

CHILDREN'S ORTHOPAEDICS A comprehensive nonoperative treatment protocol for developmental dysplasia of the hip in infants

A PROSPECTIVE LONGITUDINAL COHORT STUDY

Aims

Brace treatment is the cornerstone of managing developmental dysplasia of the hip (DDH), yet there is a lack of evidence-based treatment protocols, which results in wide variations in practice. To resolve this, we have developed a comprehensive nonoperative treatment protocol conforming to published consensus principles, with well-defined a priori criteria for inclusion and successful treatment.

Methods

This was a single-centre, prospective, longitudinal cohort study of a consecutive series of infants with ultrasound-confirmed DDH who underwent a comprehensive nonoperative brace management protocol in a unified multidisciplinary clinic between January 2012 and December 2016 with five-year follow-up radiographs. The radiological outcomes were acetabular index-lateral edge (AI-L), acetabular index-sourcil (AI-S), centre-edge angle (CEA), acetabular depth ratio (ADR), International Hip Dysplasia Institute (IHDI) grade, and evidence of avascular necrosis (AVN). At five years, each hip was classified as normal (< 1 SD), borderline dysplastic (1 to 2 SDs), or dysplastic (> 2 SDs) based on validated radiological norm-referenced values.

Results

Of 993 infants assessed clinically and sonographically, 21% (212 infants, 354 abnormal hips) had DDH and were included. Of these, 95% (202 infants, 335 hips) successfully completed bracing, and 5% (ten infants, 19 hips) failed bracing due to irreducible hip(s). The success rate of bracing for unilateral dislocations was 88% (45/51 infants) and for bilateral dislocations 83% (20/24 infants). The femoral nerve palsy rate was 1% (2/212 infants). At five-year follow-up (mean 63 months (SD 5.9; 49 to 83)) the prevalence of residual dysplasia after successful brace treatment was 1.6% (5/312 hips). All hips were IHDI grade I and none had AVN. Four children (4/186; 2%) subsequently underwent surgery for residual dysplasia.

Conclusion

Our comprehensive protocol for nonoperative treatment of infant DDH has shown high rates of success and extremely low rates of residual dysplasia at a mean age of five years.

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Introduction

Developmental dysplasia of the hip (DDH) is one of the most common musculoskeletal conditions in newborns, with an incidence of 11.5 per 1,000 live births.¹ Early diagnosis of DDH and nonoperative management with a brace is the most effective overall strategy. Optimizing the nonoperative treatment strategy of infant DDH is important to

improve outcomes, minimize complications, and reduce the need for surgical intervention.²

There is broad consensus on the general principles of Pavlik harness treatment for DDH, yet guidelines were developed primarily from expert opinion rather than rigorous scientific data, due to a paucity of evidence.^{3,4} As a result, published principles of DDH treatment are broadly permissive,

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Fig. 1

Flowchart of patients through the study. FAB, fixed abduction brace; PH, Pavlik harness.

which perpetuates wide practice variation and limits the ability to rigorously compare treatments and improve pathways.^{2,5-7}

Standardized treatment protocols have been shown to dramatically improve outcomes and efficiency in DDH management.⁸ However, existing protocols are limited by a lack of detailed criteria for inclusion and classification of dysplasia, arbitrary allocation to bracing, lack of standardized treatment pathways, inconsistent weaning, and variable duration of brace use. In addition, protocol-based studies are often lacking long-term follow-up, are limited by clinician variability, or are affected by the absence of norm-referenced outcome measures of residual dysplasia with which to define successful management.⁹⁻¹³

Several international orthopaedic societies and a recent Cochrane Review have urgently called for the development of reproducible evidence-based pathways for nonoperative management of DDH in infants aged under six months.^{2,5,6} Development of these protocols will reliably guide and predict the success of brace treatment, detail the risk of late radiological dysplasia, and characterize those hips which need closer follow-up. Evidencebased pathways will also form a baseline for comparative studies and generate questions for randomized controlled trials to further refine management and improve outcomes. We therefore developed a comprehensive nonoperative treatment protocol for infant DDH conforming to published consensus principles, with well-defined a priori criteria for inclusion and classification of dysplasia, and criteria for success and failure of brace treatment with detailed long-term radiological follow-up. We then performed a prospective longitudinal cohort study of a large consecutive series of infants managed using the protocol to characterize its effectiveness in treating DDH.

