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CLINICAL RESEARCH

Higher Pavlik Harness Treatment Failure Is Seen in Graf Type IV Ortolani-positive Hips in Males

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Abstract

Background Patients with developmental dysplasia of the hip (DDH) whose hips are dislocated but reducible (Ortolani positive) are more likely to experience Pavlik harness treatment failure than are patients with dysplastic and reduced but dislocatable (Barlow positive) hips. However, data regarding factors associated with failure are limited and conflicting.

Questions/Purposes We asked: (1) What is the frequency of Pavlik harness treatment failure among Ortolani-positive hips, Barlow-positive hips, and dysplastic hips? (2) What are the factors predictive of failure of Pavlik harness treatment for Ortolani-positive hips?

Methods In this retrospective study we identified 150 patients who underwent the Pavlik harness method for treatment of DDH between August 2011 and July 2015. Six patients initially treated at an outside facility, four patients with associated conditions, and three who pursued treatment elsewhere were excluded. A total of 137 patients (215 hips) with a median age at the time of Pavlik placement of 30 days (range, 4–155 days) were included. Of the 215 hips, 78 (36.3%) were Ortolani positive, 60 (27.9%) were Barlow positive, and 77 (35.8%) were stable, with the diagnosis of dysplasia made on ultrasound. All patients were treated with the Pavlik harness method. The primary outcome was failure of the Pavlik harness to achieve and maintain concentric hip reduction assessed by examination and ultrasound. All patients were followed after completion of Pavlik treatment for a minimum of 2 months (mean, 3 months; range, 2–4 months). In addition, 90% (122 of 137) of the patients were followed for a minimum of 6 months. Patient-specific data including family history, breech versus cephalic presentation at birth, age, sex, laterality, and hip abduction were recorded. Ultrasound data at the time of diagnosis included Graf classification, alpha angle, and percentage of femoral head coverage.

Results The Pavlik harness method failed in 27% (21 of 78) of hips that were Ortolani positive, 8% (six of 77) with dysplasia, and 5% (three of 60) that were Barlow positive. After controlling for potential confounding variables, such as range of hip abduction, male sex (adjusted odds ratio

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Each author certifies that his or her institution approved the human protocol for this investigation, that all investigations were conducted in conformity with ethical principles of research, and that informed consent for participation in the study was obtained.
This work was performed at Children's Hospital Colorado, Aurora, CO, USA.

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[OR], 6.9; 95% CI, 2.0–24.2; p = 0.002) and Graf Type IV ultrasound classification (dislocated hip with alpha angle less than 43° and labrum displaced downward) (OR, 4.4; 95% CI, 1.3–15.4; p = 0.019) were identified as independent predictors of failure of Pavlik treatment among Ortolani-positive hips.

Conclusions Ultrasound imaging of the hip should be part of the initial assessment for Ortolani-positive hips, as the ultrasound classification was found to have prognostic implications. Parents of male infants with Graf Type IV hips should be counseled regarding the higher risk of Pavlik failure. Future well-designed prospective controlled studies are necessary to establish whether alternative strategies to the Pavlik harness might improve the early outcomes of DDH in males with Graf Type IV hips.

Level of Evidence Level III, therapeutic study.

Introduction

The Pavlik harness [21–23] is a common orthosis used to treat developmental dysplasia of the hip (DDH) in patients younger than 6 months. Greater than 90% success may be expected in hips that are stable on examination but dysplastic on ultrasound images [8] and for those dislocatable with the Barlow [3] maneuver [6, 12, 14, 25]. However, treatment failures of 30% to 60% have been reported in dislocated reducible Ortolani-positive hips [2, 14, 16, 19, 20, 24, 30–32]. Failure of the Pavlik harness method has been associated with an increased risk of osteonecrosis of the femoral head [29]. Continuous use of the harness in the setting of clinical failure may create an anatomic deformity of the posterolateral aspect of the acetabulum. This so-called "Pavlik harness disease" aggravates the acetabular dysplasia and makes closed reduction difficult [11]. Prolonged use of the harness in hips that remain dislocated also might create adherence of the femoral head to the posterior capsule, which may result in the decision to perform an open reduction [28]. Therefore, it is crucial to identify factors that might better predict failure of Pavlik harness treatment to possibly avoid such complications, allow for early consideration of an alternative form of treatment, and to set realistic expectations with each patient's family.

