■ CHILDREN'S ORTHOPAEDICS

Optimizing time in harness

FACTORS ASSOCIATED WITH SONOGRAPHIC RESOLUTION OF DEVELOPMENTAL DYSPLASIA OF THE HIP DURING PAVLIK TREATMENT

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Aims

The primary aims of this study were to determine the time to sonographic correction of decentred hips during treatment with Pavlik harness for developmental dysplasia of the hip (DDH) and investigate potential risk factors for a delayed response to treatment.

Methods

This was a retrospective cohort study of infants with decentred hips who underwent a comprehensive management protocol with Pavlik harness between 2012 and 2016. Ultrasound assessments were performed at standardized intervals and time to correction from centring of the femoral head was quantified. Hips with < 40% femoral head coverage (FHC) were considered decentred, and hips with > 50% FHC and α angles > 60° were considered corrected. Survival analyses using log-rank tests and Cox regression were performed to investigate potential risk factors for delayed time to correction.

Results

A total of 108 infants (158 hips) successfully completed the bracing protocol and were included in the study. Mean age at treatment initiation was 6.9 weeks (SD 3.8). All included hips centred within two weeks of treatment initiation. At two, five, eight, and 12 weeks following centring of the femoral head, 13% (95% CI 8 to 19), 67% (95% CI 60 to 74), 98% (95% CI 95 to 99), and 99% (95% CI 98 to 100) of hips had cumulatively achieved sonographic correction, respectively. Low α angles at presentation were found to be a risk factor for delayed time to correction (hazard ratio per 1° decrease in α angle 1.04 (95% CI 1.01 to 1.06); p = 0.006).

Conclusion

The majority of decentred hips undergoing Pavlik treatment achieved sonographic correction within eight weeks of centring and radiological severity at presentation was a predictor for slower recovery. These findings provide valuable insights into hip development during Pavlik treatment and will inform the design of future prospective studies investigating the optimal time required in harness.

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Introduction

Developmental dysplasia of the hip (DDH) is a common childhood condition that represents a spectrum of abnormalities, from mild acetabular dysplasia to complete dislocation of the hip.[1] It is widely accepted that early concentric reduction of the femoral head is necessary to promote normal acetabular development and limit the risk of developing early-onset osteoarthritis of the hip.[2-4] The Pavlik harness (PH) is the most widely used first-line treatment for DDH.[5,6] This form of brace treatment achieves a gentle reduction of the hip while permitting dynamic movement of the joint. The Pavlik method is very effective, with reported rates of success varying between 79% to 95%.[7,8]

Despite the widespread use of the PH, there is no universally accepted bracing protocol or agreement on the optimal duration for bracing. Pavlik originally recommended a "few months" and two recent expert consensus studies recommended at least six and eight weeks of treatment following radiological confirmation of a centred hip.[6,9,10] However, there is limited evidence to support these recommendations, and as a result there

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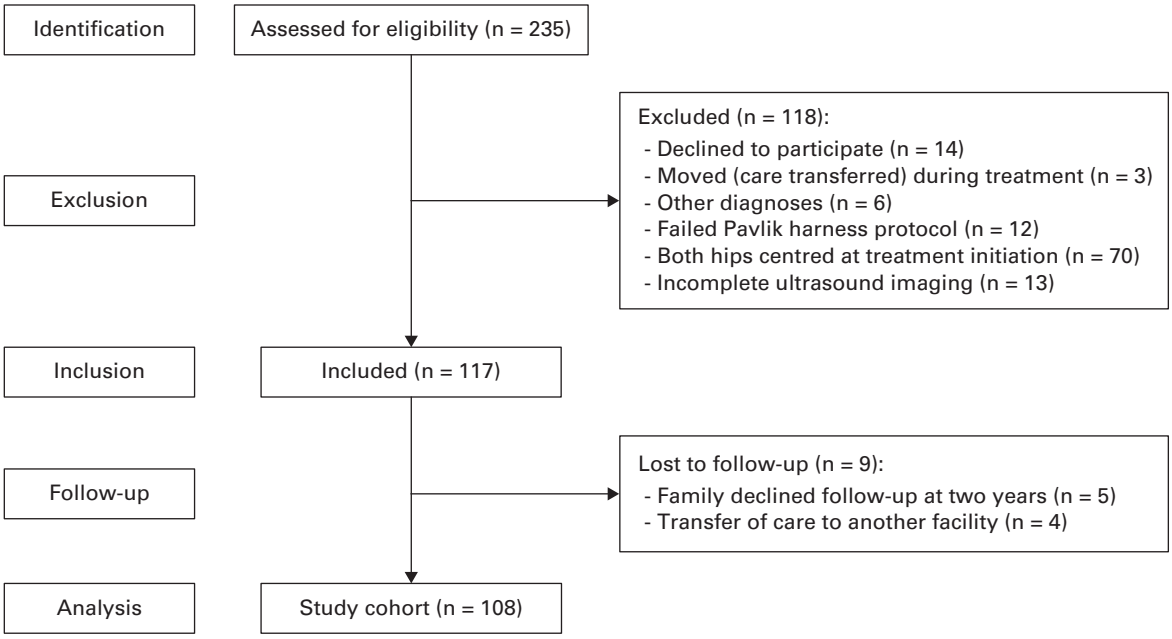

