Prolonged Brace Treatment Does Not Result in Improved Acetabular Indices in Infantile Dislocated Hips

Vidyadhar V. Upasani, MD, James D. Bomar, MPH,* Ryan E. Fitzgerald, MD,* Alexander J. Schupper, MD,* and Simon P. Kelley, MBChB, PhD, FRCS;† for International Hip Dysplasia Registry*

Background: The Pavlik harness (PH) is commonly used to treat infantile dislocated hips. However, significant variability exists in the duration of brace treatment after successful reduction of the dislocated hip. The purpose of this study was to evaluate the effect of prescribed time in brace on acetabular index (AI) at two years of age using a prospective, international, multicenter database.

Methods: We retrospectively studied prospectively enrolled infants with at least 1 dislocated hip that were initially treated with a PH and had a recorded AI at 2-year follow-up. Subjects were treated at 1 of 2 institutions. Institution 1 used the PH until they observed normal radiographic acetabular development. Institution 2 followed a structured shorter brace treatment protocol. Hip dislocation was defined as <30% femoral head coverage at rest on the pretreatment ultrasound or International Hip Dysplasia Institute (IHDI) grade III or IV on the pretreatment radiograph.

Results: Fifty-three hips met our inclusion criteria. Hips from Institution 1 were treated with a brace ×3 longer than hips from institution 2 (adjusted mean 8.9 ± 1.3 vs. 2.6 ± 0.2 mo) ($P < 0.001$). Institution 1 had an 88% success rate and institution 2 had an 85% success rate at achieving hip reduction ($P = 0.735$). At 2-year follow-up, we observed no significant difference in AI between Institution 1 (adjusted mean 25.6 ± 0.9 degrees) compared with Institution 2 (adjusted mean 23.5 ± 0.8 degrees) ($P = 0.1$). However, 19% of patients from Institution 1 and 44% of patients from Institution 2 were at or below the 50th percentile of previously published age-matched and sex-matched AI normal data ($P = 0.049$). Also, 27% (7/26) of hips from Institution 1 had significant acetabular dysplasia (more than 2 SD from the mean), compared with a 22% (6/27) from Institution 2 ($P = 0.691$). We found no correlation between age at initiation of bracing and AI at 2-year follow-up ($P = 0.071$).

Conclusions: The PH brace can successfully treat dislocated infant hips, however, prolonged brace treatment was not found to result in improved acetabular development at 2-year follow-up.

Level of Evidence: Level III.

Key Words: DDH, Pavlik harness, brace duration

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From the *Rady Children's Hospital, San Diego, San Diego, CA; and †The Hospital for Sick Children, Toronto, Ontario, Canada.

The International Hip Dysplasia Registry: Kishore Mulpuri, Emily Schaeffer, Nicole Williams, Travis Matheney, Wudbhav Sankar, Leo Donnan, Emily Dodwell, Pablo Castaneda, Jose Herrera-Soto, Vidyadhar V. Upasani, Alex Aarvold, Nick Clarke, Harry Kim, Simon P. Kelley, Alaric Aroojis, Hitesh Shah, Venkatadass Krishnamoorthy, Sandeep Patwardhan, Chittaranjan Sahu, Zhongli Zhang, Sukhdeep Dulai, Jacob Jaremko, Ge Yihua, Thierry Benaroch, David Bade, Stephanie Pun, Yanzhou Wang, Jingwei Liu, Xie Yang, Martin Gottliebsen.

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Reprints: Vidyadhar V. Upasani, MD, 3020 Children's Way, MC5062, San Diego, CA 92123. E-mail: vupasani@rchsd.org.

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Developmental dysplasia of the hip (DDH) is the most common hip disorder that affects newborn children. Epidemiologic studies show that 1% to 3% of newborns are diagnosed with DDH at birth.[1,2] Because of the predominance of this affliction, a significant amount of attention has been placed on optimally classifying and treating DDH. The spectrum of disease is broad, from mild under coverage of the femoral head that may go unnoticed until young adulthood, to a dislocated hip that necessitates treatment early in a child's life. Because of this heterogeneity, it is difficult to study DDH as one discreet disease, but instead we must analyze each category of disease severity. In this study, we focus on dislocated hips, both reducible and irreducible.

