

RELIABILITY AND VALIDITY OF CLINICAL AND ULTRASOUND EXAMINATIONS OF DEVELOPMENTAL DYSPLASIA OF THE HIP

Predrag Grubor¹, Rade Tanjga² and Milan Grubor²

Developmental dysplasia of the hip (DDH) is the most common congenital deformation of the musculoskeletal system and its successful treatment is closely related to early diagnosis.

The study is aimed at examining the incidence of developmental dysplasia of the hip (DDH) and at analysing the validity of clinical examination, which is used for the early detection of DDH in the neonatal period, compared to ultrasound examination.

The study involved 400 neonates born in the Banja Luka Region. A new questionnaire was open during the first regular ultrasound and clinical examination of the neonates' hips and anamnestic and clinical data were recorded in it: the asymmetry of the gluteal, inguinal and femoral folds (Bade sign), the result of abduction test separately for each hip, the Ortolani sign of luxation and the Palmen sign of reposition, then hip sonography. A Toshiba ultrasound machine with a 7.5 MHz linear probe was used. The method employed was Professor Reinhard Graf's.

Out of the total number of the children with a positive sonographic finding for DDH, 63.16% of them have one of the clinical signs of DDH. The ability of a clinical finding to identify those patients who do not have DDH and have a negative sonographic finding is 79.8%. Out of the total number of the examined children with a positive clinical finding, only 15.58% of them also have a positive sonographic finding for DDH.

This research has showed that clinical examination of the hips is of low sensitivity, specificity and reliability, and that not all types of DDH can be detected. Clinical examination must remain an integral part of every infant's examination, but it constitutes a complementary diagnostic procedure to ultrasound examination. The ultrasound examination of DDH has created new possibilities and has filled the void that existed due to the deficiency of clinical tests, and at the same time it has reduced the number of X-ray examinations of the hips.

This research has confirmed that clinical examination of the hips does not meet the screening criteria. It must remain an integral part of an infant's examination because it, among other things, provides the information which enables the orthopaedic surgeon to choose the most beneficial therapeutic procedures in DDH treatment. *Acta Medica Medianae 2011;50(1):26-31.*

Key words: developmental dysplasia of the hip, clinical examination, ultrasound examination

Traumatology Clinic Banja Luka, Republika Srpska¹
School of Medicine Banja Luka, Republika Srpska²

Contact: Predrag Grubor
No. 20/24, Aleja Svetog Save, Banja Luka
Republic of Srpska, Bosnia and Herzegovina
E-mail: predraggrubor@gmail.com

Introduction

Developmental dysplasia of the hip (DDH) is the most common congenital deformation of the musculoskeletal system and its successful treatment is closely related to early diagnosis (1). The commencement, duration and intensity of the effects of the causative factors directly influence the level of morphological, anatomical and biomechanical changes in the hip. The primary

causative factors and secondary morphological changes are reversible. Therefore, the modern concept of the health care of children must be directed to early detection and timely application of the most effective preventive and therapeutic procedures (2).

The treatment results are better if the deformation is identified immediately after the child's birth and such preventive or therapeutic procedures are prescribed that provide physiological development of the hip joint. DDH treatment that commences in the neonatal period lasts 3 - 4 months with a good chance of full recovery. Employing therapeutic procedures from the third month of life requires a treatment the length of which is minimum 9 months, with a still good prognosis for recovery (3, 4). Starting early with

of the treatment allows the use of the physiological potential for the growth and development of the hip joint, so that the therapeutic procedures are simpler, take less time, and result in the lessening of the need for surgical interventions (5), which all together significantly reduces the treatment costs (6).

Diagnostic procedures used nowadays are based on clinical, ultrasound and radiological examinations of the hips (7).

Clinical examination is a subjective diagnostic procedure that depends on the knowledge, skill and experience of the examiner. Clinical examination of the hips can, with experience, only partially diagnose the subluxation and luxation of the hip, while dysplasia remains undetected (7).

Radiological diagnostics is inappropriate for routine application because, in addition to the damaging effects of radiation, it cannot show all morphological structures of the hip joint at the age of up to 4 months of the newborn. CT scan and magnetic resonance are diagnostic methods, inappropriate as the method of choice when diagnosing DDH (8).

X-ray examination is not a reliable diagnostic instrument in the first four months of life, when ossification is still in its early stages. It shows only the ossified parts of the skeleton and, moreover, there are damaging effects of ionising radiation (9).