Methods

Study design and setting. This was a single-centre, prospective cohort study of all eligible infants who underwent a comprehensive nonoperative management protocol for infant DDH in a unified multidisciplinary infant hip clinic between January 2012 and December 2016, with radiological follow-up at a mean of five years post-treatment. The study was approved by our institutional research ethics board, and caregivers provided written informed consent for study participation.

Patients. Referrals to our infant hip clinic were received from primary care providers citing abnormal clinical examination of the hips, with or without an abnormality on hip ultrasound. We then assessed each infant clinically and sonographically and

Table I. Patient characteristics.

Variable	Total
Total, n	196
Female, n (%)	171 (87)
First born, n (%)	135 (69)
Breech, n (%)	89 (45)
Family history, n (%)	45 (23)
Mean age at start of PH, wks (SD; range)	7.121 (3.94; 0.5 to 22)
Initial diagnosis, right hip	
Centred, n (%)	116 (59)
Normal	42 (21)
Stable dysplasia	11 (6)
Subluxable	63 (32)
Decentred, n (%)	80 (41)
Subluxated	43 (22)
Dislocated	37 (19)
Initial diagnosis, left hip	
Centred, n (%)	84 (43)
Normal	19 (10)
Stable dysplasia	9 (5)
Subluxable	56 (29)
Decentred, n (%)	112 (57)
Subluxated	50 (26)
Dislocated	62 (32)
Bilateral pathology, n (%)	135 (69)
Bilateral dislocations, n (%)	24 (12)
Unilateral dislocation, n (%)	51 (26)

PH, Pavlik harness; SD, standard deviation.

identified a consecutive cohort of infants aged up to six months with a confirmed ultrasound diagnosis of DDH. Patients were entered into the study at the time of treatment initiation by the responsible clinician, either an advanced practice physiotherapist (CSB) or a fellowship-trained orthopaedic surgeon (JHW, MFG, SPK). Infants were excluded if there was an underlying neuromuscular disease, teratologic dysplasia, prior treatment elsewhere, or if follow-up radiographs were not available.

A Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) diagram of inclusion, exclusion, and those analyzed is presented in Figure 1.¹⁴ Of the 993 infants who attended for clinical and sonographic assessment during the study period, 21% (212/993 infants, 354 abnormal hips) were found to have DDH and therefore started the treatment protocol and were included in the study cohort. Of those who started treatment, 95% (202/212 infants, 335 hips) successfully completed bracing and 5% (10/212 infants, 19 hips) failed bracing treatment due to one or more irreducible hips. The characteristics of the final study cohort are presented in Table I.

Diagnosis and classification of dysplasia. Ultrasound imaging followed the American Institute of Ultrasound in Medicine (AIUM) guidelines for identifying DDH with images of the flexed hip in two orthogonal planes, including static coronal views at rest and transverse views with and without stress.¹⁵ DDH was defined by measuring the α angle,¹⁶ femoral head coverage (FHC),¹⁷ if the hip was centred or decentred on the static coronal view, and the presence or absence of instability on stress testing in the transverse plane. An α angle equal to or > 60° was considered normal,¹⁶ and a FHC > 50% was considered

Table II. Comparison between the study cohort and those lost to follow-up.

Characteristic	Cohort	Lost to follow-up	p-value
Hips, n	196	16	
Female, n	171	13	0.450*
First-born, n	135	12	0.781*
Breech, n	89	4	0.126*
Family history, n	45	6	0.224*
Mean age at start of PH, wks (SD)	7.12 (3.94)	8.62 (5.70)	0.237†
Initial diagnosis, right hip, n			0.110*
Centred	116	13	
Decentred	80	3	
Initial diagnosis, left hip, n			0.437*
Centred	84	5	
Decentred	112	11	
Bilateral pathology, n	135	9	0.403*
Bilateral dislocations, n	24	1	0.700*

*Fisher's exact test.

