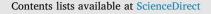
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Pavlik Harness initiation on Barlow positive hips: Can we wait?

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ABSTRACT

We investigated if infants with a Barlow positive hip(s) have natural hip stabilization and can thus avoid Pavlik Harness (PH) treatment. We conducted a chart review for infants who presented within two weeks of life, had a Barlow positive hip, and were deferred treatment. Of the thirty infants, eighteen were treated with PH at 4–6 weeks or 12 weeks due to persistent dysplasia. Twelve infants avoided PH entirely. There were zero cases of PH failure. Parents can be counseled that deferring treatment until at least 4–6 weeks of age might avoid treatment altogether without an increased risk of harness failure.

1. Introduction

Developmental dysplasia of the hip (DDH) is a disorder of the hip joint characterized by abnormal development between the femoral head and the acetabulum, often with associated capsular laxity.¹ Within the first few days of life, infants are screened for DDH using physical exam techniques including assessing for limb length inequality with the Galeazzi sign and hip instability with the Barlow and Ortolani maneuvers.² The Barlow maneuver tests whether a reduced femoral head can be subluxated or dislocated out of the acetabulum with a posteriorly directed pressure.² A hip joint is considered unstable, or Barlow positive, if the femoral head has palpable instability within the acetabulum or elicits an audible "clunk" upon dislocation.

Infants who present prior to 6 months of age with an unstable hip(s) are often treated immediately with a Pavlik Harness (PH), even if only a few days to weeks old.^{3,4} The purpose of the PH is to position the lower extremities in a safe position that improves the concentric reduction of the femoral head in the acetabulum, facilitating improved development of the dysplastic hip joint. The PH provides stability to the hip joint without restricting complete movement of the lower extremities, in contrast to other treatment options for hip dysplasia such as a spica cast.³ The rate of successful hip stabilization in DDH with PH treatment alone is 80–95%.^{5–7} This includes treatment of hips that are Barlow positive, Ortolani positive (dislocated but reducible at rest), or stable but underdeveloped. The rate of successful stabilization in Barlow positive hips specifically is 93%.⁷ However, it has been noted that 88% of infants who test positive for the Barlow maneuver have natural hip stabilization within the first few weeks of life.⁵ Accordingly, some

authors recommend that infants who present with a Barlow positive hip be initially deferred treatment and monitored by follow-up ultrasonography and clinical examinations prior to PH initiation.²

To our knowledge, no study exists that details a protocol for intentionally deferring treatment of infants who present with a Barlow positive hip in the first two weeks of life. We have implemented a protocol for deferring PH treatment until 4-6 weeks of age for infants who present to the orthopaedic clinic with reduced, dislocatable hips (Barlow positive). We feel that hips that are persistently unstable at 4-6 weeks of age will not stabilize naturally. To prove our protocol safe and effective, those infants who did not receive treatment for Barlow positive hip dysplasia should have the same rate of stabilization as those infants who did eventually require PH treatment. The stabilization rate in these two cohorts should be comparable to stabilization rates for patients who are treated with PH immediately upon presentation (greater than 90%), as is indicated by the literature. The purpose of this study was to determine whether our protocol for deferring PH treatment of infants with Barlow positive hips decreased the need for PH or other treatments while having an equivalent rate of successful hip stabilization. In doing so, we investigated the role of shared decision making in determining when to initiate Pavlik Harness treatment in infants with Barlow positive hip(s).

2. Methods

We obtained Institutional Review Board (IRB) approval for a retrospective review of medical charts and surgical records between January 2010 and March 2016. We included infants who presented

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with unstable hip(s) within the first two weeks of life (demonstrated by diagnosis of DDH, hip instability, or hip dislocation), tested Barlow positive at their initial orthopaedic surgery evaluation, and were deferred PH treatment in exchange for clinical monitoring. Infants were excluded if they had a dislocated hip at rest (Ortolani positive), a neuromuscular condition, a teratologic hip dislocation, were lost to follow-up prior to one year of age, or began PH treatment at the initial visit per the family's wishes. Failure of treatment was defined as a case in which a child eventually required surgery or failed to obtain a concentrically reduced hip with PH treatment.

