

DETECTION AND NONOPERATIVE MANAGEMENT OF PEDIATRIC DEVELOPMENTAL DYSPLASIA OF THE HIP IN INFANTS UP TO SIX MONTHS OF AGE

SUMMARY

American Academy of Pediatrics



DEDICATED TO THE HEALTH OF ALL CHILDREN[™]



The Pediatric Orthopaedic Society of North America





Disclaimer

This Clinical Practice Guideline was developed by an AAOS clinician volunteer Work Group based on a systematic review of the current scientific and clinical information and accepted approaches to treatment and/or diagnosis. This Clinical Practice Guideline is not intended to be a fixed protocol, as some patients may require more or less treatment or different means of diagnosis. Clinical patients may not necessarily be the same as those found in a clinical trial. Patient care and treatment should always be based on a clinician's independent medical judgment, given the individual patient's clinical circumstances.

OVERVIEW

This clinical practice guideline is based upon a systematic review of published articles related to the detection and early management of hip instability and dysplasia in typically developing children less than 6 months of age. This guideline provides practice recommendations for the early screening and detection of hip instability and dysplasia and also highlights gaps in the published literature that should stimulate additional research. This guideline is intended towards appropriately trained practitioners involved in the early examination and assessment of typically developing children for hip instability and dysplasia.

INTENDED USERS

This guideline is intended for use by appropriately trained practitioners involved in the medical evaluation of typically developing children less than 6 months of age. This would include pediatricians, family physicians, qualified mid-level practitioners with appropriate physician oversight, radiologists who perform diagnostic imaging of children, and orthopedic surgeons. Typically physicians will have completed medical training, a qualified residency in their specialty area and some may have completed additional subspecialty training. Mid-level providers would have completed a qualified training program in their specialty and would have additional training in the assessment of pediatric patients with appropriate supervision by a qualified physician pursuant to the laws of their practice environment. Allied health practitioners caring for children, practice managers, health care payers, governmental bodies, and health policy decision makers may also find this guideline useful as an evolving standard of evidence for the early diagnosis and management of DDH in typically developing children.

The early diagnosis and management of DDH is based upon the assumption that shared and informed decisions are made by the patient's guardians and the practitioner based upon a mutual communication and understanding of the available treatments and procedures applicable to the individual patient. Practitioner input based upon experience and knowledge of interpretation of clinical and imaging findings, conservative and surgical management options, and of additional accessible expertise increases the probability of optimally matching the right intervention to the right patient at the right time.

SUMMARY OF RECOMMENDATIONS

The following is a summary of the recommendations of the AAOS' clinical practice guideline on Detection and Nonoperative Management of Pediatric Developmental Dysplasia of the Hip in Infants up to Six Months of Age. This summary contains rationales that explain how and why these recommendations were developed; however, it does not contain the evidence reports supporting these recommendations. All readers of this summary are strongly urged to consult the full guideline and evidence report for this information. We are confident that those who read the full guideline and evidence report will see that the recommendations were developed using systematic evidence-based processes designed to combat bias, enhance transparency, and promote reproducibility.

This summary of recommendations is not intended to stand alone. Treatment decisions should be made in light of all circumstances presented by the patient. Treatments and procedures applicable to the individual patient rely on mutual communication between patient guardian, physician, and other healthcare practitioners.

UNIVERSAL ULTRASOUND SCREENING

Moderate evidence supports not performing universal ultrasound screening of newborn infants.

Strength of Recommendation: Moderate

RATIONALE

There is moderate evidence to <u>not</u> do universal screening of all infants for DDH. Two moderate strength studies showed no statistical difference between universal and selective ultrasound screening of the infant hip for diagnosis of late presenting DDH.^{1,2} Holen augmented clinical screening with either universal or selective (risk) ultrasound. The rate of late cases in Holen's study was 0.13/1000 with universal ultrasound screening and 0.65/1000 with selective (risk) screening. The difference in late detection was not statistically significant. Rosendahl used three matched study groups: general ultrasound screening, risk factor screening and only clinical screening. Late cases identified by group were 0.3/1000, 0.7/1000 and 1.3/1000 respectively and these differences were not statistically significant.