†Paired *t*-test.

PH, Pavlik harness; SD, standard deviation.

normal.¹⁸ Hips were considered centred on ultrasound if there were no interposed soft-tissue echoes between the base of the acetabulum and the femoral head, and if FHC was > 40%.^{16,19} FHC parameters were defined based on the upper limit of published findings from multiple studies that report a range of < 23% to 40% FHC constituting a hip dislocation on coronal view.^{17,18,20–23} Using these parameters, hips were then classified as normal, dysplastic, subluxable, subluxated, or dislocated.

Management protocol. Infants diagnosed with DDH followed the predefined management protocol based on the severity of dysplasia, where the Pavlik harness was used as the primary treatment on each occasion (Figure 2). Details of the protocol were developed using a combination of institutional experience and an interpretation of the literature at that time, leading to a pragmatic approach to standardizing care. Full-time (24 hours per day) harness treatment was used initially based on the authors' philosophy of maximizing parental compliance with treatment. Time in harness was reduced to 23 hours per day at the second visit after hip centring on ultrasound (five weeks) to reflect the balanced need for treatment compliance and parental desire to bathe the infant. Follow-up was determined based on whether the treated hip was centred or decentred on ultrasound imaging at rest. Standardized interim follow-ups allowed for brace adjustments and identification of any complications such as femoral nerve palsy, skin irritation, or failure to reduce the hip. Success of the harness treatment was characterized by normal acetabular morphology (α angle > 60°, FHC > 50%) and hip stability on final ultrasound and bracing was then discontinued without weaning. A period of 12 weeks of harness treatment for a centred hip was selected, based on institutional experience and a balanced view of the limited literature guiding treatment at that time.

Study outcomes. The radiological outcomes of this study were chosen to provide a comprehensive assessment of residual hip dysplasia and included acetabular index, measured to both the lateral edge of acetabulum (AI-L) and lateral edge of the sourcil



Hip classification based on ultrasound findings

Station at rest		Centred	Decentred			
Alpha angle	> 60°	< 60°	< 60°	< 60° < 60°		
Femoral head coverage	> 50%	> 40%	> 40%	> 30%	< 30%	
Stability on transverse view	Stable	Stable	Unstable	Unstable	Unstable	
Hip classification	Normal	Dysplastic	Subluxable	Subluxated	Dislocated	

Fig. 2

Comprehensive nonoperative management protocol. DDH, developmental dysplasia of the hip; US, ultrasound.

 Table III. Comparison between those with bracing success and those where bracing failed.

Outcome	Bracing success	Bracing failure	p-value
Hips, n	186	10	
Mean age at start of PH, wks (SD)	7.35 (3.96)	4.00 (2.49)	0.009*
Initial diagnosis, right hip, n			0.002†
Centred	115	1	
Decentred	71	9	
Initial diagnosis, left hip, n			0.006†
Centred	84	0	
Decentred	102	10	
Bilateral dislocation, n	20	4	0.022†
Unilateral dislocation, n	45	6	0.021†

*Paired *t*-test.

†Fisher's exact test.

PH, Pavlik harness; SD, standard deviation.

(AI-S), centre edge angle (CEA), acetabular depth ratio (ADR), International Hip Dysplasia Institute (IHDI) grade,²⁴ and avascular necrosis (AVN) on five-year follow-up radiographs. AI-L, AI-S, IHDI grade, and AVN were also obtained from two-year follow-up radiographs. AI-S, AI-L, CEA, IHDI, and AVN have all been shown to have good validity and reliability.²⁴⁻²⁷

At two and five years' follow-up, each hip was classified as normal, borderline dysplastic, or dysplastic as per published population-based norm values based on sex, age, and right or left hip.^{22,26-29} Borderline dysplasia on AI-L, AI-S, and ADR was defined as 1 to 2 standard deviations (SDs) and dysplastic hips as > 2 SDs above the published normative means. Reference values for CEA categorize specific value ranges, again relative to sex, age, and laterality as normal, mild, and severe, which were renamed normal, borderline dysplastic, and dysplastic for consistency.