2.1. Protocol

Infants younger than two weeks of age found to have a Barlow positive hip (the hip is located at rest but can be dislocated with a provocative maneuver of posterior force) are offered the option to defer PH treatment. Infants with Ortolani positive hips (the hips are dislocated at rest but reducible) or Barlow negative/Ortolani negative dislocated hips (the hips are irreducible despite being dislocated) are not offered the option to defer PH treatment.

Families are educated that deferral of PH treatment is somewhat controversial due to the lack of support of PH deferral in the literature. Parents who choose to defer PH treatment are instructed to avoid swaddling their infant's legs and to discourage pediatricians or other healthcare providers from examining the hips due to the theoretical risk of introducing iatrogenic instability or additional capsular laxity.

Infants whose families choose to defer PH treatment return to clinic between 4 and 6 weeks of age at which point the senior author conducts a clinic visit and obtains a stress hip ultrasound. Infants found to have an unstable hip(s) at this visit (either by examination or by ultrasound) are treated with a PH until the hip(s) has clinically stabilized and the ultrasound alpha angle is greater than or equal to 60°. Infants who are found to have clinically stable hips at their 4–6 week follow-up visit with an ultrasound alpha angle greater than or equal to 60° are not started on PH treatment. They are recommended to return for a followup visit at 12 weeks of age and one year of age with an AP pelvis radiograph. Infants who are found to have clinically stable hips at their 4–6 week follow-up visit with an ultrasound alpha angle less than 60° (indicating hip immaturity or mild dysplasia) are again deferred PH treatment. They are recommended to return for follow-up at 12 weeks of age.

The follow-up visit at 12 weeks of age in infants with clinically stable hips and alpha angles less than 60° consists of a clinical examination and a repeat stress ultrasound. Infants found to have a Graf I normal ultrasound (alpha angle greater than or equal to 60°) again defer PH treatment and receive a follow-up x-ray at one year of age. Infants found to have a persistently abnormal alpha angle less than 60° begin PH treatment for at least six weeks until the ultrasound alpha angle normalizes to greater than or equal to 60°. All infants treated with a PH receive follow-up x-rays three months after PH treatment completion and again at one year of age. They are also followed until skeletal maturity to monitor for residual or recurrent hip dysplasia.

2.2. Data

We collected baseline data including the child's gender, birth presentation, age at presentation to the orthopaedic surgeon, age at time of deferred PH treatment, laterality, and ultrasound demonstration of stability. We collected clinical outcome data including whether the infant's hip(s) stabilized without intervention, if and when PH treatment was initiated, whether PH treatment was successful, the duration of PH treatment (if used), and the infant's one year follow-up radiographic acetabular index (Table 1).

2.3. Statistical analyses

This study did not contain a comparison group so statistical analysis was descriptive.

3. Results

A total of 30 infants (39 hips) were identified. These infants tested positive for the Barlow maneuver within two weeks of age and returned to clinic for follow-up for at least one year. There were 26 (87%) females and 4 (13%) males. Left hip instability was found in 18 infants, right hip instability in 3 infants, and bilateral instability in 9 infants. Another 5 infants presented within two weeks of age for hip instability but were excluded: 3 infants had a dislocated hip at rest (Ortolani positive), one infant was lost to follow-up, and one infant began PH treatment at the initial visit per the family's wishes.

Of the 30 infants, 19 infants (63%) (25 hips) had clinical hip stabilization without PH treatment by 4-6 weeks of age. Eleven infants (37%) (14 hips) were treated with a PH at 4-6 weeks of age due to persistent instability as documented by ultrasound or clinical exam. These infants were treated in a PH harness full time (23 + hours per day) for an average of 7 weeks (range of 3-11 weeks) prior to harness weaning. All fourteen hips successfully stabilized with PH treatment. Of the 19 infants who had stable hips at 4-6 weeks of age, seven infants (23%) (8 hips) required PH treatment at 12 weeks of age due to persistent dysplasia noted on ultrasonography (alpha angle less than 60°). These seven infants were treated for an average of eight weeks (range of 6-10 weeks) prior to weaning. All of these infants had a hip ultrasound alpha angle greater than 60° at the time of weaning. Twelve infants (40%) (17 hips) avoided PH treatment entirely by following this protocol. No infants required intervention beyond PH, whether treated with PH or not. All infants received follow-up radiographs at one year of age. The range of acetabular indices at one year of age was $12-42^{\circ}$. and the average acetabular index was 24°. Thirty two hips (82%) had an acetabular index less than 24°. The patient who had an acetabular index of 42° at one year of age returned for follow-up visits over the next year with continued improvement of acetabular indices.

