Is There a Benefit to Weaning Pavlik Harness Treatment in Infantile DDH?

Joshua T. Bram, BS, Shivani Gohel, BS,* Pablo G. Castañeda, MD,† and Wudbhav N. Sankar, MD**

Background: Following successful treatment of developmental hip dysplasia with a Pavlik harness, controversy exists over the benefit of continued harness use for an additional "weaning" period beyond ultrasonographic normalization versus simply terminating treatment. Although practitioners are often dogmatic in their beliefs, there is little literature to support the superiority of 1 protocol over the other. The purpose of this study was to compare the radiographic outcomes of 2 cohorts of infants with developmental hip dysplasia treated with Pavlik harness, 1 with a weaning protocol and 1 without.

Methods: This was a comparative review of patients with dislocated/reducible hips and stable dysplasia from 2 centers. All patients had pretreatment ultrasounds, and all started harness treatment before 3 months of age. On the basis of power analysis, a sufficient cohort of hips were matched based on clinical examination, age at initiation, initial α angle, and initial percent femoral head coverage. Patients from institution W (weaned) were weaned following ultrasonographic normalization, whereas those from institution NW (not weaned) immediately ceased treatment. The primary outcome was the acetabular index at 1 year of age.

Results: In total, 16 dislocated/reducible and 16 stable dysplastic hips were matched at each center (64 total hips in 53 patients). Initial α angle and initial femoral head coverage were not different between cohorts for either stable dysplasia ($P = 0.59$, 0.81) or dislocated/reducible hips ($P = 0.67$, 0.70), respectively. As expected, weaned hips were treated for significantly longer in both the stable dysplasia (1540.4 vs. 1066.3 h, $P < 0.01$), and dislocated/reducible cohorts (1596.6 vs. 1362.5 h, $P = 0.01$). Despite this, we found no significant difference in the acetabular index at 1 year in either cohort (22.8 vs. 23.1 degrees, $P = 0.84$ for stable dysplasia; 23.9 vs. 24.8 degrees, $P = 0.32$ for Ortolani positive).

Conclusions: Despite greater total harness time, infants treated with additional Pavlik weaning did not demonstrate significantly different radiographic results at 1 year of age compared with those who were not weaned. However, differences in follow-up protocols between centers support the need for a more rigorous randomized controlled trial.

Level of Evidence: Level III.

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

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Developmental dysplasia of the hip (DDH) is the most common congenital anomaly of the lower extremity, ranging in severity from mild acetabular insufficiency to frank dislocation.[1] The most common treatment for children under 6 months of age with ultrasonographic or clinical examination evidence of significant dysplasia is bracing with the Pavlik method. This method involves the use of a harness that encourages hip flexion and abduction, which guides the femoral head into the socket thereby facilitating acetabular remodeling. The success rate of the Pavlik harness varies with age at initiation and DDH severity, but ranges from >90% for stable dysplasia[2] to 63% to 93% for dislocated/reducible hips (eg, Ortolani positive).[3–5]

Even after successful Pavlik treatment, the risk of residual radiographic acetabular dysplasia is reported to be between 2.4% and 33.8%.[6,7] As a result, some practitioners advocate for continued harness use beyond ultrasonographic normalization to mitigate this issue. For many providers, a weaning period following normalization achieves this additional wear-time while satisfying a family's need for progress toward brace discontinuation. Others, however, favor stopping the harness after ultrasonographic normalization without a weaning period as "normal is normal." Even among experts, there is no strong consensus regarding the role, importance, or optimal manner of harness weaning.[8] Not surprisingly, the controversy over weaning stems from a lack of data on the topic. To our knowledge, only 1 previous study has directly compared weaning with immediate harness cessation. However, this study was limited by cohort heterogeneity and used surgeon reintervention (a subjective endpoint) as the primary outcome measure.[9] A systematic review of late acetabular dysplasia after Pavlik treatment similarly observed no difference in dysplasia rates on the basis of the use of a weaning period, though specific protocols varied and the authors were unable to conduct a rigorous analysis.[10]

From the *Division of Orthopedics, Children's Hospital of Philadelphia, Philadelphia, PA; and †Department of Orthopedic Surgery, NYU Langone Health Orthopedic Hospital, New York, NY.