Fig. 1

Flowchart of patients though the study.

remains significant variation in practice with reported times in harness ranging from 21 days to nine months.[11,12] The extremes in treatment approach are reflective of the broadly contrasting theories on the role of a harness and the natural history of the condition. Some advocate for continued treatment following stable concentric reduction to encourage normal acetabular development and minimize the risk of recurrence and residual acetabular dysplasia (RAD).[13,14] An alternative theory is that a stable concentric reduction alone is required to induce a spontaneous gradual correction of acetabular dysplasia, and that prolonged bracing is not necessary to facilitate this process.[11,15]

Despite the relative safety of the Pavlik method, it is not completely benign, and is associated with a risk of femoral head avascular necrosis (AVN), femoral nerve palsy, and skin-related complications.[16,17] Qualitative studies have also highlighted parental concerns relating to feeding, parent-child bonding, and car seat safety.[18] In addition, the socioeconomic cost of unnecessary harnessing is likely to be significant, given the large number of children who are affected by this condition.[19] Determining the optimal time in harness is therefore important for achieving good clinical outcomes while also limiting costs, parental burden, and potential complications of treatment.

The primary aims of this study were to establish the time to sonographic correction of decentred hips during PH treatment and to investigate potential risk factors for a delayed response to treatment. The secondary aim of this study was to investigate a possible association between a delayed response to treatment and risk of RAD. Characterization of hip development during treatment will help determine thresholds for a minimum time required in harness. We expect the findings of this study to inform the design of definitive prospective studies investigating the optimal time required in harness, and generate meaningful hypotheses for future testing.

Methods

Study design and setting. This was a retrospective study utilizing data collected prospectively for a single-centre longitudinal cohort study performed to evaluate the outcomes of a comprehensive nonoperative management protocol for DDH between 2012 and 2016.[8] The protocol for this study was approved by our institutional research ethics board.

Study participants. Patients with a diagnosis of DDH, who were aged ≤ six months at treatment initiation and presented with at least one decentred hip, were suitable for inclusion. All included participants had successfully completed a course of bracing following a comprehensive, standardized protocol and had radiological follow-up at a mean of two years post treatment. Children with non-idiopathic dysplasia, those who failed the nonoperative treatment protocol, or those who had incomplete follow-up were excluded from the study.

Diagnosis and classification of dysplasia. The diagnosis and classification of DDH was based on recommendations set out by the American Institute of Ultrasound in Medicine. DDH is defined by an α angle < 60°, femoral head coverage (FHC) < 50%, a centred or decentred hip on the static coronal view, and with or without instability on stress views in the transverse plane.[20] Hips were classified as decentred (subluxated or dislocated) on ultrasound if FHC was < 40% with or without interposed soft-tissue echoes between the base of the acetabulum and the femoral head.[21-23] Severely decentred hips with a FHC of < 30% were classified as dislocated, although all decentred hips with a FHC < 40% underwent the same treatment pathway within our protocol.

Table I. Study cohort demographic data, pathology at initiation of treatment, and incidence of residual dysplasia.