Previous studies have described clinical and ultrasound parameters that define failure of the Pavlik harness treatment method of Ortolani-positive hips [13, 14, 18, 19, 27]. However, there are conflicting results regarding age [13, 14, 31, 32], sex [4, 13, 14, 31, 32], bilaterality [10, 14, 20, 31], and ultrasound findings at initial examination [10, 16, 19, 24, 28, 30, 32]. Methods of data collection in these previous retrospective studies have varied, and they did not address the full spectrum of potential factors that may lead to failure such as detailed patient and family history, physical examination, and ultrasound findings.

We therefore investigated the results from a dedicated pediatric hip clinic to ask: (1) What is the frequency of Pavlik harness failure observed on ultrasound imaging among Ortolani-positive, Barlow-positive, and stable dysplastic hips? (2) What are the factors predictive of failure of Pavlik harness treatment for Ortolani-positive hips?

Patients and Methods

After obtaining institutional review board approval, our hospital's (Children's Hospital Colorado) electronic medical record system was queried to identify patients treated for DDH with a Pavlik harness from August 2011 to July 2015. August 2011 was used to define the start of our retrospective cohort because it represented the time when a dedicated hip clinic was established at Children's Hospital Colorado. The hip clinic included one fellowship-trained pediatric orthopaedic surgeon (ENN), one registered nurse (AE), one physician assistant (RS), and one administrative assistant (MK). Our indications for Pavlik harness treatment were based on age between birth and 6 months, clinical examination of the hip, and ultrasound findings. The Pavlik harness was the single orthotic device used initially in all patients with an Ortolani-positive hip, a Barlow-positive hip, and for stable hips on physical examination with ultrasound findings suggestive of hip dysplasia (alpha angle smaller than 50°, femoral head coverage less than 33%, or positive axial stress maneuver). Contraindications for Pavlik harness treatment were patients with an irreducible hip with complete dislocation observed on ultrasound images [14] and patients older than 6 months. This study includes all patients seen for DDH at the hip clinic during the described period. A total of 137 patients (215 hips) were included in this study (Fig. 1). Complete followup data after completion of treatment at an average of 3 months (range, 2–4 months) were available for all hips (100%; 215 of 215). In addition, 90% (122 of 137) of the patients were followed at minimum 6 months after Pavlik harness treatment and 99% (135 of 137) of families were compliant with treatment. At the time of diagnosis, 60 (28%) hips were found to be Barlow-positive, 77 (36%) were stable with ultrasound findings of DDH, and 78 (36%) were Ortolani-positive. Of the 137 patients included, 28 (20%) were male (Table 1).

During the first part of the study period, ultrasound studies were performed by the radiology department. During the final year of the study, one dedicated ultrasound technician (HJ) performed the studies in the orthopaedic office. The charts of all patients identified in the initial query were retrospectively reviewed. The primary outcome variable of interest was early failure of the Pavlik harness treatment to achieve and maintain stable concentric reduction of the hip. Failure of the Pavlik harness method

