Incidence and risk factors for persistent acetabular dysplasia in patients with developmental dislocation of the hip treated by Pavlik Harness

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Some patients with developmental dysplasia of the hip (DDH) before 6 months of age successfully treated by Pavlik Harness (PH) still had persistent acetabular dysplasia (PAD). This study aimed to investigate the incidence and risk factors for PAD in patients with DDH treated by PH. We retrospectively reviewed the data of 89 patients (109 hips; mean age, 3.2 ± 1.5 months) with DDH treated by PH. Prior to treatment, all patients underwent ultrasound examination and classified according to Graf's method. PH was terminated once the hip achieved imaging recovery criteria. At final follow-up, the acetabular index (AI), center-edge angle (CEA) of Wiberg were measured on radiograph. Overall, 67/109 hips (61.5%) had successful PH treatment. Among these 67 hips, 58 hips (86.6%) achieved satisfactory outcome, nine (13.4%) had PAD. Age of the patients with PAD (4.3 ± 1 months) was significantly higher than those without PAD (2.8 ± 1.5 months) ($P = 0.001$). Hips with PAD had higher mean Graf grade than those with satisfactory outcome ($P = 0.014$). Logistic regression-confirmed age and Graf classification were risk factors for PAD. Overall, 55/67 (82.1%) met imaging recovery criteria to stop PH treatment, whereas 12/67 hips (17.9%) did not. The rate of PAD at final follow-up in patients achieving recovery criteria (4/55; 7.3%) was significantly lower than those not achieving it (41.7%) ($P = 0.007$). In conclusion, age and Graf classification are risk factors for PAD. If hips are not normal at the end of PH treatment, the risk of PAD increases further. *J Pediatr Orthop B* **32: 312–317**

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Introduction

Developmental dysplasia of the hip (DDH) is a common congenital hip disorder characterized by abnormal anatomical relationships between the femoral epiphysis and the acetabulum, leading to acetabular dysplasia, subluxation, and hip dislocation [1,2]. At present, early diagnosis through screening programs and early stable reduction are the key to the treatment of the disease as they promote hip development and reduce the risk of avascular necrosis (AVN) of the femoral epiphysis [2,3]. The common goal of these devices is to obtain a normal anatomy of the hip joint and to stimulate the development of the acetabulum [1].

Currently, Pavlik Harness (PH) is the most widely used abduction brace to manage DDH patients younger than 6 months age with a reported success rate ranging between 84 and 99% [4–6]. The PH maintains the hip joint at a position of 80°–90° of flexion, and less than 75° of abduction and complications such as hip joint reduction failure, femoral nerve palsy, AVN of femoral head, and residual dysplasia have been reported by several authors [6–9].

In clinical practice, we found that some patients with DDH successfully treated by PH before 6 months of age had persistent acetabular dysplasia (PAD) [10]. Although previous studies have reported up to 33.8% of PAD in DDH patients younger than 6 months of age treated by PH, factors leading to PAD following PH treatment are still controversial [7,11,12].

In this study, we retrospectively reviewed patients with DDH younger than 6 months of age treated by PH in order to investigate the incidence and risk factors for PAD following successful PH treatment.

Methods and materials

We collected the data of children younger than 6 month of age with confirmed diagnosis of DDH treated by PH at our Institution between January 2014 and May 2020. The inclusion criteria were as follows: (a) confirmed diagnosis of type II-D, III, or IV DDH according to Graf classification [13]; (b) age less than 6 months at the time of treatment by PH; (c) good compliance with PH treatment; (d) complete clinical and radiographic data; and (e) follow-up data spanning more than 12 months.

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The exclusion criteria were as follows: (a) pathological dislocation of the hip; (b) follow-up time less than 12 months; (c) incomplete clinical and radiographic data; and (d) treatment other than PH.

Eighty-nine patients (77 females and 12 males; 109 hips) met the inclusion criteria. Among the 109 hips, 48 (53.9%) were left, 21 (23.6%) were right, and 20 (22.5%) were bilateral. The mean age at the time of diagnosis was 3.2 ± 1.5 months (range, 0.3–6).