Screening of all infants with ultrasound has the potential to lead to over-treatment. Rosendahl's study found that general ultrasound screening resulted in a higher treatment rate (3.4%) than either selective ultrasound screening (2.0%) or clinical screening (1.8%). The higher rate with universal screening is statistically significant. Universal ultrasound screening requires considerable diagnostic and therapeutic effort and these studies which involve large numbers of newborns indicate that such a commitment of resources will not significantly impact the prevalence of late cases.

EVALUATION OF INFANTS WITH RISK FACTORS FOR DDH

Moderate evidence supports performing an imaging study before 6 months of age in infants with one or more of the following risk factors: breech presentation, family history, or history of clinical instability.

Strength of Recommendation: Moderate

RATIONALE

If the risk factors of family and/or breech presentation are present, there is moderate evidence to support selective ultrasound screening between 2-6 weeks of age for infants who otherwise have a normal clinical hip examination or an AP radiograph at 4 months of age. There were two studies of moderate strength that confirm significance for selective prospective screening by ultrasound in infants with history of possible clinical instability and/or risk factors: breech and family history to prevent late dislocations and need for surgery.^{16,17}

Of the 10 studies of low strength the various risk factors included were: breech, family history, sex, combination of sex and breech, combination of sex and family history, hip click, first born, swaddling, and talipes.

Breech literature included six studies all of low study strength. The results of these studies were meta-analyzed and the meta-analysis overwhelmingly supported breech presentation as a risk factor for neonatal instability. The literature terminology on breech is: breech at birth, breech delivery, and breech position at the third trimester; there is no literature to substantiate a particular duration of breech positioning as a risk factor.

Family history: four articles of low strength all showing statistical significance for family history as a risk factor for DDH.^{4,5,13,18} There was one study which showed no statistical significance. ³

One study compared treatment for dislocatable hips (at age less than one week) with no treatment for stable hips with positive family history. ⁸ The outcome was residual dysplasia at five months and was noted to be significant for the no treatment category. The authors further treated these patients from the no treatment category at age five months and compared them with the original cohort of Barlow positive patients treated at age less than one week. This time around, the outcome parameter was residual dysplasia at two years and was again noted to be significant. Other outcome measures included AVN at two years, which was not significant, and treatment failure, which was noted to be significant. This study did not have a true comparative group for analysis. There was a combination of dislocated and dislocatable hips in the Barlow positive category, which confounds the analysis.

The literature definitions of family history of DDH range from unspecified hip disorders to hip dislocation and from first degree relative (parents and siblings), to any relative

(even if distant or vague) with hip problems or DDH (all other articles). Three articles listed family history, but did not specify the relationships or specific hip problems.^{3,5,7}

One study compared ultrasound screening in infants who had risk factors alone with those who had "doubtful" clinical instability.¹⁷ Rate of detection of dislocation as confirmed by ultrasound was 13/1000 (7 to 24) vs 87/ 1000 (57 to 126/1000) respectively.

There is no substantiation in the literature of the optimal age for imaging studies in these infants with risk factors.⁸ One study performed hip radiographs at 4 months of age. Two studies^{14, 15} performed ultrasound between 2-6 weeks of age.

Examination of other quoted risk factors was done. Evidence was not found to include foot abnormalities, gender, oligohydramnios, and torticollis as risk factors for DDH.

IMAGING OF THE UNSTABLE HIP

Limited evidence supports that the practitioner might obtain an ultrasound in infants less than 6 weeks of age with a positive instability examination to guide the decision to initiate brace treatment.