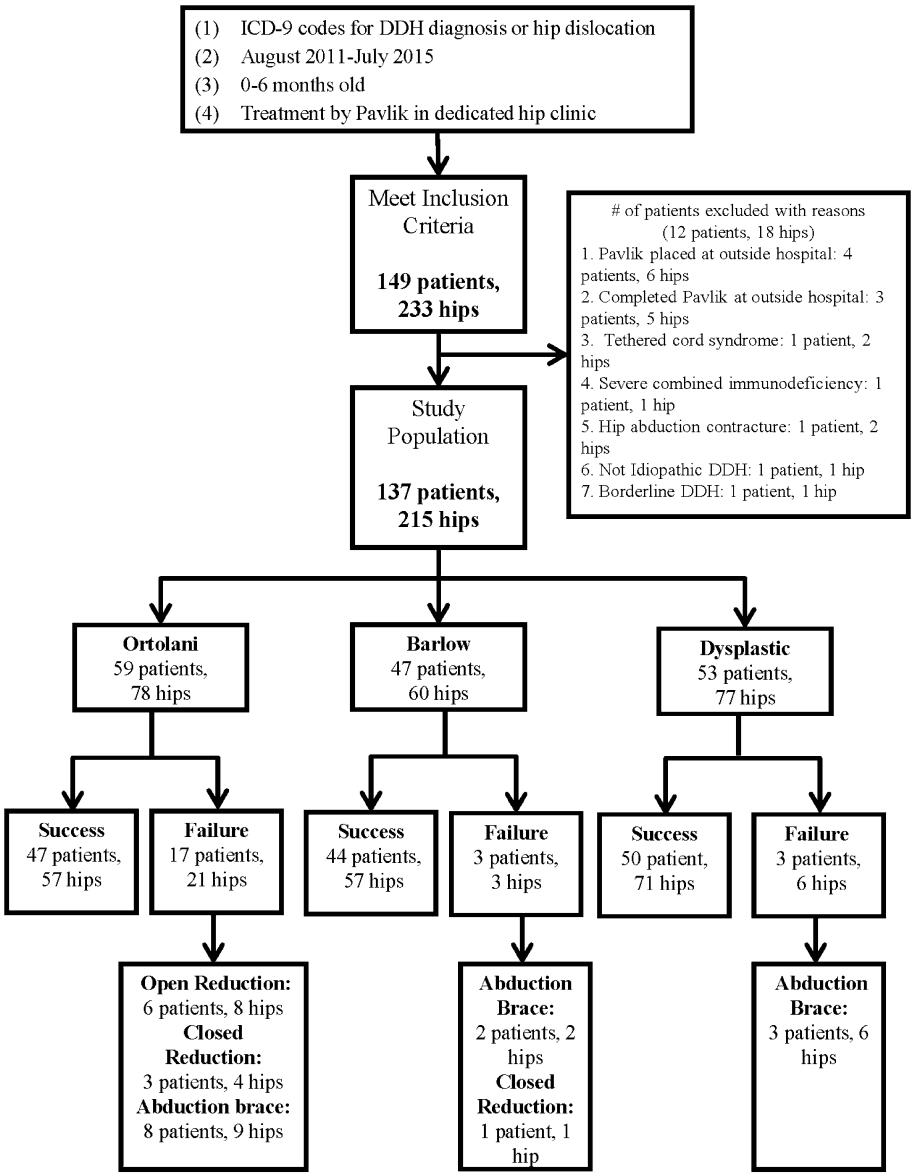

Fig. 1 The inclusion and exclusion criteria of the study are shown. ICD-9 = International Classification of Diseases, 9th Revision.

was defined as: (1) persistent instability of the hip with positive Ortolani or Barlow maneuver after 4 weeks of Pavlik harness treatment; (2) persistent dislocation and/or lack of improvement of femoral head coverage on ultrasound after 4 weeks; (3) femoral nerve palsy not improved after 1 week of discontinuing the Pavlik harness treatment.

Pavlik Treatment Protocol

During the initial clinic visit, static and dynamic ultrasound images [7, 15] of the hip were obtained. A dislocated hip that was reducible on clinical examination by the Ortolani maneuver was defined as an Ortolani-positive hip. A hip that was located but found to be unstable or dislocatable during the Barlow maneuver was defined as a Barlow-positive hip. Stable hips on physical examination with ultrasound findings suggestive of dysplasia (alpha angle less than 50°, femoral head coverage less than 33%, or positive axial stress maneuver) were defined as stable ultrasound-dysplastic hips.

The Pavlik harness was placed by the nurse (AE) during the first clinic visit. The orthopaedic surgeon (ENN) examined all patients before placement of the harness and checked the hip position in the harness to ensure hip flexion at approximately 90° to −110°. Pavlik harness wear was recommended for 24 hours per day and the families were not allowed to remove the harness at home. Infants were bathed in the clinic during subsequent visits. In general, families were educated to remove the

