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Timing of Repeat Ultrasound Examination in Treatment of Stable Developmental Dysplasia of the Hip

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Background: Worldwide a wide variation exists in duration of Pavlik harness treatment for infants up to 6 months with stable developmental dysplasia of the hip (DDH). The purpose of this study was to evaluate whether shortening the time to first routine follow-up ultrasound after initiation of Pavlik harness treatment would reduce treatment duration and whether this influenced radiologic outcome at 1 year of age. Furthermore, predictors of higher acetabular index (AI) at 1 year of age were investigated.
Methods: A retrospective study was conducted in infants with stable DDH (Graf IIb and IIc) diagnosed and treated between 2015 and 2017. Two groups were identified: first routine follow-up ultrasound at 12 weeks after Pavlik harness initiation (group I) and first routine follow-up ultrasound at 6 weeks after Pavlik harness initiation (group II). In both groups, treatment was continued until repeat ultrasound measurements (every 6 wk) showed a normalized hip. Radiologic outcome at 1 year of age was defined as residual dysplasia measured on an anteroposterior hip radiograph according to the Tönnis table.
Results: A total of 222 infants were included. The median time of Pavlik harness treatment was 12 weeks (interquartile range, 11.9 to 12.3) in group I compared with 6.1 weeks (interquartile range, 6.0 to 7.5) in group II ($P < 0.001$). Residual dysplasia at 1 year of age was detected in 20 infants (16.8%) in group I compared with 11 infants (10.7%) in group II ($P = 0.189$). The multivariable prediction model showed that positive family history and lower baseline alpha angle correlate with a higher AI at 1 year of age.
Conclusions: First routine follow-up ultrasound can be safely brought forward from 12 to 6 weeks after Pavlik harness initiation. Furthermore, infants with a positive family history for DDH and an initial low alpha angle are at higher risk to have a higher AI at 1 year of age.
Level of Evidence: Level III—retrospective study.

Key Words: developmental dysplasia of the hip, hip dysplasia, DDH, Pavlik harness, residual dysplasia

(*J Pediatr Orthop* 2021;41:203–208)

Developmental dysplasia of the hip (DDH) is one of the most common disorders in the pediatric population. Annual incidence of DDH ranges between 1% and 4% in infants up to 6 months of age in The Netherlands.[1] General risk factors for DDH are female gender, positive family history for DDH, breech birth, and swaddling of the child.[2,3] Early identification and treatment are important, as untreated DDH might cause cartilage damage leading to osteoarthritis in early adulthood.[4]

Worldwide different screening programs for DDH have been introduced.[5] The Dutch youth health care DDH guideline recommends ultrasound screening to be performed at the age of 3 months in infants with certain risk factors for DDH (positive family history of DDH or breech position >32 wk of pregnancy) or abnormalities during physical examination.[6] Once diagnosed with DDH by an orthopaedic surgeon, treatment of choice in the first 6 months of life consists of a dynamic flexion abduction device such as the Pavlik harness.[7,8] Pavlik harness treatment is one of the most effective treatment modalities for stable DDH in infants below 6 months of age with a success rate of up to 85%.[9,10] Optimal duration of treatment remains controversial for patients with stable dysplastic hips (Graf IIb and IIc). A worldwide survey among orthopaedic surgeons showed that the most frequent duration of Pavlik harness usage was 12 weeks for those who based treatment on a predefined duration.[11] Recently, a treatment algorithm for the treatment of DDH with the Pavlik harness was proposed, which stated that Graf IIb and IIc hips should be treated by a dynamic abduction device for a maximum duration of 8 weeks.[7] A survey among Dutch orthopaedic surgeons revealed a median treatment time of 2 months with the Pavlik harness in children up to 6 months of age.[12] Shortening Pavlik harness treatment duration could be beneficial to reduce the treatment burden

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None of the authors received financial support for this study.
W.W.E.S.T.: study design, data collection/measurements, statistical analyses, and manuscript preparation. M.vdS.: study design, statistical analyses, and manuscript preparation. F.Q.M.P.vD.: data collection and critical reviewer. A.M.A.W.: data collection and critical reviewer. J.J.T.: study design, data collection/measurements, statistical analyses, and manuscript preparation.
The authors declare no conflicts of interest.
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DOI: 10.1097/BPO.0000000000001766

for patients and their families. As a consequence, the risk of dynamic abduction device complications such as avascular necrosis (AVN) and femoral nerve palsy might be diminished.[13,14] As no comparative studies on long-term results of the different treatment algorithms with Pavlik harness are available, the optimal approach is still to be determined.