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Reprints: Wudbhav N. Sankar, MD, Division of Orthopaedic Surgery, 2nd Floor Wood Building, The Children's Hospital of Philadelphia, 34th and Civic Center Boulevard, Philadelphia, PA 19104. E-mail: sankarw@email.chop.edu.

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Therefore, the purpose of this study was to compare the radiographic outcomes of 2 cohorts of infants with DDH treated in a Pavlik harness—1 treated with a weaning protocol and 1 without. We hypothesized that the acetabular index (AI) in both dislocated/reducible hips and hips with stable dysplasia would be lower in those who underwent an additional weaning period compared with those who underwent immediate treatment cessation.

METHODS

This was an institutional review board-approved retrospective comparative study of infants with DDH at 2 tertiary care children's hospitals participating in a separate and ongoing prospective DDH Registry. Only patients with pretreatment ultrasound (US) in whom the harness was initiated under 3 months of age ($\leq$90 d) and with radiographic follow-up at ~12 months of age were considered for inclusion. For all criteria, uncorrected, chronologic ages were used. Patients in whom the harness failed for any reason and subsequently required a rigid brace or surgical treatment were also excluded. Reduced/dislocatable hips (eg, Barlow positive) were also excluded as these hips are less common and, therefore, harder to match between institutions. Individual hips affected by DDH were considered separately for all patients.

At institution W (weaned), infants with dislocated/reducible hips are treated full time with a Pavlik harness (ie, 24 h/d) initially. Infants are then seen at 2 weeks with an in-harness US and a gentle physical examination. If the Ortolani sign has resolved, the hips are deemed to be clinically stabilized at which point wear is reduced to 23 hours/day to allow for more liberal changes and bathing. Hips with stable dysplasia that persists beyond 6 to 8 weeks of age [defined as an α angle (AA) $\leq$60 degrees and/or femoral head coverage (FHC) $\leq$50%] are treated for 23 hours/day to start. Both types of patients are seen every 2 to 3 weeks with serial clinical examinations and US (performed by radiology technicians). Once US parameters have normalized (AA $\geq$60 degrees, FHC $\geq$50%), infants enter a staged-weaning protocol, depending on the initial clinical examination. In patients with dislocated/reducible hips, this typically consists of 2 weeks each of 18 hours/day, 12 hours/day, and 6 hours/day in the harness. An accelerated weaning period is used for hips with stable dysplasia, consisting of 4 weeks at 12 hours/day. At institution NW (not weaned), treatment is similar for the first 6 to 8 weeks of harness wear. However, after normalization of US parameters, treatment is stopped without a weaning period. Following successful harness treatment, both institutions recommend continued radiographic follow-up to monitor for residual acetabular dysplasia, including a visit at 1 year of age.

Medical records were reviewed at both centers to determine the date of harness initiation, and baseline demographics including patient sex, laterality affected, and risk factors for the development of DDH (eg, breech presentation and family history). US and physical examination findings from the first visit were reviewed to determine initial DDH severity. Ultrasonographic metrics including the AA and percent FHC were measured by each center on coronal flexion views. AA was measured using the technique originally described by Graf[11] and FHC was calculated utilizing the methodology of Morin et al[12] (Figs. 1A, B). Similar US measurements were recorded at the end of the initial treatment period (before weaning for institution W or the end of treatment for institution NW). Follow-up anteroposterior radiographs of the pelvis taken at ~1 year of age were used to measure the AI of affected hips and the corresponding International Hip Dysplasia Institute (IHDI) grade using standard picture archiving and communication system (PACS) software tools. The AI was measured as the angle between Hilgenreiner line connecting the superior aspects of the triradiate cartilages bilaterally and a line drawn from the superolateral aspect of the triradiate cartilage to the most lateral aspect of the acetabular sourcil (Fig. 1C).[13,14]

We determined the length of harness treatment by multiplying the number of hours of prescribed wear per day