Table 1. Characteristics of study population

Patient or ultrasound characteristic	Barlow-positive hips (n = 60)		Dysplastic hips (n = 77)		Ortolani-positive hips (n = 78)	
Demographics and clinical characteristics						
Bilateral, number (%)	44	73%	62	81%	50	64%
Breech, number (%)	15	25%	28	36%	37	47%
Positive family history, number (%)	9	15%	16	21%	9	12%
Female sex, number (%)	52	87%	63	82%	56	72%
Secondary diagnosis, number (%)	2	3%	5	6%	3	4%
Complication during bracing, number* (%)	3	5%	1	1%	2	3%
Age at treatment (days), median (range)	14	4–104	48	4–155	19	4–129
Limited hip abduction (<45°), number (%)	6	10%	13	17%	24	31%
Radiographic/ultrasound measurements at baseline						
Graf type, number (%)						
I = normal	0	0%	0	0%	0	0%
IIA = physiologically immature	7	12%	32	42%	0	0%
IIB = immature	0	0%	1	1%	0	0%
IIC = dysplastic	36	60%	43	56%	0	0%
IID = decentering	8	13%	1	1%	0	0%
III = dislocated (labrum pressed upward)	6	10%	0	0%	55	71%
IV = dislocated (labrum pressed downward)	3	5%	0	0%	23	29%
Femoral head coverage (%), median (range)	33	18–58	42	14–56	23	−10 to 63
Alpha angle (degrees), median (range)	47	31–62	53	38–66	44	25–60

* Complication defined as occurrence of any treatment-related event that necessitated a break in Pavlik bracing (femoral nerve palsy, skin breakdown).

harness at home three times per week after 2 or 4 weeks depending on hip stability. The nurse in the hip clinic contacted the patient's parents within 48 hours to assess compliance and to help families with any questions. Patients with Ortolani-positive hips were evaluated weekly with physical examination and ultrasound imaging for the first 4 weeks of treatment or until the hip was found to be stable. Ultrasound imaging while the patient was wearing the harness was performed without stress views. After 4 weeks, patients were followed every other week with repeated ultrasound while wearing the harness. Patients with Barlow-positive hips and stable ultrasound-dysplastic hips were seen weekly for the first 2 weeks and then every other week, and ultrasound imaging while the patient was wearing the harness was repeated during the first week of treatment and at 4 and 8 weeks. Recommended length of treatment was 12 weeks or until ultrasound imaging normalized. A normal ultrasound was defined as an alpha angle greater than 60° with more than 50% of femoral head coverage. All patients were followed until the end of the Pavlik harness treatment, for an average of 3 months of followup (range, 2–4 months) and 90% (122 of 137) of the patients were followed up at 6 months of age.

Treatment Outcomes

For the purpose of this study, we focused on the early success of Pavlik harness treatment. Among Ortolani-positive and Barlow-positive hips, treatment success was defined as a stable hip with ultrasound showing reduction of the femoral head into the acetabulum 4 weeks after initiation of treatment. Pavlik harness failure was defined as persistent instability or inability to reduce the hip that previously had been reducible on physical examination with a confirmed dislocation on ultrasound. In addition, persistent ultrasound abnormalities (alpha angle <60° and/or percentage of coverage of femoral head <50%) observed after 12 weeks of treatment were considered as failure of the hip to improve with the harness.

Major complications were defined as those requiring temporary or definitive discontinuation of Pavlik harness treatment, including femoral nerve palsy or skin injury. For patients with femoral nerve palsy, the harness was discontinued and reapplied if full quadriceps function returned. Patients with femoral nerve palsy that persisted for more than 1 week were considered to have failure of Pavlik treatment [18].

Data Collection

Patient- and hip-specific variables including family history of DDH (first-degree relative), presentation at birth (breech versus cephalic), age at treatment, sex, laterality (unilateral versus bilateral), associated congenital deformities, classification of hip stability and reducibility, and degree of hip abduction assessed with the hip flexed to 90° were collected from medical records. Baseline ultrasound data collected at the time of diagnosis included the alpha angle [7] and the percentage of coverage of the femoral head [15]. A fellowship-trained pediatric radiologist (MM) who was blinded to clinical assessment, reviewed the baseline images and classified the hips based on the Graf classification system [7].