Pavlik Harness treatment

All included patients underwent full-time PH treatment. Patients were reviewed weekly for the first 4 weeks to check the PH was correctly worn and to rule out complications [6,14]. Three to four weeks after the beginning of PH treatment, patients underwent hip ultrasound (HUS) in order to assess the quality of reduction. If reduction failed, the patient was switched to closed or open reduction. In case of successful reduction, PH was continued up to 3–4 months until the hip met ultrasound or radiographic recovery criteria. If successful reduction was achieved though acetabular dysplasia did not correct following PH treatment or the patient was older than 8–9 months, PH was discontinued and switched to an abduction brace until the hip met the radiographic recovery criteria. The ultrasound and radiographic recovery criteria were as follow: (a) type-I hip according to Graf classification [7] and (b) well-reduced hip on plain radiographs with acetabular index (AI) no more than one SD above the mean value for normal age matched children, as reported by Shi *et al.* [15,16]. Patients were then divided into two groups whether they met recovery criteria (ultrasound or radiographic) or not: (a) group A: patients meeting recovery criteria and (b) group B: patients not meeting recovery criteria.

Ultrasound and radiographic assessment

Hip ultrasound (HUS) was performed according to the methods described by Graf [17,18]. Sonographers with more than 5 years of experience and training in HUS performed all the examinations. HUS was performed before PH treatment, during PH treatment at 3–4 weeks intervals, and at the end of PH treatment. The α-angle was recorded at each HUS examination [17,18].

Three months after completion of PH treatment, all patients underwent regular anteroposterior (AP) pelvis radiographs, and AI and center-edge angle (CEA) of Wiberg were measured to evaluate acetabular development during follow-up time [19]. Two pediatric orthopedic surgeons (L.Y.Q. and L.Y.H.) separately reviewed all AP pelvis radiographs on the Picture Archiving and Communication System imaging system of our Institution, and the mean value of each measurement was used for statistical analysis.

PAD was diagnosed if: (a) AI in patients younger than 4 years was greater than 1 SD than the mean value for normal age matched children [15,16,20], or there was evidence of subluxation; (b) patients older than 4 years had grade III or IV hips according to Severin classification [21]; and (c) no evidence of break in Shenton's line.

At final follow-up, AVN of the femoral head was assessed and graded according to the Bucholz and Ogden methods on AP pelvis radiographs [22]. Since type-I AVN is a temporary ischemic change that can be completely recovered, we considered type-I AVN as normal [23]. Two pediatric orthopedic surgeons (L.Y.Q. and L.Y.H.) assessed AVN independently; in case of disagreement, a third senior pediatric orthopedic surgeon (F.C.) was involved in the final decision.

Statistical analysis

Statistical analysis was performed using SPSS 22.0 (SPSS, Chicago, Illinois, USA). Data included continuous numerical variables, frequencies, and percentages. *t*-test and Chi-square test were used to compare the differences in each index among the failure of reduction group, PAD group, and the normal hip group. Logistic regression analysis was used to investigate the risk factors for failure of reduction with PH and PAD. As some patients who met the HUS criteria to stop PH treatment had PAD at last follow-up visit, we also evaluated retrospectively the diagnostic accuracy of HUS and radiograph at the at the end of PH treatment. All statistical analyses were performed by one of the authors (L.Y.Q.). $P < 0.05$ was considered statistically significant.

Results

Of the 109 hips, 30 (27.5%) were Graf type II-D, 42 (38.5%) type III, and 37 (33.9%) were type IV. Successful reduction was achieved in 67 hips (61.5%), whereas it was unsuccessful (failure of reduction) in 42 hips (38.5%).

In the successful reduction group, treatment by PH lasted 3 ± 0.5 months on average (range, 2–5), whereas it was 1.1 ± 0.2 months (range, 0.7–1.5) in the failure of reduction group ($t = 24.1$; $P < 0.001$). Table 1 outlines the clinical data of successful reduction and failure of reduction group (Table 1); no significant difference on sex and side between the two groups was detected ($P > 0.05$). Patients with successful reduction (3 ± 1.5 months) were significantly younger than those with failed reduction (3.5 ± 1.4 months) ($P = 0.048$). The rate of successful reduction in Graf type II-D (86.7%) and Graf type III (71.4%) was significantly higher than that in Graf type IV (29.7%) hips ($P < 0.001$).