Because the ideal timing for repeat ultrasound after the start of Pavlik harness treatment for stable DDH is unknown and potentially influence treatment duration, the present study was conducted. We aimed to evaluate whether a first follow-up ultrasound at 6 weeks after initiation of Pavlik harness treatment instead of after 12 weeks reduced treatment duration. Furthermore, we aimed to analyze whether this protocol change influenced the percentage of infants with residual dysplasia at 1 year of age. We hypothesized that the protocol change reduced treatment duration without influencing radiologic outcome at 1 year of age. Moreover, in an exploratory analysis, we looked for potential predictors of a high acetabular index (AI) at 1 year of age as a measure of residual dysplasia.

METHODS

A retrospective study was conducted on infants who were evaluated for DDH at the Máxima MC (Veldhoven, The Netherlands) between 2015 and 2017. In line with the Dutch DDH guideline, infants with certain risk factors for DDH (positive family history for DDH or hip osteoarthritis less than 50 y of age or breech position > 32 wk of pregnancy) or abnormalities on physical examination (hip abduction < 70 degrees or side to side hip abduction difference ≥ 20 degrees) were referred to the pediatric orthopaedic surgeon at the age of 3 months.[6] In case of premature birth, the referral age was corrected by calculating the chronological age in weeks minus the number of weeks of prematurity. All referred infants were screened with ultrasound imaging by trained radiologists and at presentation at the Máxima MC physically examined and classified according to the Graf classification by one of 3 pediatric orthopaedic surgeons.[15] Inclusion criteria for this study were corrected age between 3 and 4 months at the moment of first hip ultrasound, stable DDH (Graf IIb or IIc) on ultrasonographic imaging, and treated with a Pavlik harness. Both infants with unilateral and bilateral stable DDH were eligible for inclusion. Infants over 4 months of age and infants with syndromic disorders were excluded. Infants who missed ultrasonographic confirmation of a normalized hip or 1-year follow-up were removed from this study. The Medical Ethical Committee at the Máxima MC approved the execution of this study (METC 2019-006).

Halfway through 2016, the Máxima MC treatment protocol for stable DDH was altered, in line with Dutch consensus on treatment of DDH. The timing of the first follow-up ultrasound measurement was brought forward from 12 to 6 weeks after initiation of Pavlik harness treatment. The rest of the treatment protocol remained unchanged with the advice to wear the Pavlik harness for a minimum of 23 hours a day.

In infants who met the inclusion criteria, 2 groups were identified. The first group included infants with a first follow-up ultrasound after 12 weeks of Pavlik harness initiation. The second group included infants with a first follow-up ultrasound after 6 weeks of Pavlik harness initiation. After 2 weeks, a routine follow-up appointment in the hospital was scheduled for adjustment of the Pavlik harness by a specialized pediatric nurse. In both groups, ultrasound examination was repeated every 6 weeks, and treatment was continued until routine follow-up ultrasound measurements showed a normalized hip (Graf type I). In the case of bilateral stable DDH, Pavlik harness treatment was continued until both hips normalized on ultrasonographic imaging. In both groups, a routine outpatient visit with an anteroposterior pelvic radiograph was scheduled at 1 year of age.