Statistical Methods

A generalized logistic regression analysis was used to model the odds of treatment failure among Ortolani-positive hips. Demographic, clinical, and ultrasound variables were tested as candidate predictor variables in the univariate analysis. Variables significant at the alpha level of 0.10 were tested in the multivariate model. Among the Ortolani-positive hips, patient-related factors significantly associated with treatment failure in the univariate analysis included male sex ($p = 0.003$) and limited hip abduction ($\leq 45°$) ($p = 0.014$) (Appendix 1. Supplemental material is available with the online version of CORR®.) Ultrasound factors associated with failure included Graf classification type ($p = 0.005$) and percent of femoral head coverage ($p = 0.025$). Owing to the high degree of correlation among percent coverage, Graf alpha angle, and Graf type, we elected to include only Graf type in the final model because it was the strongest predictor of treatment failure in the univariate analysis. A generalized estimating equation approach was used to account for correlation resulting from the inclusion of subjects with bilateral DDH.

A secondary analysis was used to describe changes in the ultrasound variables of interest (alpha angle and percent coverage of the femoral head) in all hip subgroups. This analysis was restricted to hips that had successful Pavlik harness treatment. Linear mixed model regression analyses were used to estimate means and 95% CIs at each of the study times (baseline, 4-week visit, and the final followup for Pavlik harness treatment).

Results

The crude incidence of treatment failure was highest in the Ortolani-positive (27%; 21 of 78) followed by the stable ultrasound-dysplastic (8%; six of 77), and Barlow-positive (5%; three of 60) hips (Table 2).

The Pavlik harness was discontinued three times (5%) in the Barlow group for skin problems (n = 2) and femoral nerve palsy (n = 1) and once (1%) in the dysplastic group for skin irritation. The brace was discontinued in two patients (3%) for temporary femoral nerve palsy in the Ortolani group. If we exclude the two patients who did not comply with the harness method, then the failure proportion for ultrasound dysplastic hips would be 5%, which was not different from that seen for the Barlow-positive hips. Improvements in ultrasound characteristics including the alpha angle and the percent coverage of the femoral head were observed in all hips successfully treated by the Pavlik method (Fig. 2). After bracing, the majority of Barlow-positive (95%; 57 of 60) and stable ultrasound-dysplastic (92%; 71 of 77) hips did not require additional intervention. Comparatively, 73% (57 of 78) of the Ortolani-positive hips did not require additional intervention (Table 3).

Sex and Graf classification type were associated with the likelihood of treatment failure in the multivariate analysis. After controlling for sex and range of hip abduction, Pavlik harness treatment was more likely to fail in Graf type IV (alpha angle $< 43°$ and labrum displaced downward) dislocated hips relative to Graf type III hips (dislocated hip with alpha angle $< 43°$ with the labrum displaced cranially) (adjusted OR, 4.4; 95% CI, 1.3–15.4; $p = 0.019$). After

Table 2. Reasons for failure of Pavlik treatment method in patients with DDH

Treatment failure	Barlow-positive hips (n = 60)	Dysplastic hips (n = 77)	Ortolani-positive hips (n = 78)
Total number of patients with failure* (%)	3 (5%)	6 (8%)	21 (27%)
Reason for failure, number (%)			
Stable reduction not achieved	3 (5%)	0 (0%)	21 (27%)
No improvement on ultrasound	0 (0%)	4 (5%)	0 (0%)
Femoral nerve palsy	0 (0%)	0 (0%)	4 (5%)
Parental noncompliance	0 (0%)	2 (3%)	0 (0%)

DDH = developmental dysplasia of the hip; * patients may have more than one reason for treatment failure.