Strength of Recommendation: Limited ***

RATIONALE

If faced with an unstable hip examination, there is limited evidence to support the use of sequential ultrasound to aid in determining when to initiate brace treatment for infants up to 8 weeks of age. Fewer children may undergo brace treatment with no difference in the occurrence of late dysplasia. One moderate strength study showed fewer children in the ultrasound group had abduction splinting in the first two years than did those in the no ultrasound group (0.78; 0.65-0.94; p=0.01).¹⁹ The primary outcome was the appearance on hip radiographs by two years. Secondary outcomes included surgical treatment, abduction splinting, level of mobility, resource use, and costs. Analysis was by intention to treat. Protocol compliance was high, and radiographic information was available for 91% of children by 12–14 months and 85% by 2 years. By age 2 years, subluxation, dislocation, or acetabular dysplasia were identified by radiography on one or both hips of 21 children in each of the groups (relative risk 1.00; 95% CI 0.56–1.80).

Surgical treatment was required by 21 infants in the ultrasound group (6.7%) and 25 (7.9%) in the no-ultrasound group (0.84; 0.48-1.47). One child from the ultrasound group and four from the no-ultrasound group were not walking by 2 years (0.25; 0.03-2.53; p=0.37). Initially this study was graded as high strength, but was downgraded to moderate strength because the rate of splint treatment was not the primary outcome. Additionally, it is unclear that all subjects were normal infants with DDH and no confounding diagnoses.

In this study infants with hips that had minor instability were not immediately treated. Experienced doctors performed the clinical examinations. Even though there is even distribution between the groups in terms of number of history of instability, subgroup analysis of dislocated versus dysplastic hip results were not available.

IMAGING OF THE INFANT HIP

Limited evidence supports the use of an AP pelvis radiograph instead of an ultrasound to assess DDH in infants beginning at 4 months of age.

Strength of Recommendation: Limited ***

RATIONALE

There is limited evidence that an AP pelvis radiograph is preferred to the use of ultrasound to assess for DDH in infants from 4-6 months of age. This evidence does not distinguish between children with normal or abnormal physical examinations or between children with and without risk factors for DDH. One moderate-strength study investigated the radiographic assessment of every ultrasound positive hip in children four to six months of age.²⁰ Seventy-four infants with ultrasound positive hips for acetabular dysplasia who met criteria for treatment received an AP pelvis radiograph. Of these 74 infants, 30 were found to have satisfactory acetabular indices and did not receive treatment.

Limitations of this study include the lack of long-term follow-up of the infants to determine if the radiographic assessment altered outcome and failed to address the optimal time of conversion from ultrasound to radiographic assessment in infants with DDH.

SURVEILLANCE AFTER NORMAL INFANT HIP EXAM

Limited evidence supports that a practitioner re-examine infants previously screened as having a normal hip examination on subsequent visits prior to 6 months of age.

Strength of Recommendation: Limited

RATIONALE

If faced with a child who has a normal physical examination, there is limited evidence that performing subsequent hip physical examination screening of children up to 6 months of age will detect additional children with DDH. The reviewed literature does not include the screening of children up to walking age when other examination findings such as gait abnormalities may allow for detection of additional children with DDH. One low strength study presented evidence that repeated studies at three months were productive in identifying late diagnosed DDH. ²² Another low strength study noted that exams at eight months of age had a high rate of false positives, but no yield of true positives.²¹

There is no literature to define the optimal frequency or duration of follow-up surveillance.

STABLE HIP WITH ULTRASOUND IMAGING ABNORMALITIES

Limited evidence supports observation without a brace for infants with a clinically stable hip with morphologic ultrasound imaging abnormalities.

Strength of Recommendation: Limited ***

RATIONALE

For an infant with a normal physical examination and ultrasound abnormalities, there is limited evidence to support observation without treatment of that infant with serial ultrasound evaluation up to 6 weeks of age. One low-strength study evaluated a group of at-risk patients who were evaluated by ultrasound between two and six weeks of age with clinically stable hips showing ultrasonographic abnormalities that were randomized to treatment with Pavlik harness or observation. ²³ The two primary outcome measures were the acetabular coverage on ultrasound and acetabular index on radiograph. While acetabular coverage, measured ultrasonographically, improved in both groups, and was statistically better in the splinted group at the final, three month follow-up, there was no difference in acetabular index.