Patient charts were retrospectively reviewed. Patient characteristics (birth date, firstborn child, cesarean section, preterm birth, and twins), affected hip (left, right, or bilateral), general risk factors for DDH[2,3] (gender, positive family history in first-/second-degree relative for DDH or hip osteoarthritis less than 50 years of age, breech presentation > 32 weeks of pregnancy and swaddling of the child), and physical examination [abduction in degrees, leg length discrepancy (Galeazzi test), Barlow and Ortolani sign] were collected from the infants' medical file. Ultrasound examination was performed by trained radiologists and classified by 1 specifically trained researcher and 1 specifically trained orthopaedic resident, based on the Graf classification (α-angle, β-angle, and bony rim).[15] At routine follow-up appointments, physical examination (abduction in degrees) and ultrasound examination were repeated. At the 1-year follow-up appointment, physical examination (abduction in degrees) and an anteroposterior pelvic radiograph [Shenton's line, AI and International Hip Dysplasia Institute (IHDI) classification] were performed.[16] Treatment duration was rated as the total amount of weeks spent in the Pavlik harness. The success rate at 1 year of age was defined as the percentage of infants without residual dysplasia on the anteroposterior pelvic radiograph. Residual dysplasia was based on the AI and defined as an AI > 2 SD above the value expected for the age, gender, and side, as defined by Tönnis; mild residual dysplasia was defined as an AI 1 to 2 SD.[17] Medical records and radiographs were reviewed to monitor complications such as AVN and femoral nerve palsy. The Kalamchi-MacEwen classification system was used to determine the rate of AVN.[18]

Statistical analysis was conducted using SPSS Statistics V.22.0 (IBM Corp, Armonk, NY). Baseline characteristics were presented as mean with SDs for continuous variables and counts with percentages for discrete variables. Descriptive statistics were calculated for baseline characteristics of all infants in group I, first follow-up ultrasound at 12 weeks, and group II, first follow-up ultrasound at 6 weeks. Unpaired sample *t* test and χ^2 test were used to compare baseline characteristics between the subgroups. The assumption of normality was checked with the Kolmogorov-Smirnov test and a scatterplot was used to visualize the distribution. To examine whether the protocol change reduced treatment duration, we performed a Mann-Whitney U test. A χ^2 test was used to compare (mild) residual dysplasia, Shenton's line, and IHDI grade at 1 year of age between the 2 groups. To identify predictors for residual dysplasia at 1 year of age, linear regression

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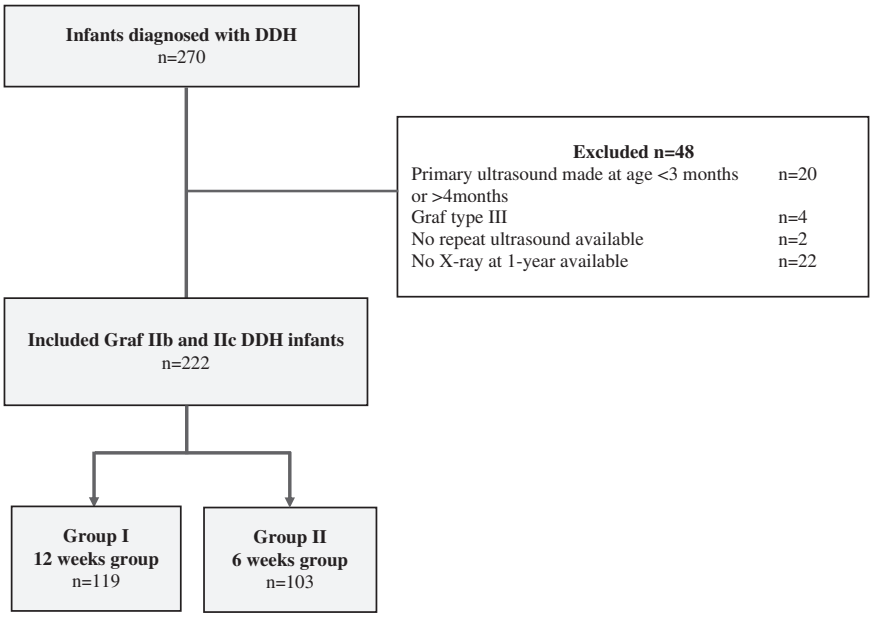

FIGURE 1. Flowchart of selected infants with stable developmental dysplasia of the hip (DDH) divided into 2 groups.