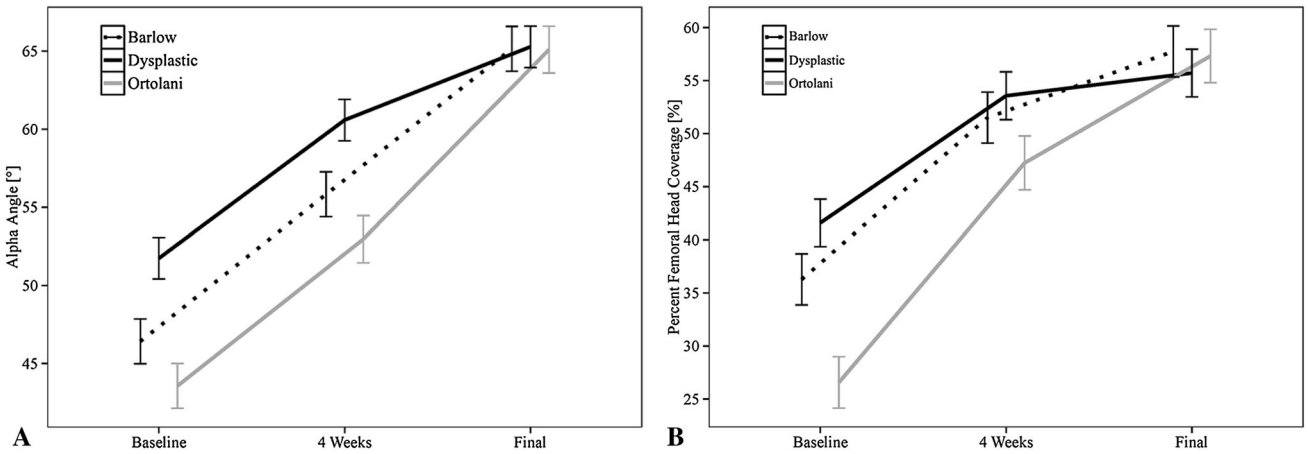

Fig. 2A–B Ultrasound measurements of the (**A**) alpha angle and (**B**) percentage of femoral head coverage of the 215 hips at the time of diagnosis, 4 weeks into treatment, and at the end of Pavlik treatment are shown.

Table 3. Additional treatment after Pavlik harness failure in patients with DDH

Additional treatment method	Barlow-positive hips (n = 60)	Dysplastic hips (n = 77)	Ortolani-positive hips (n = 78)
Closed reduction, number (%)	1 (2%)	0 (0%)	4 (5%)
Abduction brace, number (%)	2 (3.3%)	6 (8%)	9 (12%)
Open reduction, number (%)			
Anterior approach	0 (0%)	0 (0%)	1 (1%)
Anteromedial approach	0 (0%)	0 (0%)	7 (9%)

DDH = developmental dysplasia of the hip.

controlling for range of hip abduction and Graf type, hips in male patients were more likely to have Pavlik treatment fail relative to hips in female patients (adjusted OR, 6.9; 95% CI, 2.0–24.2; p = 0.002). With the numbers available, limited abduction was not associated with treatment failure (adjusted OR, 3.0; 95% CI, 0.8–11.2; p = 0.096).

Discussion

The Pavlik harness is an accepted method for treatment of DDH in patients younger than 6 months. Although the incidence and risk factors associated with Pavlik harness failure have been reported, previous studies may have been limited by lack of complete assessment of patient factors such as clinical examination [14, 19, 20, 24, 31, 32] and failure to review ultrasound findings at the time of diagnosis [13, 31, 32]. We found that failure of Pavlik harness treatment was greatest among patients with Ortolani-positive hips and that male sex and Graf classification were associated with failure of treatment.

Our study has several limitations. First, we acknowledge that the complete picture of success of Pavlik harness treatment requires long-term followup. However, in this study, we focused on the early success of the Pavlik method, which is the ability to achieve and maintain a concentric reduction of the hip to define predictive risks of early failure. Ninety percent (122 of 137) of the infants were seen after 6 months of Pavlik treatment which may be enough to detect cases of redislocation. However, followup to skeletal maturity is required to determine the occurrence of osteonecrosis of the femoral head and residual acetabular dysplasia. Second, there is a risk for assessment bias because the ultrasound images were reviewed by one of the authors (MM). However, to lower the risk of bias, the assessor was blinded to clinical findings and to treatment outcomes. Although we did not test for variability and repeatability of the ultrasound classification, a previous study established the interrater reliability as 0.59 and intrarater reliability as 0.57 [26]. Along the same lines, we did not assess variability of the assessment of hips as Ortolani positive, Barlow positive, or stable dysplastic on

ultrasound images. However, the ability to correctly identify neonatal hip stability has been reported to be related directly to the examiner's level of experience [5]. In this study, all infants were assessed by the senior author (ENN) who has extensive experience in examining the pediatric hip. Third, for the first part of this study, ultrasound imaging was performed by one of five technicians (HJ, EL, RH, KG, KD), which might have created measurement variability. However, all the technicians were trained in hip ultrasound technique using the same imaging protocol. For the last year of the study, one technician (HJ) at the orthopaedic office performed all ultrasound imaging.