Ultrasound diagnostics has forced itself as the method of choice in diagnosing all types of DDH immediately after a child's birth. It is easy to perform, harmless and it gives neither false-positive nor false-negative test results (10). Ultrasound examination of the hips, which may be performed as early as in the first days of life, is an objective method of high sensitivity and sensibility. This method holds a very important place in children's orthopaedics as it allows visual assessment of the hip joint, especially the cartilage part of the acetabular roof and the proximal part of the femur, which do not show on the radiograph in the neonatal period. Graf and Harcke's examination techniques are the most common ultrasound examination techniques for the hips in the world and are the major representatives of different approaches to DDH classification (11).

Clinical examination and taking X-ray of the hips have been tried as diagnostic procedures in DDH examination and have not given the expected results in performing regular examinations (12).

Basically, clinical knowledge and skills in the ultrasound application of the Graf method have become the primary factor for the examination, early detection and application of the most effective (13) preventive and therapeutic procedures in DDH.

Aim

This study is aimed at examining the incidence of DDH and analysing the validity of

clinical examination, which is used for the early detection of DDH in the neonatal period, compared to ultrasound examination.

The aim is to verify that ultrasound examination is the method of choice in diagnosing developmental dysplasia of the hip joint and the only diagnostic procedure that meets the examination/screening criteria.

Material and methods

The patients are 400 neonates born in the Banja Luka Region and examined in the orthopaedic surgery in the period between August 1, 2010 and November 1, 2010.

A questionnaire was open during the first regular hip examination of the newborns in the orthopaedic surgery and the data used for statistical processing were recorded in it. Only the children who were less than 45 days old during the first examination were assigned in this group. The newborn was examined clinically after anamnestic data were taken from the parents.

The data on the asymmetry of the gluteal, inguinal and femoral folds (Bade sign), the result of abduction test separately for each hip, the Ortolani sign of luxation and the Palmen sign of reposition had to be recorded in the section of the questionnaire envisaged for the clinical examination of the hips.

The hip sonography followed the clinical examination. A Toshiba ultrasound machine with a 7.5 MHz linear probe was used. The method employed was Professor Reinhard Graf's.

Sensitivity - Sn, specificity - Sp, positive predictive value - PPV, negative predictive value - NPV, prevalence - pre-test probability - P, likelihood ratio LR (positive (LR+) and negative (LR-)) and post-test probability - PTP were taken into account in order to assess the reliability and validity of clinical examination compared to ultrasound findings (treated as 'gold standard').

The so-called diagnostic table was created for the research needs and it was basically a 2x2 contingency table where the patients were classified as follows:

- compared to the reference method (sonographic finding) - table columns: the first column containing the patients with DDH present and the second column containing the patients with no DDH;

- compared to the examined diagnostic method (clinical finding) - table rows: the first row containing the patients with a positive clinical finding for DDH and the second row containing the patients with a negative clinical finding for DDH.

The diagnostic table defined in this way provides four DDH values: a (positive ultrasound finding), b (negative ultrasound finding), c (negative clinical finding), and d (positive clinical finding). The sum of 'a' and 'b' is the number of patients with a positive clinical finding and the

sum of 'c' and 'd' is the number of patients with a negative clinical finding. Table 1 was made on the basis of the definition of the parameters used for assessing the validity and reliability of the clinical finding compared to the gold standard (sonographic finding) in diagnosing developmental dysplasia of the hip (DDH).

Table 1: Contingency table model for calculating the sensitivity (Sn), specificity (Sp), positive predictive value (PPV) and negative predictive value (NPV) of DDH diagnostic methods.

Contingency table	Finding	Sonographic finding		
		Positive	Negative	Total
Clinical finding	Positive	a	b	a+b
	Negative	c	d	c+d
	Total	a+c	b+d	a+b+c+d

Results

The results obtained are given in a table format (Tables 2 to 5) and they represent the so-called diagnostic contingency tables which show the results of the clinical finding: Bade sign, abduction test and the two clinical signs combined, respectively.

Table 2: Contingency table (diagnostic table) for clinical finding

Contingency table	Finding	Sonographic finding		
		Positive	Negative	Total
Clinical finding	Positive	12	65	77
	Negative	7	316	323
	Total	19	381	400

Table 3: Contingency table (diagnostic table) for Bade sign

Contingency table	Finding	Sonographic finding		
		Positive	Negative	Total
Bade sign	Positive	6	57	63
	Negative	13	324	337
	Total	19	381	400

Table 4: Contingency table (diagnostic table) for abduction test

Contingency table	Finding	Sonographic finding		
		Positive	Negative	Total
Abduction test	Positive	8	14	22
	Negative	11	367	378
	Total	19	381	400

Table 5: Contingency table (diagnostic table) for the two clinical signs combined

Contingency table	Finding	Sonographic finding		
		Positive	Negative	Total
Two clinical signs combined	Positive	4	6	10
	Negative	15	375	390
	Total	19	381	400

Individual parameters of reliability and validity are calculated on the basis of the diagnostic tables and that is shown in Summary Table 6.