4. Discussion

The Pavlik Harness is an effective treatment for DDH in infants with a success rate of 80–95% when initiated prior to six months of age.^{5,6} Lerman et al. reports a 93% success rate of the Pavlik Harness in infants with Barlow positive hips specifically, the population we were investigating.⁷ Even so, the timing of PH treatment initiation in infants with Barlow positive hips is controversial considering 88% of hips will naturally stabilize within the first few weeks of life.⁵ Thus, PH treatment prior to four weeks of age may not be necessary.

Deferring PH treatment in infants with Barlow positive hips can provide benefits to both the infant and the parents. First, the infant's hips might naturally stabilize and the PH can be avoided entirely. In this study, deferring treatment in infants with Barlow positive hips resulted in 40% of infants requiring no treatment. Deferring PH treatment can also decrease the stress put on the parent/infant relationship in an infant's early weeks. When infants are placed in a PH, there may be difficulties during crying, bathing, breastfeeding, sitting in car seats, and using baby equipment.⁸⁻¹⁰ Breastfeeding difficulties are especially important to consider. Difficulty breastfeeding has been shown to increase stress and depression levels in new mothers.⁹ In addition, difficulties with these routine child-care tasks can frustrate parents and reduce PH treatment compliance, resulting in possible increased PH failure rates.^{2,8} By waiting until 4-6 weeks of age to initiate PH treatment, parents are given more time to become comfortable with routine child-care tasks and may therefore be more likely to maintain compliance during the treatment regimen. Deferring PH treatment until 4-6 weeks of age also offers parents more time to understand the diagnosis

 Table 1

 Baseline and outcome data.

Patient #	Age Presented (days)	Age at 4–6 week f/u (days)	Received Barlow Exam 4–6 week f/u (Y or N)	PH Initiated at 4–6 week f/u (Y or N)	Alpha Angles at 12 week f/ u Right (°)		PH initiated at 12 week f/u (Y or N)	Harness Length (weeks)	Acetabular Index R at 1 year (°)	Acetabular Index L at 1 year (°)
1	9	37	N	Ν	77	66	Ν	N/A	18	23
2	7	34	Ν	Ν	72	68	Ν	N/A	16	12
3	4	31	Y	Ν	68	63	Ν	N/A	31	29
4	4	33	Y	Y	61	57	N	3	20	28
5	5	32	Ν	Ν	70	66	Ν	N/A	27	21
6	10	44	Y	Y	54	48	Ν	8	24	24
7	5	32	N	Ν	65	64	Ν	N/A	24	23
8	9	32	N	Ν	66	61	Y	6	21	24
9	7	34	N	Ν	66	69	Ν	N/A	20	18
10	7	35	Y	Y	64	68	Ν	6	20	22
11	6	33	Ν	Ν	67	65	Ν	N/A	27	24
12	11	32	N	Y	68	62	Ν	6	17	19
13	10	31	Y	Y	58	63	Ν	8	25	26
14	5	33	Ν	Ν	60	62	Ν	N/A	23	24
15	11	38	N	Y	66	64	Ν	6	20	20
16	9	36	N	Y	65	58	Ν	7	30	28
17	7	41	Y	Y	71	57	Ν	5	21	42
18	4	52	Ν	Ν	65	61	Y	6	20	23
19	7	34	Ν	Ν	61	65	Ν	N/A	23	20
20	3	35	Ν	Ν	62	63	Ν	N/A	19	21
21	5	47	Y	Y	68	60	Ν	11	29	30
22	7	21	Ν	Ν	72	57	Y	7	28	31
23	8	36	Ν	Ν	63	65	Y	7	21	21
24	12	46	Ν	Y	61	57	Ν	11	25.7	27.4
25	10	38	Ν	Ν	62	63	Y	10	23	24
26	10	38	Ν	Ν	48	58	Y	8	28	28
27	9	43	Ν	Y	52	52	Ν	8	28	28
28	15	49	Y	Ν	72	62	Y	9	24	23
29	5	24	Ν	Ν	62	65	Ν	N/A	21	19
30	9	30	Ν	Ν	62	67	Ν	N/A	18	19

of DDH, educate themselves on the available treatment options, and see a pediatric orthopaedic surgeon who is specifically trained in DDH management and appropriate PH application.