The mean follow-up time of successful reduction hips ($n = 67$) was 23.3 ± 13.7 months (range, 12–65.6). At final follow-up, type II AVN occurred in three hips (4.5%). The mean AI and CEA were 21.6° ± 3.6° (range, 14–33) and 17.5°±7° (range, 0–31.5), respectively. Nine out of 67 hips (13.4%) developed PAD (Table 2). The mean age of patients with PAD (4.3 ± 1 months; range, 2.2–5.6) was

significantly higher than mean age of patients without PAD (2.8 ± 1.5 months; range, 0.3–6) ($P = 0.001$). The rate of PAD in patients younger than 3 months (1/32; 3.1%) was significantly lower than the rate of PAD in patients older than 3 months of age (8/35; 22.9%) ($P = 0.029$). Hips with PAD had significantly higher Graf type than those without PAD ($P = 0.001$). The rate of PAD in Graf type II-D and III hips was significantly higher than those Graf type IV hips ($P < 0.05$). There was no significant difference on sex and side between the two groups ($P > 0.05$) (Table 2). Logistic regression analysis confirmed age and higher Graf grading were risk factors for PAD (Table 3).

Among the 67 hips with successful reduction, 55/67 (82.1%; group A) met the ultrasound (35/55 hips) or radiographic (20/55 hips) criteria to stop PH treatment, whereas 12/67 hips (17.9%; group B) did not met ultrasound nor radiographic criteria (Table 4). Patients in group A had significantly lower age than patients in group B ($P < 0.001$), whereas there was no significant difference between groups on sex, laterality, Graf classification, and length of PH treatment ($P > 0.05$) (Table 4). The rate of PAD at final follow-up in group A patients (4/55; 7.3%) was significantly lower than age of group B patients (5/12; 41.7%) (Fisher's exact test; $P = 0.007$) (Table 2). All hips with PAD in group A ($n = 4$) met ultrasound criteria to stop PH treatment. No hip meeting radiographic criteria to stop PH treatment developed PAD at final follow-up.

All group B hips ($n = 12$) underwent abduction brace treatment when PH was discontinued; seven out of 12 hips (58.3%) achieved satisfactory outcome. At the end of PH treatment, the diagnostic accuracy of HUS (31/37; 83.8%) was significantly lower than conventional radiographs (30/30; 100%) (Fisher's exact test; $P = 0.029$).

Among the 42 hips that failed to achieve successful reduction following PH treatment, 13/42 hips (eight patients; 31%) were lost follow-up; 26 of the remaining 29 hips were treated with closed reduction and cast immobilization, whereas 3/29 required open reduction after failure of closed reduction. The mean follow-up time of unsuccessful reduction hips was 27.5 ± 15.8 months (range, 12–70). At final follow-up, the mean AI and CEA were 23.4° ± 5.7° and 12.5° ± 11°, respectively. Two hips (6.9%) developed type II AVN. Twenty-one hips (72.4%) had satisfactory outcome, and eight hips (27.6%) had PAD.

Table 1. Comparison of clinical data between successful reduction group and failure of reduction group

	Successful reduction			
Parameters	No	Yes	χ^2	*P*
Hips	42 (38.5%)	67 (61.5%)	-	-
Age (months)	3.5 ± 1.4	3 ± 1.5	1.998	0.048
Sex				
Female	34 (37%)	58 (63%)	0.618	0.588
Male	8 (47.1%)	9 (52.9%)		
Side				
Left	15 (31.3%)	33 (68.7%)	2.435	0.291
Right	8 (38.1%)	13 (61.9%)		
Bilateral	19 (47.5%)	21 (52.5%)		
Graf classification				
II-D	4 (13.3%)	26 (86.7%)	25.538	<0.001
III	12 (28.6%)	30 (71.4%)		
IV	26 (70.3%)	11 (29.7%)		

Table 2. Clinical data of patients with satisfactory outcome and persistent acetabular dysplasia at final follow-up