Statistical analysis. Baseline characteristics and initial treatment outcomes, including age at initiation of treatment, sex, birth position, birth order, family history of DDH, laterality, initial severity of dysplasia, bracing success, and complications, were assessed using descriptive statistics. Fisher's exact test was used to compare categorical data and paired *t*-tests were used for continuous data. One-way analysis of variance (ANOVA) was used to compare radiological means relative to initial diagnosis. The prevalence of residual dysplasia at two- and five-year follow-up was evaluated using descriptive statistics based on transformed data relative to published norms. Significance was set at an alpha < 0.05. Statistical analyses were completed using SPSS v. 22.0 (IBM, USA).

Results

Table II depicts a comparison between the study cohort and those lost to follow-up, and Table III shows a comparison between those with bracing success and those with bracing failure. There were no significant differences found between those lost to follow-up and the study cohort. All lost to follow-up had successfully completed bracing. Statistically significant differences were found between those with bracing success and those who failed in mean age at start of bracing and initial pathology.

Variable	Right	Left		
Two years, n (%)				
Total	142	162		
AI-L				
Normal	77 (54)	117 (72)		
Borderline	44 (31)	36 (22)		
Dysplastic	21 (15)	9 (6)		
AI-S				
Normal	85 (60)	96 (59)		
Borderline	46 (32)	46 (28)		
Dysplastic	11 (8)	20 (12)		
Five years, n (%)				
Total	145	167		
AI-L				
Normal	138 (95)	159 (95)		
Borderline	5 (3)	7 (4)		
Dysplastic	4 (3)	1 (1)		
AI-S				
Normal	140 (97)	163 (98)		
Borderline	5 (3)	4 (2)		
Dysplastic	1 (1)	0 (0)		
CEA				
Normal	138 (95)	162 (97)		
Borderline	5 (3)	5 (3)		
Dysplastic	2 (1)	0 (0)		
ADR				
Normal	144 (99)	163 (98)		
Borderline	0 (0)	3 (2)		
Dysplastic	1 (1)	1 (1)		

ADR, acetabular depth ratio; Al-L, acetabular index-lateral edge; Al-S, acetabular index-sourcil; CEA, centre-edge angle.

All those who failed bracing had a least one dislocated hip at initial presentation.

The overall success rate of bracing for unilateral dislocations was 88% (45/51 infants) and 83% (20/24 infants) for bilateral dislocations. There were no femoral nerve palsies in those who completed bracing (including those lost to radiological follow-up after bracing was completed) and two femoral nerve palsies in those who failed bracing, giving an overall femoral nerve palsy rate of 1% (2/212 infants).

The 186 infants (312 hips) who successfully completed bracing had five-year radiographs taken at a mean age of 63 months (SD 5.929; 49 to 83) and of these, 181 children (304 hips) also had two-year radiographs (mean age of 25 months (SD 2.846; 18 to 37)). At both two-year and five-year follow-up there were no significant differences in mean residual dysplasia based on severity of initial dysplasia, or side affected (Supplementary Table i). At mean five-year follow-up, none of these hips had undergone surgical intervention, all were IHDI grade I, and none had AVN.

The prevalence of residual radiological dysplasia was then reviewed with the exclusion of initially normal hips. Table IV depicts the presence of residual dysplasia when radiological measures are considered independent from one another.