In our study, the overall proportion of patients experiencing Pavlik harness failure was 14% (30 of 215 hips), 27% (21 of 78 hips) for patients with Ortolani-positive hips, 5% (three of 60 hips) for patients with Barlow-positive hips, and 5% (four of 77 hips) for patients with stable ultrasound-dysplastic hips. Our findings were similar to those of previous studies indicating that a high proportion of Barlow-positive hips and stable ultrasound-dysplastic hips can be treated successfully with the Pavlik harness [6, 8, 12, 14, 19, 25, 31]. Despite our strict protocol, the rate of failure in Ortolani-positive hips was similar to those of previous studies reporting a 30% to 60% incidence of treatment failure in dislocated hips [2, 16, 19, 20, 24, 31, 32].

Male sex was an independent risk factor for failure of Pavlik harness treatment in Ortolani-positive hips. Only one previous study reported an association between male sex and a high risk of failure of Pavlik harness treatment [4]. Numerous studies [2, 13, 14, 17, 19, 20, 24, 32] have not shown this association; however, these studies may have been limited in power owing to a small number of male patients. The proportion of males in those studies ranged between 8% and 20%. Nevertheless, in the current study, there was a greater (28%) proportion of male patients with a dislocated Ortolani-positive hip. Graf ultrasound classification at the time of diagnosis also was an independent factor predictive of treatment failure in Ortolani-positive hips. This observation is corroborated by several other studies showing a higher risk of Pavlik method failure for Graf Type IV hips [16, 19, 24, 30]. In frankly dislocated Graf Type IV hips, the femoral head presses the acetabular labrum and the cartilaginous roof downward, which makes reduction more difficult and has been reported to cause hyaline cartilage transformation that appears echogenic on ultrasound [1]. In contrast, White et al. [32] did not identify the Graf classification as a predictor of treatment outcome, yet in their study, ultrasound was not obtained at the time of diagnosis, which may have altered their findings. We believe that our findings highlight the importance of obtaining hip ultrasound images at the time of diagnosis, before Pavlik harness treatment is implemented. Our data and those of previous studies [16, 19, 24, 30] show that the severity of ultrasound findings have prognostic implications.

We were surprised that limited abduction was not associated with treatment failure. One prior study found that limited abduction ($< 60°$) was a risk factor for failure of reduction and development of osteonecrosis [13]. However, the average age of patients at initiation of Pavlik harness treatment was 4 ± 1.08 months, which is much older than the average age of patients in our study. This would be expected because as the child grows, the range of abduction motion worsens as a consequence of contracture of the adductor muscles. With the numbers available, we also did not find an association between age and bilaterality and risk of Pavlik harness failure. Although our findings may have been limited by our numbers, controversy surrounds the association between age and success of Pavlik harness treatment. Although some prior studies [10, 19, 31, 32] have reported younger age is associated with a higher success rate after Pavlik treatment, others [13, 14, 24] have not found this association. Controversy also exists for bilateral DDH. Although previous studies [2, 13, 31] have reported bilateral involvement as a risk factor, several other studies [9, 10, 17, 19, 32] failed to confirm this association.

We used a systematic protocol for the Pavlik harness method for all patients with DDH presenting to a dedicated pediatric hip clinic, allowing for investigation of patient risk factors, physical examination, and baseline ultrasound findings. The results of our study suggest that hip ultrasound should be part of the initial clinical assessment for Ortolani-positive hips because the Graf classification was shown to have important prognostic implications. Our data are useful resources for the orthopaedic surgeon when he or she is educating families regarding the likelihood of failure of the Pavlik harness method during treatment of DDH. A high success proportion can be expected for Barlow-positive and stable hips dysplastic on ultrasound; the probability of failure is greater for Ortolani-positive hips. Male sex and Graf Type IV ultrasound classification were found to be independent risk factors for Pavlik harness failure. Parents of infants with a high probability of Pavlik harness failure should be appropriately educated at the initiation of treatment. Future well-designed, prospective, controlled studies will be necessary to establish whether alternative strategies to the Pavlik harness might improve the outcomes in patients identified as being at high risk for treatment failure.

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