Study cohort by patients (n = 108)	Value
Female, n (%)	94 (87)
Breech presentation, n (%)	49 (45)
First-born, n (%)	82 (76)
Family history, n (%)	28 (26)
Bilateral decentred hips, n (%)	50 (46)
Bilateral dislocation, n (%)	21 (19)
Unilateral dislocation, n (%)	42 (39)
Mean age at start of Pavlik treatment, wks (SD; range)	6.9 (3.8, 0.5 to 18)
Mean age at two-year follow-up, mths (SD; range)	25.8 (3.2; 18 to 37)
Study cohort by hips (n = 158)	
Mean initial percent coverage (SD; range)	22.3 (9.7; 0 to 40)
Mean initial α angle, ° (SD; range)	45.5 (7.0; 12 to 58)
RAD classification at two-year follow-up, n (%)	
Normal	108 (68)
Borderline	33 (21)
Dysplastic	17 (11)

RAD, residual acetabular dysplasia.

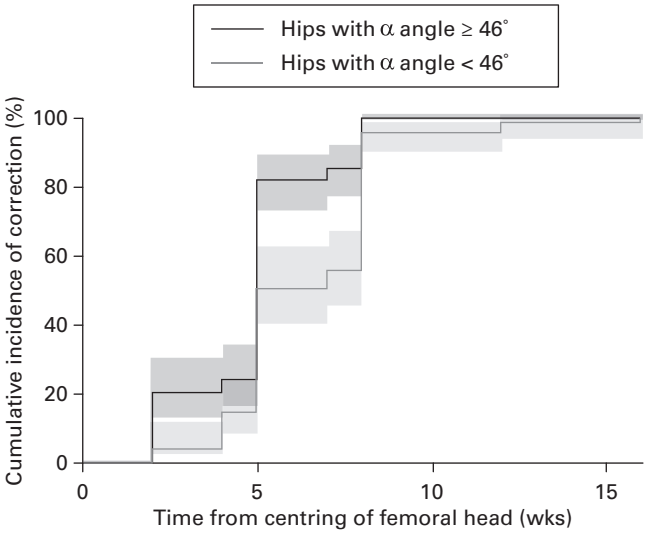

Fig. 2

Cumulative incidence of correction for hips with α angles above and below the median value (46°) at presentation. Bold lines represent cumulative incidence, and shaded regions represent 95% CI.

Management protocol. For decentred hips, the standardized treatment protocol involved full-time application of PH with weekly ultrasound scans in brace until the hip was centred. Following radiological confirmation of a centred femoral head, an additional 12 weeks of PH was prescribed. Ultrasound assessments were subsequently planned at standardized intervals of two, five, eight, and 12 weeks. Provided the hip had achieved normal radiological parameters, the harness was discontinued without weaning at the 12-week assessment. Hips with α angles ≥ 60° and FHC ≥ 50% were considered to have corrected.[22]

Study outcomes. The time to achieving sonographic correction was quantified in weeks from both initiation of treatment and from centring of the femoral head. Pelvic radiographs taken at a mean of two years post treatment were used to measure acetabular indices-lateral edge (AI-L). After referencing AI-L measurements against age- and sex-matched normal population values,[24] each hip was classified as being normal or having borderline dysplasia or dysplasia. Borderline dysplasia was defined as between one and two standard deviations above normative means, and dysplasia as over two standard deviations above normative means. Two-year radiographs were also used to classify hips according to their International Hip Dysplasia Institute (IHDI)[25] grade, and assess for features of AVN using the Bucholz and Ogden classification.[26]

Statistical analysis. Baseline characteristics (sex, foetal presentation, birth order, family history of DDH, age at treatment initiation, laterality, and severity of dysplasia), median time to sonographic correction, and cumulative incidence of correction were reported using descriptive statistics. Survival analyses were performed to model time to sonographic correction and investigate factors associated with rate of correction. Potential predictors investigated included sex, foetal presentation, family history, age at treatment initiation, bilateral pathology, and severity of dysplasia based on α angles and FHC. These predictors were studied individually using Kaplan-Meier analyses with log-rank tests for categorical variables and a univariate Cox proportional hazard regression for continuous variables. A multivariate Cox proportional hazards model was subsequently applied, incorporating sex, age at treatment initiation, severity at presentation (α angles and FHC), and any variables that were found to have a significant or marginally significant ($p < 0.10$) association with time to correction on univariate analyses.