Although this spectrum of disease has been recognized, there remains no consensus on approach and treatment method. In North America, it is common to perform ultrasound screening based on an individual's risk factors and physical exam.[3] Previous risk factors identified for DDH include being a first-born child, breech position

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presentation, female sex, and having a family history of DDH.[3–5] Furthermore, radiologic screening, including ultrasound or X-ray, is performed if the patient has an exam consistent with an unstable or dislocated hip. When these hips are identified, a Pavlik harness (PH) is the most common first-line treatment used in North America. This treatment method has been reported to have a success rate ranging from 58% to 97%, with much lower rates of avascular necrosis compared with other, more rigid orthoses.[5–8] The Pavlik technique allows hip and knee flexion, which allows for a gentle reduction, while maintaining the dynamic nature of the joint, whereas other orthoses provide static hip abduction as the hip develops.[7–9]

There is still a dearth of information in the literature on a standardized bracing protocol. The heterogeneity of DDH and the lack of patient numbers at most individual institutions have left the questions regarding such protocols unanswered. As a result, there exists a wide range in bracing treatment across institutions and no standardized duration or method of bracing. This has become evident even among the centers contributing to large registries such as the International Hip Dysplasia Study Group [International Hip Dysplasia Institute (IHDI)].

The purpose of this study was to evaluate the effect of prescribed time in a PH on the acetabular index (AI) at 2 years of age in patients with hips dislocated at rest, using an international, multicenter, prospective cohort. We hypothesized that increased time in the PH would improve acetabular indices at 2 years of age.

METHODS

A research study group for the prospective study of idiopathic DDH was established among various institutions around the world. Institutional Review Board or Ethics Committee approvals were granted at all sites before initiating data collection and written consent was obtained for each subject included in the study. The study data was collected prospectively and managed using REDCap (Research Electronic Data Capture),[10] a browser-based metadata-driven EDC system for designing clinical and transitional research. The study group standardized the criteria for diagnosing and classifying dislocated hips but they allowed independent treatment protocols to be able to study practice variation and outcomes. This study includes subjects from two North American Institutions, Institution 1 is located in the Western United States, Institution 2 is located in Eastern Canada.

Institutional Philosophy

Institution 1 treated dislocated hips, both reducible and irreducible, with a PH full time (24 h/d). These patients are followed weekly with serial ultrasound examinations. Once the ultrasound examination of an Ortolani-positive hip is reduced and stable, the time in brace is reduced to allow the child out of the brace for bathing. If the hip has not stabilized by 4 to 6 weeks in the harness, the patient may be transitioned to a fixed abduction brace. If the hip continues to be unstable, the child will be scheduled for an arthrogram and examination under anesthesia. Similarly, in hips that presented as dislocated and irreducible, once the hip has reduced, time in brace is reduced to allow the child out of the brace for bathing. Hips that do not achieve in harness reduction after 3 to 4 weeks in the brace are scheduled for closed versus open reduction under anesthesia. If the hip is reduced and stable in the harness, the child is left in the brace until there is further improvement in the acetabulum (decrease in AI, development of a sharp lateral edge of the acetabulum). As the child grows, the PH may be switched out for a fixed abduction brace for comfort. There is no set end date for discontinuation of brace treatment at Institution 1.

Institution 2 has a more regimented approach to bracing these hips. Dislocated hips are treated with a PH 24 hours per day and followed weekly with serial ultrasounds for a maximum of 3 weeks. If the hip has more than 40% femoral head coverage on any of the serial ultrasounds, they begin their 12-week treatment protocol. The child is followed with ultrasound at 2, 5, 8, and 12 weeks. Brace time is reduced to 23 hours per day at the 5-week mark. For hips that fail to achieve more than 40% femoral head coverage during the first 3 weeks, they are either scheduled for reduction under anesthesia (for irreducible hips), or transitioned to a fixed abduction brace (for hips that are reducible). Reducible hips will be followed weekly with an ultrasound for a maximum of 3 additional weeks. If the hip has not stabilized in the fixed abduction brace at that point, they are scheduled for reduction under anesthesia. If the hip has stabilized, they begin their 12-week treatment protocol. The child is followed with ultrasound at 2, 5, 8, and 12 weeks. Brace time is reduced to 23 hours per day at the 5-week mark. At the end of the 12-week bracing course, if the ultrasound is normal, the brace is discontinued and the child is followed at 1 year with hip radiographs. If the hip is abnormal at the end of the 12-week course of bracing, they may continue with the brace until there is further improvement in the acetabulum (decrease in AI, development of a sharp lateral edge of the acetabulum) or until the child has been in the brace for a total of 20 weeks. At 20 weeks, or normal ultrasound, the brace will be discontinued and the child is followed at 1 year with hip radiographs.