TREATMENT OF CLINICAL INSTABILITY

Limited evidence supports either immediate or delayed (2-9 weeks) brace treatment for hips with a positive instability exam.

Strength of Recommendation: Limited $\star\star\star\star\star$

RATIONALE

For infants with a positive hip instability exam, there is conflicting evidence about whether a period of observation or immediate brace treatment leads to a difference in later dysplasia or persistent hip instability leading to later brace treatment. One moderate strength and three low strength studies looked at radiographic differences between an early versus late brace treatment group. ^{24, 25} (follow-up), 26, 27, 28</sup> None of these studies differentiate dislocated from dislocatable hips.

Gardiner found a significant difference in the radiographic appearance of the femoral capital epiphysis and delayed iliac indentation at 6 months for a no treatment group compared to a brace group.²⁵ Twenty-nine percent of the non-treatment group had cross-over and were treated at two weeks. Limitations were not defining the femoral capital

epiphyseal ossification subcategories and iliac indentation and not explaining the relevance of either.

Molto compared Von Rosen splinting immediately after birth to splinting after two weeks. ²⁶ The outcome criterion was acetabular index. They noted a significant improvement in the acetabular index at 15 months in the immediate treatment group (76 patients) as compared to the 27 patients in the second group treated after two weeks.

Paton reported on 75 hips in 2 groups, including 37 patients (59 hips) in the early splint treatment group versus 11 patients (16 hips) in the late splint treatment group.²⁷ Outcome measures included continued instability that required late splint treatment after six weeks, radiographic abnormality, AVN, or surgical intervention at walking age. Authors noted no significant differences when treatment started at less than one week in the early treatment group versus nine weeks on average in the delayed treatment group. This study included both dislocatable and dislocated hips with outcome measures not specifically correlated to the nature of the instability.

TYPE OF BRACE FOR THE UNSTABLE HIP

Limited evidence supports use of the von Rosen splint over Pavlik, Craig, or Frejka splints for initial treatment of an unstable hip.

Strength of Recommendation: Limited ***

RATIONALE

There are no high quality comparative effectiveness studies between different types of braces for the treatment of DDH. Limited evidence suggests that rigid braces may have higher rates of resolution of hip dysplasia than non-rigid braces. Two low strength studies compared rigid bracing to soft bracing for initial treatment of unstable hips in infants. ^{29,30} Heikkila compared the Frejka pillow with the von Rosen splint. ²⁹ There were 920 patients treated with Frejka pillow and 180 patients treated with von Rosen splint. Fifty-five of 920 from the Frejka pillow group had treatment failure, while 1 out of 180 from the von Rosen splint group failed treatment. These differences were significant. A limitation of this study is that it was a historical comparative study of two cohorts over two time periods. AVN rates were inadequately reported. The authors did not differentiate between dislocated and dislocatable hips.

Three splints were compared in the Wilkinson study: Craig, Pavlik, and von Rosen.³⁰ Four of 28 in the Craig splint group, 13 of 43 in the Pavlik group, and 0 of 26 in the von Rosen group required further treatment in the form of plaster or operation.

This recommendation is based on the braces that were studied, but other similar fixedposition braces may or may not work as well as the braces mentioned in the evidence.

MONITORING OF PATIENTS DURING BRACE TREATMENT

Limited evidence supports that the practitioner perform serial physical examinations and periodic imaging assessments (ultrasound or radiograph based on age) during management for unstable infant hips.

Strength of Recommendation: Limited $\star\star\star\star\star$

RATIONALE

If brace treatment is initiated, there is limited evidence that episodic serial physical and imaging reassessments during the treatment cycle can lead to changes or duration of the treatment plan. Two low strength studies report monitoring of brace treatment using physical exam, ultrasound, and radiography following the appearance of the ossific nucleus.^{31,32} Both studies identified failure of reduction or persistent dysplasia in patients undergoing brace treatment. These findings necessitated a change in treatment plan or duration. No parameters for optimal timing or frequency of imaging were established by research protocol.