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Management of Irreducible Hip Dislocations in Infants With Developmental Dysplasia of the Hip Diagnosed Below 6 Months of Age

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Background: Infants with dislocated irreducible (D/I) hips can be substantially harder to treat than infants with dislocated but reducible hips. The purpose of this study was to compare treatment methods and outcomes for infants with D/I hips in order to optimize management of this difficult patient cohort.

Methods: A multicenter prospective hip dysplasia study database was analyzed from 2010 to 2016. Infants aged below 6 months with clinically and radiologically confirmed D/I hips were included in the study. Teratological hips (syndromic/neuromuscular) were excluded.

Results: In total, 59 hips in 52 patients were included. All hips were clinically Ortolani negative and radiologically dislocated but irreducible on presentation and had at least 20 months of follow-up. Mean age at diagnosis was 1.9 months (range, 0.1 to 5.9 mo). There were 33 left hips, 12 right hips, and 14 bilateral hips (7 patients). In total, 48 of 59 hips were treated in Pavlik harness. The remainder were treated by alternative braces or primary closed or open reductions. Pavlik treatment was successful in 27 of 48 hips. Pavlik treatment was abandoned in 21 D/I hips, 3 due to femoral nerve palsy and the remainder due to failure to achieve reduction. There was no statistical correlation between Pavlik success and age at diagnosis ($P = 0.22$), patient sex ($P = 0.61$), or bilateral compared with unilateral D/I hips ($P = 0.07$). Left hips were more likely to be successfully reduced in Pavlik harness than right hips ($P = 0.01$). Five complications occurred: 3 patients developed femoral nerve palsy in Pavlik harness, while 2 patients developed avascular necrosis, both after failed Pavlik treatment and subsequent surgery.

Conclusions: Pavlik harness treatment has been demonstrated to be a safe and sensible first-line treatment for infants with D/I hips. Left hips were more likely to be successfully reduced in Pavlik harness than right hips, but age, sex, and bilaterality were not correlated. The outcomes demonstrated from this multicentre prospective database inform management of this complex patient cohort.

Level of Evidence: Level II—prognostic study: less-quality prospective study.

Key Words: developmental dysplasia of the hip, irreducible, Pavlik harness, infants, multicenter, prospective database, dislocation, reduction

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Developmental dysplasia of the hip (DDH) is the most common pediatric hip condition, affecting 4 to 7/1000 live births, but the true prevalence is difficult to accurately quantify. Severity ranges from mild instability in a reduced hip to complete hip dislocation. The Pavlik harness is one of the most commonly used orthoses for the nonoperative management of DDH, with success rates of 95% to 100% reported for management of hip instability.[1,2] However, infants with hips dislocated at rest continue to have the poorest prognosis, regardless of management.[3–7] In these cases, the dislocated hip can either be reducible or irreducible during a clinical examination. Those hips that are irreducible present particular challenges to treatment, with harness treatment failure rates reported in 37% to 100% of patients.[3–7] Harness failure typically necessitates surgical intervention in the form of closed or open reduction in order to achieve concentric reduction of the hip.

The variability in incidence, diagnosis, and treatment outcomes of DDH reported in the literature highlights the lack of standardized screening and management

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protocols and emphasizes the need for stronger supporting evidence. Some of this variability arises due to the broad spectrum of DDH pathology. Most previous studies are single center, retrospective and have no radiologic confirmation of hip position. To address this knowledge gap, we established a multicentre prospective observational study of children who have been diagnosed with hips dislocated at rest. This study excludes all teratological hips, whereby dislocation is secondary to other causes (neuromuscular, syndromic, chromosomal abnormalities, sacral agenesis, myelodysplasia, arthrogyposis). Therefore, all hips in this study are primarily dislocated and fall within the true definition of DDH.

The purpose of this study was to examine variations in treatment modalities for infants diagnosed below 6 months of age with dislocated irreducible (D/I) hips at rest. This study aimed to identify variables associated with increased risk of treatment failure for this particularly challenging patient cohort.