It may be concluded on the basis of the obtained parameters that the sensitivity (Sn) of the Bade sign amounts to 31.58%, of the abduction test to 42.11%, of the two clinical signs combined to 21.05% and of the total clinical finding to 63.16%. Out of the total number of the children with a positive sonographic finding for DDH, 63.16% of them had positive results in the clinical examination too. The ability of the clinical finding to identify patients with a positive sonographic finding amounts to 63.16%. In view of the fact that orthopaedic examinations were performed by highly experienced orthopaedic surgeons, it may be concluded that the sensitivity of the clinical finding is moderately low. Any result exceeding 90% may be considered very high and acceptable for a diagnostic method. As for the sensitivity of the individual clinical signs and the sensitivity of the two clinical signs combined, the results show they are below 50%. That suggests that the clinical signs by themselves do not suffice to detect DDH.

On the basis of the obtained specificity (Sp) of the Bade sign (14.96%), abduction test (3.67%), two clinical signs combined (1.57%) and total clinical finding (20.2%), we conclude that 79.8% have a negative clinical finding. The ability of the clinical finding to identify the patients with no DDH and with a negative sonographic finding is 79.8%. This suggests that the clinical signs by themselves do not suffice to diagnose DDH.

Positive predictive value (PPV) is the probability (percentage) of patients with positive clinical and sonographic findings for DDH. On the basis of the obtained positive predictive value of the Bade sign (9.52%), abduction test (36.36%), two clinical signs combined (40.00%) and total clinical finding (15.58%), we conclude that out of the total number of the children with a positive clinical finding only 15.58% of them have a sonographic finding for DDH, too. As for the positive predictive value of the individual clinical signs and the positive predictive value of the two signs combined, the results show they are below 50%. That suggests that the clinical signs by themselves do not suffice to detect those patients who really have a positive sonographic finding for DDH.

Table 6: Summary diagnostic parameters

Dijagnostički parametar	Badeov znak	Abdukcioni test	Udružena dva klinička znaka	Klinički nalaz
Senzitivnost	0,3158	0,4211	0,2105	0,6316
Specifičnost	0,1496	0,0367	0,0157	0,8294
Pozitivna prediktivna vrijednost	0,0952	0,3636	0,4000	0,1558
Negativna prediktivna vrijednost	0,9614	0,9709	0,9615	0,9783
Prevalenca	0,0475	0,0475	0,0475	0,0475
Odnos vjerodostojnosti pozitivnog rezultata	0,3713	0,4371	0,2139	3,7020
Odnos vjerodostojnosti negativnog rezultata	4,5734	15,7556	50,1316	0,4442
Vjerovatnoća-poslije dijagnostičke metode (LR+)	0,8816	0,8976	0,8109	0,9867
Vjerovatnoća-poslije dijagnostičke metode (LR-)	0,9892	0,9968	0,9990	0,8991

Negative predictive value (NPV) is the percentage of patients with negative clinical and sonographic findings for DDH. On the basis of the obtained negative predictive value of the Bade sign (96.14%), abduction test (97.09%), two clinical signs combined (96.15%) and total clinical finding (97.83%), we conclude that out of the total number of the children with a negative clinical finding 97.83% of them have a negative sonographic finding for DDH. As for the negative predictive value of the individual clinical signs and the negative predictive value for the two signs combined, the results show they are above 90%. That suggests that the clinical signs by themselves do not suffice to detect those patients who have a negative sonographic finding.

Prevalence (P) or clinical pre-test probability is the percentage of patients who really have a positive sonographic finding. On the basis of the obtained prevalence of the Bade sign (4.75%), abduction test (4.75%), two clinical signs combined (4.75%) and total clinical finding (4.75%), the DDH prevalence in our case amounts to 4.75%.

It follows from the obtained likelihood ratio positive (LR+) of the clinical examination, for the Bade sign (0.3713), abduction test (0.4371), two clinical signs combined (0.2139) and total clinical finding (3.7020), that it is almost four times (more precisely 3.7020) more likely that, compared to children with a negative sonographic finding, a child with a positive sonographic finding will have a positive result of clinical examination. As for the likelihood ratio of the individual clinical signs and the likelihood ratio of the two signs combined, the results show they are far below 1, i.e. that the probability that a positive result came from a patient with DDH is low for the individual clinical signs.