To study a possible association between rate of sonographic resolution in harness and RAD, time to achieving correction in patients who went on to develop RAD was compared to patients who had normal hips at two-year follow-up. In addition, rates of two-year RAD of corrected and uncorrected hips were compared at each ultrasound assessment. A Mann-Whitney U test was used to compare continuous data, and Fisher's exact tests were used to compare categorical data. Statistical significance was defined as $p < 0.05$, and data was analyzed using SPSS v. 29.0.1.0 (IBM, USA).

Results

Figure 1 presents a STROBE diagram of screened participants. Of the 235 infants screened, 108 were eligible for inclusion and had adequate follow-up; of these, 50 participants presented with bilateral decentred hips, resulting in 158 hips available for analysis. Overall, 107 participants (157 hips) had successfully completed the harness protocol with 12 weeks of treatment following centring of the femoral head. One patient (one hip) required 16 weeks of treatment before achieving normal radiological parameters. All hips were IHDI grade 1 and no features of significant AVN (Bucholz and Ogden grade 2 or above) were seen on plain radiographs at two years' mean follow-up. Patient demographics, ultrasound parameters at presentation, and incidence of RAD at two-year follow-up are presented in Table I.

In total, 135 hips centred within one week of PH treatment, and the remaining 23 required a second week. The median time

Table II. Comparison of two-year residual acetabular dysplasia rates for corrected and uncorrected hips at each stage of sonographic assessment.

Timing of ultrasound	Borderline dysplasia and dysplasia (AI > 1 SD)			Dysplasia (AI > 2 SD)		
	Corrected hips, n (%)	Uncorrected hips, n (%)	p-value*	Corrected hips, n (%)	Uncorrected hips, n (%)	p-value*
2 weeks	7/20 (35)	26/138 (19)	0.137	3/20 (15)	14/138 (10)	0.455
5 weeks	24/106 (23)	9/52 (17)	0.534	10/106 (9)	7/52 (13)	0.423
8 weeks	33/155 (21)	0/3 (0)	1.000	17/155 (11)	0/3 (0)	1.000
12 weeks	33/157 (21)	0/1 (0)	1.000	17/157 (11)	0/1 (0)	1.000

*Fisher's exact test.
AI, acetabular index.

to achieving sonographic correction was six weeks from initiation of harness and five weeks from centring of the femoral head. At two, five, eight, and 12 weeks following confirmation of a centred femoral head, the cumulative incidence of sonographic correction was 13% (95% CI 8 to 19), 67% (95% CI 60 to 74), 98% (95% CI 95 to 99), and 99% (95% CI 98 to 100), respectively. Univariate analysis identified a significant association between time to sonographic correction and initial α angles (hazard ratio per 1° decrease in α angle: 1.04 (95% CI 1.01 to 1.06); p = 0.003). No other variables were found to have a significant or marginally significant association with time to correction. Multivariate analysis also identified initial α angles to have a significant association with time to correction (hazard ratio per 1° decrease in α angle; 1.04 (95% CI 1.01 to 1.06); p = 0.006) when controlling for age, sex, and FHC. Age, sex, and FHC did not demonstrate a significant association with time to correction within the multivariable model. Survival curves comparing sonographic recovery of hips equal to, above, and below, the median value for presenting α angles (46.0°) are presented in Figure 2.

At mean two-year follow-up (25.8 months (SD 3.2; 18 to 37)), 17 hips (11%) had dysplasia as defined by AI-L values beyond two standard deviations from the mean of age- and sex-matched normal population values. None of these hips underwent surgical intervention and remained under radiological surveillance. All hips were IHDI grade I, and none had AVN. No statistical association was found between time for hips to achieve radiological correction and risk of RAD. A comparison of RAD rates of corrected and uncorrected hips at each stage of assessment is presented in Table II.

Discussion

The goal of early brace management for DDH is to eliminate the need for childhood surgical intervention and limit the risk of early onset degenerative changes. There is a paucity of evidence available to guide clinicians on the optimal duration required in PH to promote normal hip development, giving rise to wide practice variation. It is important to recognize the burden that harness treatment places on caregivers and healthcare services, and achieving a better understanding of hip development during treatment is a necessary step towards minimizing this burden. This study was performed to characterize the rate of sonographic correction of decentred hips during full-time Pavlik treatment in a cohort of infants undergoing a standardized comprehensive treatment protocol, and found that 98% of hips had achieved sonographic correction within eight weeks of becoming centred.