	Table V. Patients with	features of borderline	and residual dysplasia at	five-vear radiographs.
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Age at radiograph, mths	Right hip					Left hip				Management	
	Initial diagnosis	AI (L)	AI (S)	CEA	ADR	Initial diagnosis	AI (L)	AI (S)	CEA	ADR	
60	Dislocated*	D*	B*	B*	D*	Dislocated*	D*	B*	B*	D*	Bilateral staged Salters
51	Dysplastic*	D*	D*	D*	N*	Subluxable†	B†	B†	B†	N†	Bilateral staged Salters
58	Subluxable*	D*	B*	B*	N*	Dislocated [†]	B†	B†	B†	N†	Bilateral staged Salters
60	Subluxated*	D*	B*	D*	N*	Normal	N	N	N	Ν	Right Salter
65	Dysplastic†	N†	Nt	B†	Nt	Dislocated [†]	N†	Nt	B†	B†	Resolved by 8 yrs
61	Subluxated [†]	B†	N†	B†	N†	Subluxated [†]	B†	N†	Nt	N†	Resolved by 8 yrs
62	Subluxated [†]	B†	Nt	B†	Nt	Dislocated	Ν	Ν	N	Ν	Resolved by 8 yrs
62	Dislocated [†]	N†	B†	N†	N†	Dislocated	N	N	N	Ν	Resolved by 8 yrs
64	Subluxated	Ν	Ν	Ν	Ν	Subluxable†	N†	Nt	N†	B†	Resolved by 8 yrs
68	Normal†	B†	B†	N†	N†	Dislocated [†]	B†	B†	B†	N†	Pending 8-yr radiograph
61	Dislocated [†]	B†	N†	N†	N†	Subluxated [†]	B†	N†	N†	B†	Pending 8-yr radiograph
53	Normal†	B†	Nt	N†	Nt	Dislocated [†]	B†	Nt	N†	N†	Pending 8-yr radiograph
72	Subluxable	Ν	N	N	Ν	Dislocated [†]	B†	N†	N†	N†	Pending 8-yr radiograph

*One or more dysplastic measure.

†One or more borderline dysplastic measure.

Al, acetabular index; B, borderline; D, dysplastic; L, lateral; N, normal; S, sourcil.

Table V depicts the prevalence of residual dysplasia in initially pathological hips with measures interpreted in conjunction. The prevalence of borderline dysplasia after successful brace treatment at five-year follow-up was 5% (16/312 hips) and the prevalence of dysplasia was 1.6% (5/312 hips). Any child with confirmed dysplasia at the five-year follow-up (n = 4) underwent corrective surgery with a Salter osteotomy, reflecting a 2% surgical rate (4/186 children) in those who completed brace treatment. All hips with borderline dysplasia at five-year follow-up (n = 9) were observed until the age of eight years, of which five resolved spontaneously. Four are still pending eight-year reviews.

Discussion

In this paper we report the five-year outcomes of a comprehensive nonoperative protocol for the management of DDH in a consecutive series of infants aged under six months. We found an overall 95% success rate using our bracing protocol, with 1.6% residual acetabular dysplasia at five years' follow-up and no evidence of AVN. Only four of 186 children who successfully completed the nonoperative protocol underwent surgery for residual dysplasia. The core strengths of our study were the development of a comprehensive treatment pathway in a single setting, using prospective data with minimal loss to follow-up, and extensive norm-referenced radiological follow-up data. The robust methodology affords confidence in our protocol, which will be widely applicable and reproducible in other centres and can form the basis for comparison studies.

We did not wean any infant from the harness, nor did we return to use supplementary bracing for any child with early residual dysplasia after primary bracing was discontinued. Although the literature shows that supplementary bracing leads to a more rapid improvement in the acetabular index for early residual dysplasia,^{12,30} we speculate that it was unlikely that this would have improved our long-term results, given that the late residual dysplasia rate was extremely low. When interrogating four different measures of acetabular dysplasia at five years' outcome, we found that AI-L and CEA were most sensitive to identifying dysplasia when compared to AI-S and ADR. No additional hip was classified as having residual dysplasia by adding AI-S and ADR. This finding is in line with the literature that highlights that AI-L and CEA are the most important markers of residual dysplasia and, if not corrected, will lead to dysplasia at maturity and premature arthritis.^{10,28}

A previous systematic review reported that the lowest rates of long-term radiological dysplasia after successful Pavlik treatment are obtained when a standardized treatment pathway is used (3.8% vs 17.6%).⁹ However, in 17 studies reviewed, the treatment protocols were inconsistently reported, and variables such as age at treatment initiation, duration of brace utilization, and age at final follow-up varied significantly across the studies, with only six of the 17 reporting five-year follow-up.⁹