analysis was performed. AI at 1 year of age was chosen as a dependent variable. As independent variables, we included affected side, gender, family history of DDH in first-degree or second-degree relative, breech position >32 weeks of pregnancy, firstborn child, swaddling, twins, alpha angle at an initial ultrasound, and duration of treatment. First, univariable linear regression analysis was performed with a significance set at a $P < 0.05$. Subsequently, significant variables from the univariable linear regression analysis were applied in a multivariable linear regression analysis. A statistical significance level was set at $P < 0.05$

RESULTS

During the study period, a total of 270 infants were diagnosed with DDH. Of this series, 222 infants met the inclusion and exclusion criteria. The first group, including infants with the first follow-up ultrasound after 12 weeks of Pavlik harness initiation, consisted of 119 infants. The second group, including infants with the first follow-up ultrasound after 6 weeks of Pavlik harness initiation, was composed of 103 infants (Fig. 1). The baseline characteristics of the study population are reported in Table 1. The mean age of the first hip ultrasound was at 3.6 ± 0.5 months. The vast majority of the infants were female (83%) and a predominance of left-sided DDH (56%) was seen. Graf IIb (85%) was observed more frequently than Graf IIc (15%). Regarding baseline characteristics, no significant differences between the 2 groups were present ($P > 0.05$).

Treatment Duration in Pavlik Harness

The DDH protocol change led to a decrease in the time spent in the Pavlik harness. The median time of Pavlik harness treatment was 12.0 weeks (interquartile range, 11.9 to 12.3) in the group with the first follow-up ultrasound at 12 weeks compared with 6.1 weeks (interquartile range, 6.0 to 7.5) in the group with the first follow-up ultrasound at 6 weeks after Pavlik harness treatment ($P < 0.001$). In the group with the first follow-up ultrasound at 12 weeks after Pavlik harness treatment initiation, 109 infants (91.6%) normalized to Graf I after

TABLE 1. Baseline Characteristics of the Study Population

	First Ultrasound at 12 wk (N = 119)	First Ultrasound at 6 wk (N = 103)	*P*
Age first ultrasound, mo	3.6 ± 0.5	3.5 ± 0.5	0.59
Sex			0.95
Female	99 (83%)	86 (83%)	
Affected side			0.05
Right	44 (37%)	23 (22%)	
Left	58 (49%)	66 (64%)	
Bilateral	17 (14%)	14 (14%)	
Family history of DDH	59 (50%)	45 (44%)	0.38
Breech position	41 (34%)	50 (49%)	0.10
First born child	35 (29%)	45 (44%)	0.08
Cesarean section	11 (9%)	6 (6%)	0.26
Preterm birth (< 37 wk)	4 (3%)	0 (0%)	0.06
Twins	2 (2%)	2 (2%)	0.94
Swaddling	0 (0%)	1 (1%)	0.30
Graf type			0.10
Graf type IIb	97 (82%)	92 (89%)	
Graf type IIc	22 (18%)	11 (11%)	
Alpha angle, degrees	53.1 ± 4.6	54.2 ± 3.9	0.07

Data presented as n (%) or mean ± SD.
DDH indicates developmental dysplasia of the hip.

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TABLE 2. Radiological Outcomes at 1 Year of Age

	First Ultrasound at 12 wk	First Ultrasound at 6 wk	*P*
Residual dysplasia	20 (16.8%)	11 (10.7%)	0.189
Mild residual dysplasia	33 (27.7%)	32 (31.1%)	0.586
Mean Acetabular Index (deg.)	24.8 ± 4.2	25.2 ± 4.0	0.471
Shenton's line disrupted	21 (17.6%)	16 (15.5%)	0.674
IHDI classification			0.351
Grade I	111 (93.3%)	99 (96.1%)	
Grade II	8 (6.7%)	4 (3.9%)	
Grade III	0 (0%)	0 (0%)	
Grade IV	0 (0%)	0 (0%)	

Values reported as n (%) or mean ± SD.
IHDI indicates International Hip Dysplasia Institute.