Study Cohort

Subjects were included if they were found to have a dislocated hip at initial presentation, were initially treated with a PH at <6 months of age, and had an x-ray examination at 2 years of follow-up (22 to 26 mo). All subjects had idiopathic DDH. All dislocations were verified by ultrasound or X-ray at initial diagnosis. From these imaging modalities, hips were considered dislocated if the femoral head was <30% covered on the coronal view of the ultrasound or if they were IHDI grade III or IV on X-ray.[11,12] Similarly, hips were considered reduced using the same ultrasonographic and radiographic parameters, with all reductions being confirmed by either ultrasound or x-ray. Hips were excluded if they: did not have an AI recorded between 22 and 26 months of follow-up (n = 47), were not treated with a PH (n = 3), were over age 6 months at initiation of treatment (n = 2), were still in a brace at

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2 years follow-up (n = 2), or did not have a documented brace end date (n = 1).

Outcomes of Interest and Independent Variables

Our primary outcome of interest was AI at 2 years of age. In order to minimize the effect of age on AI, subjects that were followed for longer than 2 years were truncated and only the AI collected between 22 and 26 months follow-up was used. The AI values of our cohort were classified using the percentile data presented by Novais et al[13] with significant acetabular dysplasia being classified as AI measurements in the 90th percentile or greater using the data reported by Novais et al[13] which is broken down by age and sex. We are purposefully not defining "normal" AI at an arbitrary cutoff point, instead we are comparing each individual's AI to the population reported by Novais and colleagues. There is no clear data to support the assumption that within 2SD of the mean does not lead to symptomatic dysplasia requiring surgical treatment during adolescence or adulthood. Success of brace treatment was defined as ultrasound or radiographically confirmed improvement of femoral head coverage of more than or equal to 50%. Demographic information collected included: sex, side of dislocation, date of birth, birth weight, fetal presentation, birth method, family history of acetabular dysplasia, and swaddling history. Other variables compared between institutions included: age at initiation of treatment, duration of treatment, reducibility of the hip, and the need for surgical reduction. Duration of treatment was calculated by subtracting the date the brace was prescribed from the date that the brace was discontinued. Compliance was not monitored for this study. In subjects that underwent a surgical reduction, time in the postoperative spica cast was recorded and counted in the duration of brace treatment. When classifying prescribed brace wear, "full time" brace wear was defined as a minimum of 20 hours per day. Among treating physicians whose patients were included in this study, there are varying approaches to the amount of time an infant should spend in a brace per day. It was not uncommon for some surgeons to prescribe 24 hours/day brace wear for a week, and if the hip stabilized on US at the 1-week mark, they would decrease the brace wear to 23 hours/day. Others started at 23 hours/day and reduced it to 20 hours/day. Because of this, we defined full time as a minimum of 20 hours/day.

Statistical Analysis

Basic descriptive statistics are presented. Adjusted mean ± SE is presented unless stated otherwise. The hip was used as the unit of analysis. Generalized linear mixed models were utilized for analysis of continuous outcome variables, with subject as a random factor and institution as a fixed factor to account for nonindependence because of bilaterality. Linear models were fit for interval dependent variables, with the Satterthwaite approximation and robust estimation if model assumptions were violated. The adjusted means were obtained from the generalized linear mixed models linear models. A binary logistic mixed model was fit for evaluating the need for surgical reduction. At follow-up, AI measurements were compared with the age-matched and sex-matched AI values reported by Novais et al[13] and evaluated with the Pearson χ^2. Statistical analysis was performed using SPSS (version 27; IBM, New York, NY). Significance was defined as $P < 0.05$.

RESULTS

Fifty-three hips (44 patients) were included. Institution 1 treated 26 hips; Institution 2 treated 27 hips. The majority (80%) of the patients in this study were female (83% of hips). 27% of patients were breech at birth. 30% of patients had a family history of hip dysplasia, 16% had an immediate family history, and 14% had an extended family history of hip dysplasia. Additional demographic data can be found in Table 1.

All hips were treated with a PH. Treatment was initiated at an adjusted mean age of 1.0 ± 0.3 months (range: 0.2 to 4.8 mo) at Institution 1 and 1.1 ± 0.1 months (range: 0.2 to 2.4 mo) at Institution 2 ($P = 0.73$). The majority of hips at both institutions were successfully reduced without the need for open or closed reduction. Institution 1 had an 88% (23/26 hips) success rate and institution 2 had an 85% (23/27 hips) success rate ($P = 0.735$). When removing subjects that required surgical reduction, Institution 1 achieved reduction at an adjusted mean of 14.5 ± 2.5 days after initiation of brace treatment. Institution 2 achieved reduction at an adjusted mean of 17.8 ± 2.5 days after initiation of brace treatment ($P = 0.363$).

