable economic investment. In contrast, the United States, the United Kingdom, and Spain reserve selective ultrasound for patients with high-risk factors or abnormal physical examination findings.

More than a decade ago, the Mexican College of Orthopedics and Traumatology published a consensus to guide the timely diagnosis of developmental dysplasia of the hip. Its resolution was: "*Preventing a clinical entity such as DDH does not mean anticipating its presentation—because children will continue to be born with this problem—but rather having a program for its timely detection and early treatment, and therefore avoiding the appearance of sequelae*".[9] This publication culminated in the update of the clinical practice guideline (CPG) for the diagnosis and treatment of DDH, published in 2013.[30] These two regulations are the most current, and their objective is to guide health personnel, particularly at the primary care level, on risk factors, adequate physical examination, and imaging methods to confirm the diagnosis of DDH.

The integration of a simplified DDH section into the well-child record would help raise awareness among parents,[31] who are the first point of contact with the child. This is important for two reasons: first, because society becomes sensitized to the intentional search for this pathology; and second, because family history is the main risk factor for presenting this condition. If a positive case is found, an intentional search within the family will be encouraged.

Increased training of specialized human resources at primary, secondary, and tertiary levels of care is required for the management of DDH. Adequate training of healthcare providers is necessary to provide ongoing education to primary care staff.[32] Physicians and radiology technicians must have technical knowledge of imaging methods for timely diagnosis and be able to initiate conservative treatment (Pavlik harness) and ensure timely referral to a tertiary care specialist.[33]

Efforts must be made to train first-contact health providers, since they are responsible for monitoring the healthy child.[34] It should be noted that in our country, providers vary greatly, ranging from neonatologists in large cities to general nurses and assistants in rural communities.[35]

The fragmentation of the Mexican health system is an important barrier to the timely referral of infants with DDH. The increasing use of information technologies could be a solution to this problem, improving the referral and counter-referral system, as mentioned by two participants: "*Think about an information system that will allow traceability of referrals, to identify whether referral and care were timely*" (participant 7). "*Another difficult point in pediatric diseases is the referral and counter-referral process; although cases are detected in a timely manner, time is lost in reaching the secondary level of care*" (participant 2).

As a result of this work, three health policy recommendations can be made:

1. Implement an educational campaign to raise awareness at primary care level about the importance of birth evaluation and follow-up during the first year of life. It is essential that this campaign includes service providers from the Ministry of Health. It is necessary to promote epidemiology, risk factors, proper physical examination with appropriate performance of maneuvers (Ortolani and Barlow), ideal imaging methods according to the patient's age, and appropriate referral pathways.

2. Add a section on DDH to the well-baby card. This should include risk factors: breech presentation, female sex, and family history of DDH. In addition, normal versus abnormal physical examination findings should be highlighted, i.e., a negative Ortolani or Barlow test or skinfold asymmetry with 20 degrees of abduction (table I).

3. Ensure timely referral to a DDH diagnostic and treatment center for newborns identified as high risk. To achieve this, it is necessary to establish a national reference list for specialized DDH management, identifying facilities with pediatric orthopedic specialists and orthopedists with the skills to properly manage DDH.

Limitations

This paper presents a proposed instrument that can be used for mass screening for the early diagnosis of developmental dysplasia of the hip. Because its validation was carried out by an expert panel, its main limitation may be that this validation is based on qualitative elements. The next step is to conduct a sensitivity analysis of the instrument to determine its effectiveness in identifying true positive cases.

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