12 weeks of treatment, whereas 9 infants (7.6%) normalized after 18 weeks and 1 infant (0.8%) after 24 weeks of treatment. In the group with the first follow-up ultrasound at 6 weeks after Pavlik harness treatment initiation, 84 infants (81.6%) normalized to Graf I after 6 weeks of treatment, whereas 18 infants (17.5%) normalized after 12 weeks and 1 infant (0.9%) after 18 weeks of treatment.

Residual Dysplasia

Residual dysplasia at 1 year of age was detected in 31 infants (14%); 20 infants (16.8%) in the 12 weeks control ultrasound group and 11 infants (10.7%) in the 6 weeks control ultrasound group. No statistically significant difference was seen after DDH treatment protocol change in terms of residual dysplasia ($P = 0.189$). Also, in other radiologic parameters related to treatment success, no differences between the 2 groups were seen (Table 2).

Complications

One case of AVN of the femoral head was seen (grade I). This patient had a Pavlik harness treatment duration of 18 weeks, after an initial first follow-up ultrasound after 6 weeks of treatment. AVN was detected after Pavlik harness treatment at the age of 1 year and a wait-and-see policy was initiated.

Prediction of AI at 1 Year of Age

In the univariable linear regression analysis, positive family history for DDH ($P = 0.04$) and low pretreatment alpha angle ($P = 0.03$) were seen as significant predictors for a higher AI at 1 year of age (Table 3). Subsequently, these 2 variables were added into a multivariable model, where both positive family history for DDH ($P = 0.03$) and low pretreatment alpha angle ($P = 0.02$) remained significant predictor variables. The multivariable model, containing these 2 variables, had an R^2 of 0.043.

DISCUSSION

The main finding of the present study is that the first routine follow-up ultrasound can be safely brought forward from 12 weeks to 6 weeks after Pavlik harness initiation. This protocol change leads to a decrease of time spent in the Pavlik harness with comparable numbers of residual dysplasia at 1 year of age. In addition, we showed that infants with a positive family history for DDH and a low alpha angle at initial ultrasound are predisposed to a higher AI at 1 year of age.

Evidence on optimal treatment duration with the Pavlik harness of infants with stable DDH is lacking. The change in treatment protocol in the Máxima MC, in which the ultrasonographic monitoring was brought forward from 12 weeks to 6 weeks after Pavlik harness treatment initiation, was introduced halfway through 2016. A survey in 2018 among Pediatric Orthopaedic Society of North America and European Pediatric Orthopaedic Society members revealed that respondents who treat on a predefined duration, the most frequent treatment duration was 12 weeks.[11] Based on a recent qualitative study addressing expert opinion, a group of worldwide experts on DDH advised a minimum of 6 weeks of Pavlik harness treatment in stable DDH, with ultrasound monitoring every 4 to 6 weeks.[19] The present study shows that the change in treatment protocol in the Máxima MC led to a significant decrease of time spent in the Pavlik harness with a constant number of residual dysplasia at 1 year of age. As the protocol change was introduced at a specific point in time, namely July 1, 2016, selection bias was avoided. Our study shows that the first follow-up ultrasound can safely be brought forward from 12 weeks to 6 weeks

TABLE 3. Predictors of Higher Acetabular Index at 1 Year of Age

	Univariable Analysis		Multivariable Analysis	
	Regression Coefficient (95% CI)	*P*	Regression Coefficient (95% CI)	*P*
Bilateral DDH	1.49 (−0.10 to 3.08)	0.07	—	—
Sex male	−1.33 (−2.76 to 0.11)	0.07	—	—
Family history	1.09 (0.01 to 2.16)	0.04	1.23 (0.16 to 2.30)	0.03
Breech position	−0.31 (−1.42 to 0.80)	0.59	—	—
First born	−0.19 (−1.38 to 0.99)	0.75	—	—
Swaddling	0.86 (−7.28 to 8.99)	0.84	—	—
Twin	−2.95 (−7.02 to 1.13)	0.16	—	—
Alpha angle	−0.13 (−0.26 to −0.01)	0.03	−0.15 (−0.27 to −0.03)	0.02
Duration treatment	0.02 (−0.15 to 0.18)	0.86	—	—

CI indicates confidence interval; DDH, developmental dysplasia of the hip.