Likelihood ratio negative (LR-) is the reliability that the negative test result of a clinical examination came from a child that really has DDH. It may be concluded on the basis of the obtained likelihood ratio negative for clinical examination (0.4442) that the probability that a child that really has DDH will be identified as healthy during a clinical examination is low. As for the likelihood ratio of the clinical signs, Bade sign (4.5734),

abduction test (15.7556), two clinical signs combined (50.1316), the results show they are far above 1, i.e. that the probability that a negative result came from a patient with no DDH is low, which supports the reliability of the clinical signs in identifying those patients who really do not have DDH.

Discussion

Clinical examination must remain an integral part of every infant's examination, but as a complementary diagnostic procedure to ultrasound examination (14). Advances in medicine, especially technological ones, have created new possibilities and have filled the void that existed due to the deficiency of clinical tests, and at the same time they have reduced the number of X-ray examinations of the hips. The progress has been made due to the application of ultrasound (15).

Past experiences with the application of ultrasound in developmental dysplasia of the hip have showed that ultrasound can be applied in screening as well (4-15). Ultrasound can detect all types of developmental dysplasia of the hip as early as in the maternity ward, and repeated ultrasound examinations at certain intervals may separate those hips that are developing normally from those that are developing subluxations and luxations.

DDH incidence varies and it ranges widely from 2 to 50, and higher, per 1000 births (2, 3). The great difference in the prevalence is the result of non-uniform terminology, size of the examined population, ethnic features, child's age at the time of examination, examiner's experience, examination technique, and interpretation of the results obtained. The incidence is lowest in Hong Kong (0.01%), then in Northern Ireland (0.14%), Sweden (0.17%), America (between 0.2% and 0.4%), and in Great Britain it amounts to about 1.5% (9). According to Vrdoljak and Matasović's reports, the screening results for DDH in Croatia show that the incidence stands around 2%, although there are regions where it amounts to as little as 0.2% but also as much as 4%. The DDH incidence in Serbia has in recent years stood around 2%. In 2002 and 2003, 4016 newborns

were clinically examined by ultrasound at the Neonatal Department of the Gynaecology and Obstetrics Clinic in Novi Sad and at the Banjica Institute for Orthopaedic Surgery in Belgrade and the DDH incidence established amounted to 1.95%.

The incidence of developmental dysplasia of the hip established on the basis of clinical examination varies in the available bibliography between 1.66% (Barlow) and 40% (Šoć, Breclj). This data does not only depend on the examiner, but also on the region and time in which the research was conducted, as well as on the age of the children at the time of the hip examination. In the 1960's, Šoć and Breclj conducted DDH researches in Donja Zeta and found that the DDH prevalence was higher than 40%. At the same time, Barlow presented completely opposite data and stated a very low DDH incidence rate. He examined children at birth and then followed them until they were 4 months old and he came to the conclusion that 60% of the hips that were unstable at birth stabilised in the first week, and 88% in the next 2 months. The remaining 12% had residual instability. The given data suggests that performing only a clinical examination is an insufficient and unreliable DDH screening method, but it needs to be performed as part of the examination of a child's hips.

Our clinical examination detected 59 (19.33%) children in the examined sample with some of the clinical signs of DDH. 51 children had only one positive clinical sign, specifically 41 (13.66%) had a positive Bade sign, 9 (3.00%) had a positive abduction test, and 1 (0.33%) had positive Ortolani and Palmen signs. 8 (2.66%) children had a positive Bade sign and abduction test. The other 241 (80.33%) children did not have a single clinical sign of DDH. The first sonographic examination of the children in the examined sample detected DDH in 13 children (4.33%), specifically in 9 (69.23%) females and 4 (30.76%) males. In 3 (23.07%) it was a bilateral malformation and in 10 (76.92) a unilateral malformation. In total, 16 diseased hips, 8 right and 8 left, were detected.

The data on the prevalence of DDH is very variable. In Croatia, the prevalence of DDH ranges between 2 and 4.3% (2). In Sweden, it amounts to 1.7 per 1000, while in BiH the prevalence of some DDH type is the highest in Europe and it amounts to 75 newborns per 1000 (3). Skokić et al. state, based on ultrasound examinations, that the prevalence of DDH in Tuzla amounts to 8.86% in the risk group, while it amounts to 48 per 1000 live births in the general population (4). These results show a somewhat higher prevalence in comparison with previous researches conducted in Tuzla, when DDH incidence amounted to 6.31% (5).

This research has showed that clinical examination of the hips is of low sensitivity, specificity and reliability, and that it cannot detect all types of DDH. Still, even such concept has yielded significant results, but a greater number of children with DDH were detected only after the fourth month of life and later, when the diagnosis was confirmed by the x-ray of the hips (14).