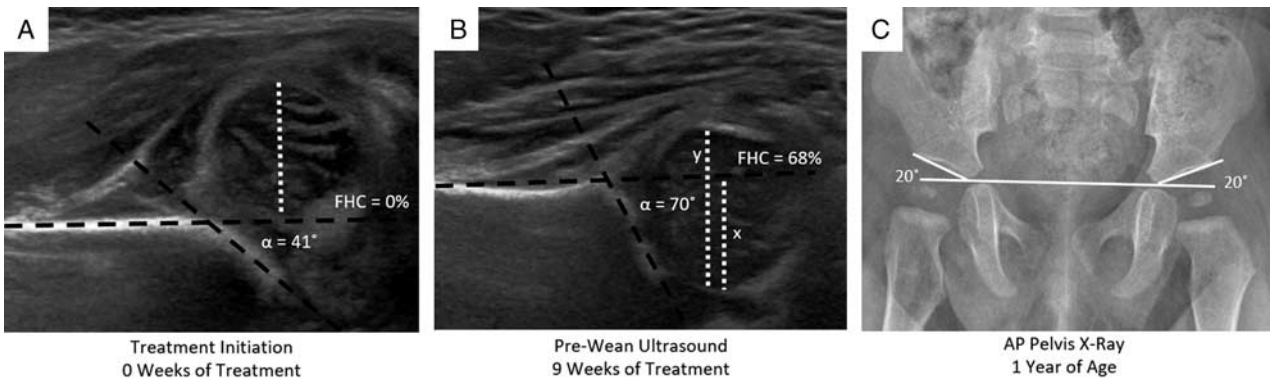

FIGURE 1. A, Coronal flexion ultrasound (US) in a 7-day-old female with a dislocated/reducible right hip. α angle was measured according to the technique of Graf[11] and the percent femoral head coverage (FHC) according to the technique of Morin et al.[12] B, Repeat US after 9 weeks of treatment demonstrates normalization of US parameters. A staged-weaning period was then prescribed over 6 weeks. C, Follow-up anteroposterior (AP) radiograph of the pelvis 1 year of age demonstrates normal acetabular indices for age.

by the prescribed number of days. For example, a patient undergoing 4 weeks of full-time (23 h/d) treatment followed by an accelerated wean consisting of 4 weeks of part-time (12 h/d) treatment would have theoretically worn the harness for 980 total hours (28 d×23 h + 28 d×12 h). This was then converted to a mean number of hours worn per day over the entire course of treatment (ie, 980 h÷56 d = 17.5 h/d).

Individual hips—already cohorted by institutional weaning protocol—were separated into groups on the basis of disease severity. Dislocated/reducible hips were matched by protocol utilizing IBM SPSS Statistics for Macintosh (Version 24.0, Armonk, NY) on the basis of the age at treatment initiation within 14 days, AA within 10 degrees, and FHC within 10%. The more common stable dysplastic hips were matched more stringently on the basis of the age at initiation within 14 days, AA within 5 degrees, FHC within 10%, and time in harness before wean (institution W) or in total (institution NW) within 7 days. A priori power analysis determined that a sample of 16 hips per group (power = 0.8, $\alpha = 0.05$, SD = 3) would be sufficient to detect a 3 degree difference in AI at 12 months.[15] This power analysis was based on a study reporting a mean 2 to 3 degrees of intraobserver variation in AI using standard PACS measurement tools.[16] Utilizing a significance threshold of $P < 0.05$, groups were compared utilizing χ^2 and Fisher exact tests for categorical variables, and Mann-Whitney *U* test for continuous variables.

RESULTS

After the application of initial exclusion criteria, 56 patients (98 hips) from institution W and 63 patients (110 hips) from institution NW were considered for inclusion (Fig. 2). Hips were then matched by protocol (ie, weaned vs. not weaned) using the aforementioned methodology. In total, 64 hips (32 dislocated/reducible hips and 32 with stable dysplasia) from 53 patients were successfully matched (Table 1). There were no significant differences in demographic factors between the W and NW cohorts, except for a higher likelihood of breech presentation in the weaned cohort (44.4% vs. 11.5%, $P = 0.014$).