At 2-year follow-up, we observed no significant difference in AI between Institution 1 (adjusted mean 25.6 ± 0.9

TABLE 1. Demographic Information

	Institution 1 26 Hips (21 Patients), n (%)	Institution 2 27 Hips (23 Patients), n (%)
Sex ($P = 1.0$)		
Female	22 (85)	22 (81)
Male	4 (15)	5 (19)
Fetal presentation ($P = 0.119$)		
Breech	4 (15)	10 (37)
Cephalic	22 (85)	17 (63)
Delivery method ($P = 0.217$)		
Cesarean	11 (42)	16 (59)
Vaginal	15 (58)	11 (41)
Family history ($P = 0.225$)		
Extended	2 (8)	6 (22)
Immediate	6 (23)	3 (11)
None	18 (69)	18 (67)
Swaddling history ($P = 0.271$)		
Swaddled	9 (35)	14 (52)
Not swaddled	17 (65)	13 (48)
Surgical reduction ($P = 1.0$)		
None	23 (88)	23 (85)
Closed reduction (CR)	1 (4)	4 (15)
Open reduction (OR)	2 (8)	0
Reducibility at presentation ($P = 0.023$)		
Reducible	26 (100)	21 (78)
Irreducible	0	6 (22)
Birth weight (kg) ($P = 0.014$)		
Mean ± SD	3.5 ± 0.4	3.2 ± 0.3
Range	2.8 to 4.3	2.4 to 3.9

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degrees) compared with Institution 2 (adjusted mean 23.5 ± 0.8 degrees) ($P = 0.1$). However, 19% of patients from Institution 1 and 44% of patients from Institution 2 were at or below the 50th percentile of previously published age-matched and sex-matched AI normal data ($P = 0.049$). Also, 27% (7/26) of hips from Institution 1 had significant acetabular dysplasia, compared with a 22% (6/27) from Institution 2 ($P = 0.691$). Significant acetabular dysplasia was defined as AI measurements in the 90th percentile or greater compared with the age-matched and sex-matched data reported by Novais et al.[13] Correlation between age at initiation of bracing and AI at 2-year follow-up was controlled for subject variation and evaluated using continuous data for both and not found to be significantly correlated ($P = 0.071$).

Hips treated at Institution 1 were treated in a brace for ~×3 longer than hips treated at Institution 2 and yet saw no benefit in AI at age 2 years compared with the cohort treated at Institution 2. These findings persisted, even when excluding hips that required a surgical reduction (Table 2). Cohort characteristics of hips treated surgically are presented in Table 3. In all cases, institution 1 began with a course of full time brace treatment, defined as ≥20 hours per day of brace wear, and then switched to part-time brace wear. Institution 2 did not convert to part-time brace wear for any subjects in this study. Institution 1's course of full time brace wear duration was significantly longer than institution 2's total brace duration (adjusted mean 5.0 ± 0.7 vs. 2.7 ± 0.2 mo respectively, $P = 0.005$). Both institutions continued brace treatment after the hip was reduced.

TABLE 2. Outcomes of Interest

	Institution 1	Institution 2	*P*
Entire cohort			
Total time in brace (mo)			
Adjusted mean ± SE	8.9 ± 1.3	2.6 ± 0.2	< 0.001
95% CI	6.4 to 12.2	2.1 to 3.2	
Acetabular index at 2 y follow-up (deg.)			
Adjusted mean ± SE	25.6 ± 0.9	23.5 ± 0.8	0.1
95% CI	23.7 to 27.5	22.0 to 25.1	
N hips (patients)	26 (21)	27 (23)	
Brace success only			
Total time in brace (mo)			
Adjusted Mean ± SE	8.4 ± 0.9	2.9 ± 0.3	< 0.001
95% CI	6.8 to 10.4	2.4 to 3.6	
Acetabular index at 2 y follow-up (deg.)			
Adjusted mean ± SE	24.9 ± 0.9	22.8 ± 0.9	0.096
95% CI	23.1 to 26.8	21.0 to 24.6	
N hips (patients)	22 (19)	23 (20)	

CI indicates confidence interval.