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without influencing radiologic outcome at 1 year of age and without affecting complication rates.

Worldwide Pavlik harness treatment has gained widespread acceptance. Nevertheless, residual acetabular dysplasia develops in 12% of infants at 1 year of age, who achieve a normalized hip (Graf type I) on ultrasound measurements after Pavlik harness treatment.[20] Identification of the subset of infants who develop residual dysplasia despite adequate treatment is essential because of its association with decreased family satisfaction and osteoarthritis in early adulthood. Therefore, it is of major importance to look for potential predictors for residual dysplasia to intervene in an early stage and to determine a defined follow-up protocol for this subset of infants. Limited research has been performed on predictors of a high AI at 1 year of age in stable DDH. Novais et al[20] reported that infants with Graf type IV at diagnosis were at higher risk of residual dysplasia at 1 year of age. In addition, Alexiev et al[21] mentioned an alpha angle < 43 degrees at initial ultrasound as a potential predictor for residual dysplasia after 5 years of follow-up. The main differences compared with our study were the mean starting age of Pavlik harness treatment at 16 days of age, mean duration of treatment of 8 weeks, and a more severe Graf subtype that is associated with a higher chance of residual dysplasia at later age. Still, our results are in line with this study regarding the initial alpha angle as a predictor for residual dysplasia. The lower the alpha angle before treatment, the higher the AI at 1 year of age. We did not identify a specific cutoff value, but in general, this suggests that Graf IIc hips are at higher risk of residual dysplasia compared with Graf IIb hips. Lerman et al[22] indicated bilateral DDH as a potential predictor for Pavlik harness treatment failure. In the present study, bilateral DDH did not show to be a significant predictor for a higher AI at 1 year of age. In a larger study population, bilaterality could potentially be identified as a predictor for higher AI at 1 year of age.

An important question for future research remains if treatment by Pavlik harness alters the natural history of stable dysplastic hips.[23] The finding that the duration of Pavlik treatment does not influence the number of patients with residual dysplasia adds to this discussion. Recent research by Pollet and colleagues indicates that Pavlik treatment is not of added value for well-centered dysplastic hips, as the vast majority of these hips tend to normalize during growth.[24,25] In contrast, 20% of the stable dysplastic hips in the study by Pollet and colleagues did eventually received treatment. Furthermore, a considerable proportion of patients with stable dysplastic hips do develop residual dysplasia.[21,26] This is echoed in the results of the present study. Therefore, there is a need for a better understanding of the working mechanism of Pavlik treatment as well as increased ability to separate hips that would benefit from treatment, from those that will have a favorable course without. The finding in this study that a positive family history and an initial low alpha angle are predictive of a higher AI at follow-up implies that these groups of patients could belong to a subgroup that does need treatment. More research on this subject is warranted.

Our study has several limitations. First, we acknowledge that the full success rate of Pavlik treatment requires long-term follow-up, whereas we focused on results at 1 year of age. Although long-term follow-up is desirable, it has been shown that solely 3% of the infants with normal clinic and radiographic hips at walking age develop residual dysplasia in early adolescence.[20] Still, the general recommendation is to continue radiographic monitoring until skeletal maturity.[20] Therefore, long-term follow-up of DDH is warranted. Second, a certain extent of variability in the measurement of alpha angles on ultrasound imaging can affect the results. Previous research from our research team on a subset of the first 40 patients included in this study showed excellent intraobserver and interobserver agreement (ICC = 0.935 and 0.940, respectively). This is in line with previous research on this subject.[27,28]

In conclusion, our data suggest that the first routine follow-up ultrasound can be safely brought forward from 12 weeks to 6 weeks after Pavlik harness initiation in stable DDH. This leads to a shorter treatment duration that lowers the treatment burden for patients and parents. Both a positive family history for DDH and an initial low alpha angle are risk factors for a higher AI at 1 year of age.

ACKNOWLEDGMENTS

The authors thank Lisa Vos and Bo Ceelen for their assistance in data acquisition in this study.

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