TABLE 1. Patient Demographics

Variables	Not Weaned (N = 26)	Weaned (N = 27)	*P*
Age at initiation (d)*	16.6 ± 11.0 (5-56)	15.7 ± 14.7 (3-65)	0.167
Sex†			0.420
Male	2 (7.7)	5 (18.5)	
Female	24 (92.3)	22 (81.5)	
Affected laterality			0.292
Right	9 (34.6)	15 (55.6)	
Left	11 (42.3)	7 (25.9)	
Bilateral	6 (23.1)	5 (18.5)	
Risk factors			
Breech presentation†	3 (11.5)	12 (44.4)	**0.014**
Immediate family history†	0 (0)	4 (15.4)	0.110
Extended family history	0 (0)	5 (19.2)	0.051

Bold value are statistically significant findings ($P < 0.05$).
*Mann-Whitney *U*.
†Fisher exact.

On the basis of our power analysis, 16 dislocated/reducible hips from each institution were matched (Table 2). Despite matching, age at treatment initiation was significantly younger for those treated at institution W (10.1 ± 9.1 d vs. 14.3 ± 9.0 d, $P = 0.032$). Duration of harness treatment to US normalization was also longer for those treated at institution NW (58.5 ± 11.5 d vs. 46.3 ± 8.3 d, $P = 0.001$). As expected, weaned patients spent more total time in the harness, though for fewer hours per day on average. At 1-year radiographic follow-up, weaned patients were slightly younger. However, mean AI was not significantly different between the NW and W cohorts (24.8 ± 2.6 degrees vs. 23.9 ± 2.7 degrees, $P = 0.323$). All but 1 hip (in the NW cohort) were IHDI grade 1 (Figs. 1A–C).

In total, 16 hips with stable dysplasia were also matched from each center (Table 3). Most demographic and US factors were similar between cohorts, except that percent FHC after primary treatment (before wean) was significantly greater in the W cohort compared with the NW cohort. At 1-year radiographic follow-up, weaned patients were again slightly younger. Similar to dislocated/

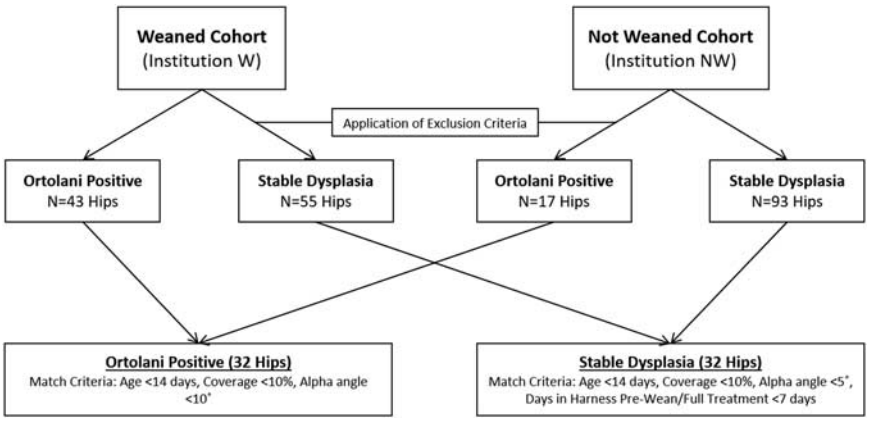

FIGURE 2. Diagram of cohorting and matching of Ortolani positive and stable dysplasia hips.

TABLE 2. Treatment Characteristics and Outcomes for Hips With Positive Ortolani Sign

Variables	Not Weaned (N = 16)	Weaned (N = 16)	*P*
Age at initiation (d)	14.3 ± 9.0	10.1 ± 9.1	**0.032**
Pretreatment US			
Percent coverage	3.8 ± 5.0	5.0 ± 6.3	0.696
α angle	39.8 ± 2.7	39.0 ± 8.0	0.669
Post-treatment (prewean) US			
Percent coverage	52.1 ± 3.1	62.1 ± 11.3	**0.001**
α angle	64.1 ± 3.3	62.9 ± 5.7	0.361
Age at follow-up x-ray	405.3 ± 42.9	373.6 ± 16.5	**0.023**
IHDI class†			1.000
I	15 (93.8)	16 (100.0)	
II	1 (6.3)	0 (0)	
Acetabular index	24.8 ± 2.6	23.9 ± 2.7	0.323
Pavlik treatment			
Harness days prewean	58.5 ± 11.5	46.3 ± 8.3	**0.001**
Total time in harness (h)	1362.5 ± 263.8	1596.6 ± 230.0	**0.007**
Mean hours per day	23.3 ± 0.1	17.8 ± 0.7	**< 0.001**