Past experiences with the application of ultrasound in DDH have showed that ultrasound can be applied in screening (4, 5). Ultrasound can detect all types of DDH as early as in the maternity ward, and repeated ultrasound examinations at certain intervals may separate those hips that are developing normally from those that are developing subluxations and luxations (5). Opinions on screening are still divided nowadays: some think that selective screening is completely sufficient (5, 6), while others are in favour of non-selective screening (4,10). Those in favour of selective screening feel that non-selective screening is impractical, costly and results in iatrogenous lesions during the treatment. We agree with those supporting non-selective screening because it is warranted in those countries where incidence is high. DDH, as a disease, meets the screening criteria, and ultrasound is the most comprehensive diagnostic method that meets the criteria for performing screening. Clinical and ultrasound examinations are nowadays used as screening tests for this disorder. The importance of ultrasound screening of the hips in the neonatal period is more and more stressed nowadays, so that DDH can be diagnosed in as many as 30% of children with primarily stable hips.

Conclusion

Analysing the incidence of DDH and establishing the deficiencies of clinical examination in detecting DDH requires taking urgent measures with a view to early detecting and treating this disorder.

This research has confirmed that the clinical examination of the hips does not meet the screening criteria. It must remain an integral part of an infant's examination because it, among other things, provides the information which allows the orthopaedic surgeon to choose the most beneficial therapeutic procedures in treating DDH.

If one transfers the concept of secondary prevention to DDH diagnostics, then the ultrasound screening of the hips should be accepted in the national programme for the prevention of this disorder as a mandatory examination of a newborn.

Ultrasound diagnostics is the method of choice for the non-selective screening for DDH.

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POUZDANOST I VALIDNOST KLINIČKOG I ULTRAZVUČNOG PREGLEDA RAZVOJNOG POREMEĆAJA KUKA

Predrag Grubor, Rade Tanjga i Milan Grubor

Razvojni poremećaj kuka (RPK) najčešća je urođena deformacija lokomotornog sistema, čiji je uspjeh liječenja usko povezan s ranom dijagnozom.

Cilj rada bio je da se ispita incidencija razvojnog poremećaja kuka (RPK) i analizira validnost kliničkog pregleda koji se koristi za rano otkrivanje RPK u neonatalnom periodu u odnosu na ultrazvučni pregled.

Ispitanike čine 400 novorođene djece rođene u banjalučkom regionu. Prilikom redovnog prvog ultrazvučnog i kliničkog pregleda kukova novorođenčadi otvarao se anketni listić u koji su unošeni anamnestički i klinički podaci: asimetrija glutealnih, ingvinalnih i femoralnih brazda (Badeov znak), rezultat abdukcionog testa posebno za svaki kuk, Ortolanijev luksacioni i Palmenov repozicioni znak, potom sonografija kukova. Korišćen je ultrazvučni aparat marke "Toshiba" sa linearnom sondom od 7,5 MHz. Primjenjivana je metoda po prof. Reinhard-u Graf-u.

Od ukupnog broja djece koja imaju pozitivan sonografski nalaz RPK, njih 63,16% ima jedan od kliničkih znakova RPK. Sposobnost kliničkog nalaza da identifikuje one bolesnike koji nemaju RPK i imaju negativan sonografski nalaz, iznosi 79,8%. Od ukupnog broja ispitanice djece koja imaju pozitivan klinički nalaz, samo 15,58% ima i sonografski pozitivan nalaz RPK.

Ovo istraživanje pokazalo je da je klinički pregled kukova niske senzitivnosti, specifičnosti i pouzdanosti i da se ne mogu otkriti svi oblici RPK. Klinički pregled mora i dalje ostati sastavni dio pregleda svakog dojenčeta, ali komplementarni dijagnostički postupak obavlja se ultrazvučnim pregledom. Ultrazvučni pregled RPK otvorio je nove mogućnosti i popunio prazninu koja je bila prisutna u nedostacima kliničkih testova, a ujedno smanjio broj rendgenskih pregleda kukova.

Ovo istraživanje je potvrdilo da klinički pregled kukova ne zadovoljava kriterijume za skrining. On i dalje mora ostati sastavni dio pregleda dojenčeta, jer između ostalog, pruža informaciju koja ortopedu omogućava najpovoljniji izbor terapijskih postupaka u liječenju RPK. *Acta Medica Medianae 2011;50(1):26-31.*

Ključne reči: *razvojni poremećaj kuka, klinički pregled, ultrazvučni pregled*