TABLE 3. Cohort Characteristics of Hips Treated Surgically

	Institution 1 (n = 3)	Institution 2 (n = 4)
Age at treatment initiation, mean ± SD	0.8 ± 0.2	1.1 ± 0.3
In months, range	0.7 to 1.0	0.7 to 1.5
Time in brace before surgical reduction, mean ± SD	8.6 ± 0.4	4.5 ± 1.7
In weeks, range	8.1 to 9.0	3.0 to 7.0
Time in spica postsurgical reduction, mean ± SD	12.7 ± 1.1	13.4 ± 1.3
In weeks, range	11.7 to 13.9	12.3 to 15.3
Dislocation status at presentation		
Reducible	3	2
Irreducible	0	2
Surgical reduction type		
Closed	1	4
Open	2	0

DISCUSSION

The primary goals in treating infants with a dislocated hip have previously been established. These goals include: obtaining a concentric reduction, maintaining that reduction, and allowing for normal femoral head and acetabular development, all while avoiding complications.[6,7,14–19] The PH is typically effective at achieving these goals, with success rates ranging from 58% to 97%.[17–19] However, many of these studies report results across the DDH spectrum, or do not explicitly define their patient population, which potentially accounts for a lot of the reported variability in success rate. Our study focuses solely on dislocated hips treated with a PH from 2 institutions that have very different philosophies regarding duration of brace treatment so that we could evaluate the effect of the brace on acetabular development to determine guidelines on the amount of time a child should be in a brace. On the basis of the current findings, we reject our hypothesis that increased time in the PH is associated with improved acetabular indices at 2 years of age.

In 2016, the IHDI study group demonstrated not only the success rate of brace treatment in a prospective cohort, but also identified the risk factors for failure of the brace for patients with a hip dislocation at rest. They defined brace failure as an inability to obtain and maintain a concentrically reduced hip without the use of surgical reduction. The 6 risk factors identified included: developing femoral nerve palsy during treatment, an initially irreducible hip, treatment initiated after 7 weeks of age, a right hip dislocation, a Graf-IV hip, and the use of a static brace. They found that hips with 0 of these risk factors had a 3% risk of failure; whereas those with at least 4 risk factors had a 100% risk of failure.[20]

However, there is a paucity of evidence to guide clinical practice in the treatment of DDH with bracing and 2 distinct bracing duration patterns can be found. In 1 group are those that use bracing only until a concentric reduction is obtained, which leads to a much shorter duration of bracing. The second group believes that maintaining the brace for a longer period after reduction of the hip allows better remodeling of the acetabulum, leading to a more developed and normal hip joint. This study attempts to explore the validity of the philosophy that increased brace time leads to a more normal hip by isolating the effect of dynamic brace duration on AI using a multicenter, prospective cohort to evaluate one effect of brace treatment in patients that presented with a dislocated hip.

In the current study, age at initiation of brace treatment was not a factor in AI at age 2 years. There was no significant difference in the adjusted mean age at

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initiation of treatment among institutions and both institutions began treatment on average earlier than the recommended 7 weeks of age from previous studies.[18,21,22]

It is interesting that with both bracing protocols, the incidence of significant acetabular dysplasia on the 2-year radiograph was not insignificant. 22% and 27% of children had AI measurements at or above the 90th percentile values reported by Novais et al.[13] The clinical importance of this finding is unclear with the current follow-up. All these children will be followed until at least 4 to 6 years of age before the decision to proceed with an acetabular osteotomy is typically made. It is important to continue to monitor this patient cohort to determine how many of these children are treated with an acetabular osteotomy during childhood.

There were limitations to this study that should be addressed. We have a low number of subjects in our study cohort, it is possible that with a larger series, there may be a significant difference in AI based on time in brace. A post hoc power analysis indicates that a sample size of ~61,000 hips would be needed to find a significant difference in AI among the 2 institutions based on our observed findings. Also, we did not monitor brace compliance, and used the prescribed time in brace as a proxy for actual time in brace. Katz et al[23] previously reported bracing compliance for AIS as being poor when using temperature sensors to evaluate actual hours in brace for 100 AIS patients. Unlike AIS bracing, however, PH bracing requires parental compliance rather than patient compliance. While we assume that overall compliance is much better than in AIS, we have not truly evaluated this in our study group. Furthermore, we are only reporting results of AI at age 2 years and we did not take into consideration other acetabular morphologic features that may have contributed to the duration of brace treatment at Institution 1. In addition, the ultimate effect of bracing needs to be followed until skeletal maturity to determine the impact of ambulatory bracing on acetabular development.

CONCLUSION

Our findings suggest that prolonged brace treatment does not result in improved AI at age 2 years. Hips treated at Institution 2 had the same AI at age 2 years as hips treated at Institution 1, even while spending about 1/3 the amount of time in a brace. We recommend close follow-up for all children treated for dislocated hips, as 22% and 27% of infants had AI measurements at or above the 90th percentile of previously published norms. Continued follow-up of this prospective cohort will be critical to determine how many children require acetabular procedures during childhood.

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