Bold values are statistically significant findings ($P < 0.05$).
Matched on starting age within 14 days, within 10% coverage, within 10 degrees α.
†Fisher's exact.
IHDI indicates International Hip Dysplasia Institute; US, ultrasound.

reducible hips, the mean AI was not significantly different between the NW and W cohorts for stable dysplasia (23.1 ± 2.2 degrees vs. 22.8 ± 3.2 degrees, $P = 0.838$). One hip in the NW cohort was IHDI grade 2. All remaining hips were IHDI grade 1.

TABLE 3. Treatment Characteristics and Outcomes for Hips With Stable Dysplasia

Variables	Not Weaned (N = 16)	Weaned (N = 16)	*P*
Age at initiation (d)	19.6 ± 15.2	19.8 ± 16.3	0.926
Pretreatment US			
Percent coverage	44.7 ± 6.4	45.4 ± 6.2	0.809
α angle	54.1 ± 6.5	54.8 ± 6.0	0.590
Post-treatment (prewean) US			
Percent coverage	53.7 ± 2.8	61.2 ± 8.4	**0.003**
α angle	66.0 ± 3.5	66.4 ± 4.1	0.897
Age at follow-up x-ray			**< 0.001**
IHDI class†	417.5 ± 37.8	375.2 ± 17.3	1.000
I	15 (93.8)	16 (100.0)	
II	1 (6.3)	0 (0)	
Acetabular index	23.1 ± 2.2	22.8 ± 3.2	0.838
Pavlik treatment			
Harness days prewean	46.3 ± 6.4	43.3 ± 4.5	0.051
Total time in harness (h)	1066.3 ± 146.4	1540.4 ± 150.1	**< 0.001**
Mean hours per day	23.0 ± 0.1	17.8 ± 0.6	**< 0.001**

Bold values are statistically significant findings ($P < 0.05$).
Matched on starting age within 14 days, within 10% coverage, within 5 degrees α, and within 7 days in harness prewean (Institution W) or total (Institution NW).
†Fisher exact.
IHDI indicates International Hip Dysplasia Institute; NW, not weaned; US, ultrasound; W, weaned.

DISCUSSION

The Pavlik harness is the most widely used orthosis for treating infantile hip dysplasia in North America, with success rates of 63% to 93% depending on disease severity and age at initial treatment.[2–5] Despite its popularity, there remains significant provider-to-provider variability in terms of treatment length, follow-up intervals, and US imaging frequency.[8] One area of ongoing controversy is the role and importance of harness weaning after the normalization of hip parameters.

Part of this controversy relates to differing levels of concern regarding the risk of residual acetabular dysplasia after seemingly successful Pavlik treatment as a younger infant. Alexiev et al and others have reported that only 2.4% to 4.6% of patients experience late acetabular dysplasia after successful reduction and stabilization in Pavlik harness as infants.[6,17,18] Sarkissian et al,[7] however, observed that 13% of patients successfully treated with Pavlik harness had residual dysplasia (AI > 30 degrees) on 6-month radiographs, which increased to 34% at 12 months (on the basis of AI > 28 degrees). Dornacher et al similarly observed that 29.4% of patients treated to ultrasonographic normalization in Pavlik had severe residual dysplasia (> 2 SD above mean according to Tönnis) at radiographic follow-up at a mean of 14.8 months.[19,20] Acetabular dysplasia that persists into adulthood is associated with the development of osteoarthritis and the need for premature total hip replacement.[21,22]

Proponents of harness weaning seek to "overtreat" a hip to reduce the risk of future residual acetabular dysplasia while still satisfying a family's need for progress toward brace discontinuation. This is supported by van der Sluijs et al,[23] who suggested that prolonged harness wear reduces acetabular dysplasia, particularly for Graf type III hips. In contrast, opponents of weaning argue that "normal is normal" and that continued harness use beyond the point of US normalization only creates unnecessary frustrations and hardship for families. A more recent systematic review by Shaw et al[10] on late dysplasia rates after Pavlik treatment (defined as AI ≥ 30 degrees at 6 months) found no difference between studies that did and did not include a weaning protocol (recorded as a dichotomous variable), though institutional protocols varied widely and a more thorough analysis was not conducted.