	PAD			
Parameters	No	Yes	t/χ^2/Z	*P*
Hips	58 (86.6%)	9 (13.4%)	-	-
Age (months)	2.8 ± 1.5	4.3 ± 1	3.923	0.001
Sex				
Female	50 (86.2%)	8 (13.8%)	-	1.000
Male	8 (88.9%)	1 (11.1%)		
Side				
Left	26 (78.8%)	7 (21.2%)	-	0.226
Right	12 (92.3%)	1 (7.7%)		
Bilateral	20 (95.2%)	1 (4.8%)		
Graf classification				
II-D	25 (96.2%)	1 (3.8)	3.395	0.001*
III	26 (86.7%)	4 (13.3%)		
IV	6 (54.5%)	5 (45.6%)		
Final acetabular index	20.8 ± 2.9	26.4 ± 4.9	4.931	0.000
Final center-edge angle	19.7 ± 4.6	5.25 ± 4.8	8.136	0.000
Achieved ultrasound or radiographic criteria to stop Pavlik harness treatment				
No	7 (58.3%)	5 (41.7%)	-	0.007
Yes	51 (92.7%)	4 (7.3%)		

PAD, persistent acetabular dysplasia.
*Mann–Whitney U test.

Discussion

This study showed 13.3% of patients with Graf type II-D, III, and IV developed PAD following successful reduction with PH. Few studies have reported PAD in patients with DDH managed by PH. Shaw *et al.* [7] systematically reviewed 17 studies and found that 280/6029 (4.6%) DDH hips treated by PH had PAD on radiographs at a mean follow-up time of 5.29 years; the majority of cases were stable hips (Graf-II type), so the proportion of PAD was relatively low. On the other hand, Nakamura *et al.* [4] reviewed 130 completely dislocated hips treated by PH and followed up for more than 14 years; they found PAD in 22/130 hips (16.9%). Similarly, Bradley *et al.* [24] reported 16.7% of PAD in unstable hips successfully reduced by PH (48/288 hips). When only unstable hips are considered, the incidence of PAD is similar to our findings.

Our study also found the occurrence of PAD after successful treatment with PH was closely related to Graf classification and age (Fig. 1), regardless of sex and laterality. The rate of PAD significantly increases higher in patients older than 3 months at the time of diagnosis and with Graf type IV hips. Our results are similar to those of Novais *et al* [11]. Particularly, they reviewed 134 hips in 84 patients with DDH treated by PH and found 11.8% of PAD; Graf type IV was the only risk factor for PAD [11]. Alexiev *et al.* [25] studied 100 hips in 55 patients with DDH treated with PH and were able

Table 3. Risk factors for persistent acetabular dysplasia

Risk factors	Coefficient	SE	Wald	*P*	RR	95% CI of RR	
Graf classification	2.127	0.772	7.586	0.006	8.391	1.847	38.124
Age	0.889	0.405	4.812	0.028	2.433	1.099	5.387
Sex	2.662	1.809	2.164	0.141	14.323	0.413	496.91
Side	−2.114	1.652	1.637	0.201	0.121	0.005	3.078

CI, confidence interval; RR, Relative risk; SE, standard error.

Table 4. Comparison between patients that achieved ultrasound or radiographic criteria (group A) to stop Pavlik harness (PH) treatment and those who did not (group B)