Standardized treatment protocols have been shown to significantly improve outcomes and efficiency in DDH management.[27] Our institution's nonoperative treatment protocol for infant DDH was developed to conform to published consensus principles, with well-defined criteria for inclusion and classification of DDH, and prescribes a standard 12-week maturation programme in PH for all hips once there is confirmation of a centred femoral head. The protocol has demonstrated high rates of success with low rates of residual dysplasia at five years.[8] While some may advocate for longer periods in harness to improve acetabular development, there is no good evidence to support this approach. A recent study comparing the outcomes of two groups of infants with dislocated hips, treated for a mean of 2.6 months and 8.9 months, demonstrated no difference in two-year incidence of RAD.[12] While our study demonstrates some variation in the time required for hips to achieve normal radiological parameters, a very high cumulative incidence of correction was seen by eight weeks. It is possible that reducing the standardized duration of bracing to this threshold has the potential to significantly improve the efficiency of our DDH management protocol without compromising long-term outcomes.

There are limited published data on sonographic resolution of decentred hips, and as such, we believe our study provides an important contribution to further optimizing standard bracing protocols. Biedermann et al[28] examined the sonographic features of infant hips and determined their subsequent course. Among a group of 18 Graf type III and eight Graf type IV hips treated with Tübinger orthosis, they found a median time to correction of 15 and 17 weeks, respectively. Their analysis grouped Graf type D hips (decentred) along with type IIc hips, and median time to correction among this group of 176 hips was ten weeks. Salton et al[29] performed a study of 132 Graf type IIc hips undergoing PH treatment to evaluate sonographic recovery, and to determine if shorter times in harness could be prescribed. The authors reported a seven-week median time to correction with 85.8% of hips achieving correction within 12 weeks. In addition, they identified low FHC and clinical instability to be significant predictors for a longer time to normalization. Our study identified low presenting α angles to be the only predictor for prolonged recovery for decentred hips, and this is relatively consistent with previous studies, demonstrating that severity at presentation is a key determinant to rate of recovery.[28,29]

There are several limitations to this work that should be considered when interpreting the findings. Given the heterogeneity in DDH presentation, timing of treatment, alternative methods of classifying affected hips, and variation in treatment

delivery and treatment compliance, we acknowledge that our findings may not be generalizable to all, however the prospective nature of our series using a standardized protocol with a consecutive series of patients, all with decentred hips, adds confidence to our findings, yet the retrospective nature of our investigation naturally limits the strength of our analysis. Time to sonographic correction would have been more accurately defined with a higher frequency of ultrasound assessments throughout treatment; with only four assessments during the 12-week programme it is likely that our reported time to correction is overestimated. It is also important to consider the inter- and intrarater variability in sonographic assessment for DDH and the uncertain clinical relevance of the thresholds used for defining corrected hips. Finally, our assessment of RAD was performed at two years; longer-term data with analyses controlling for other variables will be necessary to better understand the association between sonographic recovery and clinically relevant residual dysplasia.

This study demonstrates that the vast majority of decentred hips undergoing full-time Pavlik treatment achieve sonographic correction within eight weeks of becoming centred. A low α angle at presentation was the only predictor associated with a delayed response to treatment, and we found no significant association between time to correction and risk of RAD at two years of age. Based on these findings we believe it is possible that the duration of our standardized nonoperative protocol for managing decentred hips could be reduced from 12 to eight weeks following confirmation of a centred femoral head. A future prospective clinical trial will aim to determine if a shorter standardized harnessing protocol can deliver equivalent rates of late residual dysplasia and delayed surgical intervention.

Take home message

- We aimed to determine the time to sonographic correction of decentred hips during treatment with Pavlik harness, and identify potential risk factors for delayed treatment response.
- Overall, 98% of hips had achieved sonographic correction within eight weeks of becoming centred. Low α angles at presentation were found to be a risk factor for delayed time to correction.
- These findings provide valuable insights into hip development during Pavlik treatment and will inform the design of future prospective studies investigating the optimal time required in harness.

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