We are aware of only 1 previous study that directly evaluated the effect of harness weaning. Westacott et al[9] compared outcomes between 80 patients treated with a staged-weaning protocol versus 48 who immediately ceased harness treatment. Although they similarly observed no benefit to weaning, their methodology and outcomes were limited by several flaws. First, they included patients diagnosed with hip dysplasia up to 6 months, and nearly 15% of all children started harness treatment after 3 months. Such variation in age at treatment initiation makes it difficult to draw conclusions on the efficacy of weaning for more typical DDH

populations, as Ömeroğlu et al[2] has shown that Pavlik efficacy decreases significantly in those starting treatment after 4 months of age. Furthermore, groups were not matched by age or dysplasia severity, with no separation for stable dysplastic hips versus those with positive Ortolani signs. Moreover, their primary outcome was a requirement for reintervention, which was defined as further/repeated bracing or surgical treatment (eg, closed or open reduction). Such outcomes tend to be biased by surgeon management preferences as compared with more objective radiographic outcomes.[8]

Our study used the objective outcome of AI at 12 months of age as our primary outcome, matching weaned and nonweaned cohorts on the basis of disease severity, age at initiation, initial AA, and initial FHC for patients who all began treatment under 3 months of age. Our data suggest that for both dislocated/reducible hips and hips with stable dysplasia, there was no significant difference in radiographic outcome at 1 year of age based on whether a child was weaned or not. Although strict matching criteria only allowed for the inclusion of 53 patients and 64 hips overall, our study was adequately powered to detect a 3-degree difference in AI. A difference of 3 degrees was chosen for this power analysis on the basis of a study by Segev et al[16] that found 2 to 3 degrees intraobserver error and only 0 to 1 degrees interobserver variance in the measurement of AI with digital radiographs and PACS software. Further, our radiographic outcomes at 1 year are in line with published population norms (males = 22.8 degrees, females = 24.1 degrees) and demonstrate appropriate dysplasia resolution as would be expected for a group that did not require operative intervention.[13]

The results of our study should be interpreted within the context of its limitations. First, neither cohort had any harness compliance measures, so all calculations of wear-time were made assuming full compliance. Indeed, families may not have complied with the hours of prescribed brace wear, especially during the weaning period after being informed that the US had normalized. This, of course, would bias our results toward the null. Furthermore, this study was not prospective but rather a retrospective, comparative design. As a result, despite our attempts to match all important baseline clinical characteristics, there remain some intrinsic differences between study cohorts that may have influenced our results. For example, despite the recommendation for follow-up at 1 year, infants in the NW cohort were seen nearly 6 weeks later than infants in the W cohort. Although this is unlikely to have drastically impacted radiographic differences between groups, normative data from Novais et al[13] demonstrates that AI decreases by 1 to 2 degrees between the ages of 6 and 18 months. Even a 6-week difference in follow-up, therefore, could have marginally impacted observed AIs (ie, more time for age-related decrease in AI). More importantly, dislocated/reducible hips treated at institution NW were older at Pavlik initiation and were maintained in a harness for significantly longer than those seen at institution W during the initial treatment phase (before weaning/cessation). Although this difference was clinically insignificant for the age at harness initiation (mean, 4.2 d), it was more pronounced for treatment time (mean, 12.2 d). This resulted from institutional differences in scheduled follow-up intervals. Unfortunately, this may have biased radiographic outcomes toward the null and reduced the theoretical benefit of staged weaning. Finally, we chose to analyze both hips in bilateral cases in order to facilitate numbers and matching. This does potentially introduce some bias into the analysis.

Regardless of its limitations, our study is the first to directly compare the objective radiographic outcomes of 2 cohorts of infants with DDH treated in a Pavlik harness using strict matching criteria, 1 treated with a weaning protocol and 1 without. Our study does not demonstrate a benefit to an additional weaning period over immediate cessation for both stable dysplastic hips and dislocated/reducible hips. However, differences in follow-up protocols between centers support the need for a more rigorous randomized controlled trial.

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