Our results, however, closely align with Cashman et al,¹⁰ who report 2.4% residual dysplasia at six years after Pavlik harness treatment, approximately 85% successful brace treatment in the dislocated group, and minimal need for late surgery for residual dysplasia. They also reported that the likelihood of residual dysplasia at five years was not related to the initial severity of dysplasia at presentation, which they hypothesized was due to the brace treatment primarily correcting the environmental impact on the development of DDH, and that residual dysplasia at long-term follow-up may reflect an underlying genetic predisposition.

In contrast, our study has a more detailed protocol using contemporary advances in measurement and treatment of infant DDH. We explicitly state inclusion criteria using objective imaging measures for the classification of dysplasia severity, use the switch from Pavlik to fixed abduction brace in specific circumstances, mandate a standardized time in harness, and use objective imaging criteria for successful treatment and Pavlik harness removal. Our results are reported using normreferenced data. In addition, our protocol uses 60% fewer clinic visits for imaging than the weekly ultrasound and annual radiological assessments reported in Cashman's protocol. Taken together, we believe our protocol is easy to follow, efficient, and reproducible for physicians who wish to emulate our practice. At five-year follow-up, only four children had hips with measures of dysplasia (> 2 SDs of norm-referenced values) who required surgical correction. As such, we recommend that any hip successfully completing nonoperative treatment using our protocol with residual dysplasia at two years' follow-up should be observed due to the high likelihood of resolution by the age of five years. We also recommend that borderline dysplastic hips at five years' follow-up should continue to be monitored given the high rate of spontaneous correction by the age of eight years. Using this approach, a 2% surgical rate for residual dysplasia at five years can be predicted, which is in line with the best outcomes reported in the literature.¹⁰

The low rates of complications, brace failure, and long-term residual dysplasia of our study may be attributed to the wellestablished unified multidisciplinary infant hip clinic setting in a tertiary centre with consistent staffing and expertise. In addition, our methodology called for strict inclusion criteria of primary DDH, excluding infants with fixed dislocations associated with syndromes, infants who had initiated treatment at an outside institution, and any child aged over six months. In our experience, such infants fare less well with a standardized treatment protocol and have a higher rate of bracing failure requiring surgical intervention; we treat such infants on a caseby-case basis.

Because brace treatment is typically started based on the most severely affected hip, some borderline and mildly dysplastic hips contralateral to the severe dysplasia were treated by default, achieved normality, and may have led in part to the excellent outcomes we have demonstrated using our protocol. Including only dislocated hips in our study would lower the overall treatment success rate, however we chose to include all hips, to reflect real-life practice so that the outcomes of a unified protocol can be seen across the spectrum of DDH seen in a typical clinic. Further limitations of our study are that as a longitudinal cohort study, we were not able to make treatment comparisons such as whether a shorter time in harness would have yielded noninferior results. Having said that, a recent comparative study including data from our institution concluded that time in brace over 12 weeks was not associated with improved radiological indices of acetabular dysplasia at two-year follow-up.³¹

In conclusion, our study has shown high rates of initial treatment success and extremely low rates of residual dysplasia at a mean of five years in a prospective longitudinal cohort of infants treated for DDH using a comprehensive nonoperative protocol. As such, we encourage its use to help improve outcomes, reduce unnecessary surgery, and to be employed as a baseline for future treatment comparisons.

Take home message

- Our study addresses the gap in evidence-based treatment protocols for the brace treatment of infant developmental dysplasia of the hip (DDH).

 Our comprehensive nonoperative protocol for infant DDH conforms to published consensus principles, and shows high rates of success and extremely low rates of residual dysplasia at a mean age of five years.
 This reproducible evidence-based treatment protocol can be used to help standardize care, improve outcomes, and reduce unnecessary surgery, and can be used as a baseline for future treatment comparisons.

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Supplementary material



Table illustrating the comparison of mean hip radiological measurements for those who completed Pavlik harness treatment.

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