By allowing hips to naturally stabilize without treatment in a PH, the infant also avoids the risks associated with PH use such as skin irritation, femoral nerve palsy, and femoral head avascular necrosis (AVN).^{11–13} Although these risks occur less commonly in patients with Barlow positive hips compared to patients with Ortolani positive hips and more severe dislocations, evidence suggests that they can still occur.^{11,12} Murnaghan et al. conducted a study in which 13% of patients who developed a femoral nerve palsy while being treated with a PH were Barlow positive.¹¹ Pap et al. provides evidence that during treatment of unilateral hip dysplasia, AVN can develop even on the normal contralateral side.¹² In his study of 674 children with unilateral hip dysplasia treated with a PH, 2.7% of normal contralateral hips developed Tonnis I AVN and 0.2% developed Tonnis II AVN.¹² Deferring PH with the potential to avoid PH entirely decreases these risks.

Our study has a few limitations. A large portion of the patients whose charts we retrospectively reviewed are non-English speaking and have Medicaid insurance. Language barriers present a significant challenge for educating families about medical conditions and needs, and unpublished studies have shown that patients with Medicaid insurance are at higher risk for PH failure.¹⁴ This might have indirectly affected the data received. In addition, this study is a case series and does not contain a comparison group due to lack of data and resources. Even so, the success rate of deferred PH treatment was 100%; therefore, a comparison group of infants with Barlow positive hips treated prior to two weeks of age could only have an equal or lesser success rate. In addition, it is often difficult to distinguish between Barlow positive and Ortolani positive hips before two weeks of age. Even so, Ortolani positive hips have a decreased rate of successful hip stabilization with PH treatment compared to Barlow positive hips.⁷ As such, even if some of the hips in this study were misclassified as Barlow positive, the success rate would not be falsely elevated.

These limitations point to the need for continued prospective research on this topic. The study could be improved by diversifying the patient demographic that we review, increasing the number of cases we review, and reviewing a comparison group of patients that were not deferred treatment. Having a comparison group in future studies would allow us to investigate how delaying treatment affects the required duration of PH treatment, among other outcomes. In addition, we hope to further investigate the burden of PH treatment on families and how delaying treatment might affect this burden.

Currently, we offer deferring PH treatment to infants who present to the orthopaedic clinic within two weeks of life with a Barlow positive hip(s). We counsel the infants' parents to avoid swaddling and additional hip exams before the follow-up appointment due to risk of iatrogenic instability.⁴ We instruct the family to return to the clinic when the infant is between 4 and 6 weeks of age for an ultrasound and clinical evaluation. If instability is present at that time, we treat it with a PH. The present study demonstrates that deferring PH treatment in this manner has no correlation with PH treatment failure for infants who present with Barlow positive hips within two weeks of life. A similar previous study demonstrated that infants who begin PH treatment after 30 days of age have a similar rate of success to those who begin prior to 30 days of age.¹⁵ These findings suggest no absolute indication to initiate PH treatment prior to 30 days of life in infants who have Barlow positive hips. Forty percent of infants who deferred treatment avoided treatment entirely, and the rate of stabilization in those infants who required PH treatment was 100%. These findings demonstrate a role for shared decision making in determining when to initiate Pavlik Harness treatment in infants with Barlow positive hip(s).

Author statement

Katherine A. Cook, BS – data acquisition, analysis and interpretation of data, drafting, revision.

Meghan Schmitt, BA – data acquisition, analysis and interpretation of data, drafting, revision.

Michael Ingram, BA–data acquisition, analysis and interpretation of data, drafting, revision.

Dr. Jill Larson, MD-design, data acquisition, analysis and interpretation of data, drafting, revision.

Dr. Jamie Burgess, PhD – design, data acquisition, analysis and interpretation of data, drafting, revision.

Joseph Janicki, MD, MS - design, data acquisition, analysis and interpretation of data, drafting, revision.

Declarations of interest

None.

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