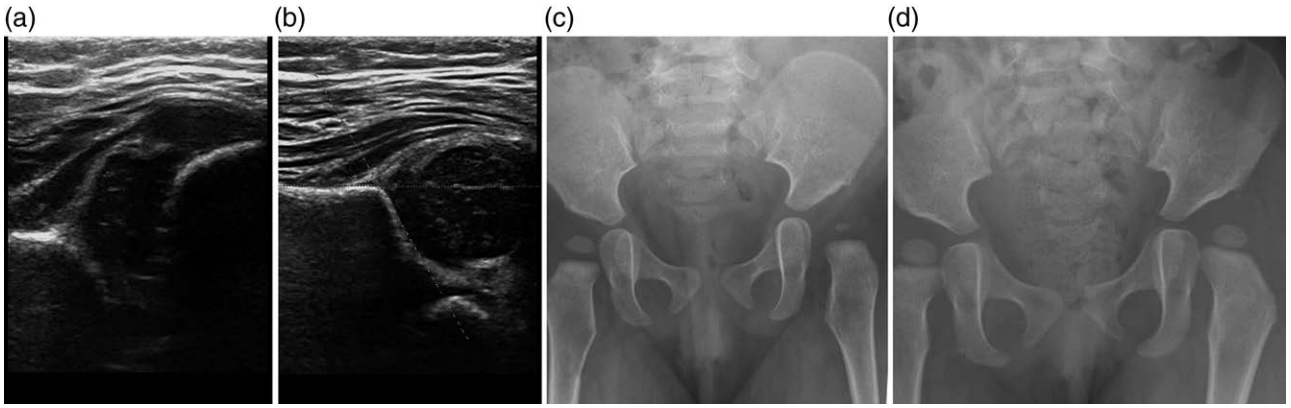
	Ultrasound or radiographic criteria to stop PH treatment			
Parameters	Yes (group A)	No (group B)	$t/\chi^2/Z$	*P*
Hips	55 (82.1%)	12 (17.9%)	-	-
Age (months)	2.7 ± 1.4	4.4 ± 1	4.846	0.000
Sex				
Female	46 (79.3%)	12 (20.7%)	-	0.196
Male	9 (100%)	0 (0%)		
Side				
Left	24 (72.7%)	9 (27.3%)	-	0.103
Right	11 (84.6%)	2 (15.4%)		
Bilateral	20 (95.2%)	1 (4.8%)		
Graf classification				
II-D	21 (80.8%)	5(19.2%)	-	0.528
III	26 (86.7%)	4 (13.3%)		
IV	8 (72.7%)	3 (27.3%)		
Duration of PH treatment (months)	3.1 ± 0.5	2.9 ± 0.4	1.177	0.243

to predicted PAD with initial ultrasound measurements. Their results suggest patients with abnormal echogenicity of the cartilage roof on initial HUS had a significantly increased incidence of PAD. In the present study, we found the incidence of PAD in patients with Graf type IV hips was significantly higher than Graf type II-D and III hips, whereas sex and side were not associated with PAD. Thus, the Graf classification and age are significant risk factors for PAD following treatment with PH for DDH. Other factors are still controversial and need to be determined by further studies with larger samples [25–27].

This study also suggests PAD following PH was mostly due to the fact that the hip had not really returned to normal when PH treatment was stopped. The incidence of PAD in patients achieving ultrasound and radiographic criteria to discontinue PH treatment (7.3%) was significantly lower than that in patients that did not meet such criteria (41.7%); interestingly, older age (>4 months) was the main factor influencing recovery criteria. Currently, the optimal duration of PH treatment remains controversial. In the present study, the length of PH treatment was 3 ± 0.5 months (range, 2–5), and it was similar to previous studies [4,11,28]. Additionally, 12 patients (17.9%) switched to abduction brace treatment after completion of PH treatment, and 58.3% of them achieved satisfactory outcome at final follow-up. Thus, it seems that 3–4 months of PH treatment is insufficient for some patients to achieve normal hip.

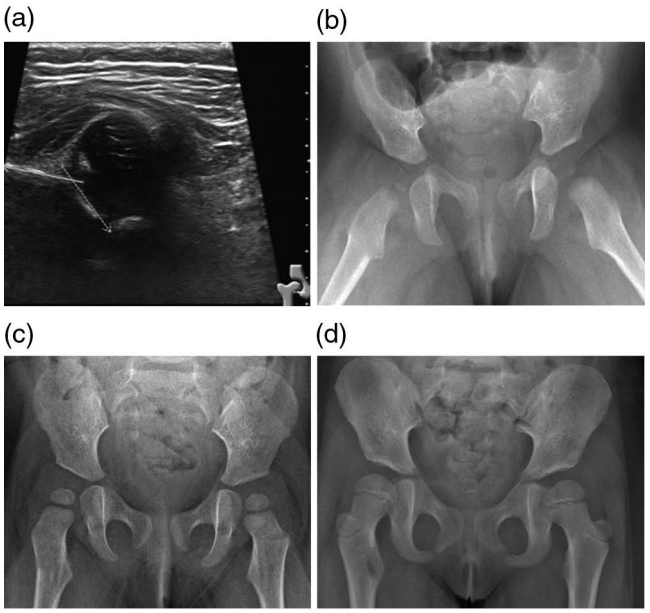
This study also showed that Graf type-I hip is not an absolute indication to discontinue PH treatment in patients with DDH. Interestingly, PAD developed in four out of 21 (19%) hips, which discontinuation of PH was based on ultrasound findings (normal). On the other hand, no hip achieving conventional radiograph recovery criteria at the removal of the PH had PAD at final follow-up (Fig. 2). Previous studies have reported PAD can occur after ultrasonographic normalization of the hip. Dornacher *et al.* [29] reported 90 patients with DDH treated with PH had normal ultrasound at completion of treatment. However, radiographs performed at a mean age of 14.8 months revealed that 29.4% had severe acetabular dysplasia [29]. The study by Bradley *et al.* [24] also reported 16.7% of hips eventually developed PAD even when ultrasound was normal at completion of PH treatment. The study by Bozkurt *et al.* [30] also suggested that radiographic examination (International Hip Dysplasia Society grading) can more reliably predict the success of PH in the treatment of DDH than ultrasonography (Graf method). The reason for this may be related to the relatively low reproducibility of ultrasonography. Although the Graf method requires strict examination procedures, including the selection of the ultrasonic probe, the placement of the patient's position, the selection of the ultrasound section, the measurement of the angle, and the judgment of the classification [17,18], there are still large differences between different examiners. When performing HUS examination, the key lies in the determination of

Fig. 1.



A 5-month-old female with left DDH (Graf Type III) treated by PH (a) for 12 weeks; at PH removal, the hip was rated as Graf type I (b). At 1 year, pelvic radiographs showed persistent acetabular dysplasia on the left side (c). The patient was treated by nighttime abduction brace. Radiographs performed at 2 years of age showed persistent acetabular dysplasia (d). DDH, developmental dysplasia of the hip; PH, Pavlik Harness.

Fig. 2.



A 3-month-old female with right DDH (Graf Type III) treated by PH (a) for 12 weeks; at PH removal, the hip achieved radiographic normalization (b). At 1 year, pelvic radiographs showed good result on the right side (c). Radiographs performed at 4 years of age showed satisfactory outcome (d). DDH, developmental dysplasia of the hip; PH, Pavlik Harness.

the standard measurement plane by the examiner, and studies have shown that slight changes in the inclination of the ultrasound probe can lead to significant differences in Graf classification [31]. Quader *et al.* [32] retrospectively analyzed 28 studies in order to investigate the consistency and reproducibility of ultrasound in the diagnosis of DDH. The results suggested that there were great differences in the angles measured by Graf method, mainly due to the low intraobserver (ICC) and interobserver reliabilities (ICC of α angle: 0.03–0.45; ICC of β angle: 0.13–0.45). Hip radiographic examination, on the other hand, has high reliability, and most studies have shown good reliability in measuring AI and CEA on conventional radiographs [15,19,20,33].

The present study indicated that bilateral dislocation is not a risk factor of PAD. Particularly, there was no significant difference on the rate of PAD in patients with

unilateral (8/46; 17.4%) versus bilateral DDH (1/21; 4.8%) ($P = 0.226$) (Table 2). At present, there is no study reporting the correlation between PAD and bilateral DDH. Some authors investigated the failure rate of PH for the treatment of dislocated hips and found that bilateral dislocated hips are not at a higher risk for failure [34].

The rate of PAD was 13.3% in patients with DDH treated by PH. Age and Graf classification are risk factors of PAD. The rate of PAD was significantly higher in patients older than 3 months and with Graf type IV hips. If the hip does not normalize at the end of PH treatment, the risk of PAD increases. Conventional radiographs can complete the ultrasound assessment to guide the termination of PH, especially in older patients.

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Ethics approval: this is a retrospective study of patients's data, and an IRB approval was obtained (2021-129A01).

Conflicts of interest

There are no conflicts of interest.

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