METHODS

The multicenter hip dysplasia database prospectively enrolled consented infants with dislocated hips at rest from 7 centers across North America, Europe, and Australia with Ethics Board Approval from each participating institution.[7] All hips were Ortolani negative on clinical examination. Only those that had radiologic confirmation of D/I status were included. This required an USS demonstrating a dislocated femoral head at rest with failure of enlocation on dynamic testing, or a plain radiograph with the hip in a high dislocated position (IHDI grade III/IV[8]). As this is a prospective observational study, all assessments were carried out in accordance with individual surgeon/center protocol. Consequently the sonographic examination was performed by the pediatric orthopaedic surgeon at some centers and by the pediatric radiologist at others. All practitioners have DDH as a subspeciality of their practice, thus the level is "expert." All hips with a neuromuscular or syndromic cause for the dislocation (ie, a teratological hip) do not fall within the definition of true DDH, and were therefore excluded. This included excessively premature infants. This study focused on the cohort of patients below 6 months of age with the most severely affected hips—dislocated but irreducible. The database was analyzed from its inception in August 2010 to April 2016 for all D/I hips. Baseline data, treatment strategies, outcomes, and complications were compared. Only patients with at least 20 months of follow-up were included in analysis, as per initial study criteria of 2 year follow-up ± 4 months.

Primary outcome was successful reduction, defined as a reduction obtained while in Pavlik harness and maintained after removal, with no requirement for further intervention in the follow-up period. Failure of Pavlik treatment was deemed as abandonment of the harness before achieving a concentric reduction for any reason. Outcomes depending on age at diagnosis, hip laterality, sex, type of treatment, and contralateral hip status were explored. Statistical analysis was performed using Excel and Graphpad Prism v6 with significance defined as $P < 0.05$. Continuous variables were compared with unpaired t test and categorical variables were compared by χ^2 test. Patients treated by an alternate method were analyzed descriptively.

RESULTS

Patient Inclusions

At review, 412 hips in 327 infants diagnosed below 6 months of age were included in the database with potential for at least 20 months of follow-up. Of these cases, 78 hips in 69 patients were confirmed as D/I clinically (by negative Ortolani test) and radiographically. However, 17 patients (19 hips) were lost to follow-up before 20 months so have been excluded from analysis. Therefore, 59 hips in 52 patients (41 female, 11 male) met inclusion criteria for this study. Mean chronological age at diagnosis was 1.9 months (range, 0.1 to 5.9 mo). There were 33 unilateral left, 12 unilateral right and 7 bilateral cases, 40 left and 19 right hips in total.

Radiologic confirmation of hip status was made by ultrasound in 56/59 hips, whereby the femoral head had <10% coverage at rest[9] and did not improve/enlocate sonographically on dynamic testing. Radiographic diagnosis was made in 3/59 hips (3 patients aged 3.7, 4.9, and 5.9 mo). These were IHDI grade III/IV hips and were clinically Ortolani negative.

Pavlik harness was the initial method of treatment for 46/59 hips (40/52 patients). One patient (2 hips) had Pavlik treatment after failed Denis-Browne brace. The Pavlik harness and alternative management groups are analyzed separately below.

Non-Pavlik Harness Management

Although Pavlik harness was the primary method of treatment for the majority of cases, and is the primary focus of this paper, alternative treatment methods were

TABLE 1. Patients With D/I Hips Managed by Alternative First-line Treatments to Pavlik Harness

Patients	Age at Baseline (mo)	Dislocated Irreducible Hip	Management
1	5.9	R	CR
2	3.3	L	CR
3	0.1	R	DB→Pavlik→CR
3	0.1	L	DB→Pavlik
4	4.9	L	CR
5	5.7	R	CR
6	3.2	L	CR
7	0.4	R	Von Rosen→CR→OR
8	3.9	L	OR
9	2.4	L	OR
10	3.7	L	OR
11	1.4	L	OR
12	5.9	L	OR

CR indicates closed reduction; DB, Denis-Browne splint; OR, open reduction.

used for 13 hips (12 patients, Table 1). Specifically, 3 hips (2 patients) had alternative braces applied first and 10 patients were treated by primary open or closed reduction surgery. All reductions were successfully maintained through follow-up. Surgical patients were diagnosed at a mean age of 4.0 months (range, 1.4 to 5.9) while mean age at surgery was 7.5 months (range, 3.2 to 11.7).

Pavlik Harness Management

In total, 48 D/I hips in 41 infants were treated in Pavlik harness, including the patient treated following failure of the Denis-Browne splint. All infant Pavlik harness programmes commenced with full time wear (23 or 24 h/d). All centers used repeated clinical and sonographic assessment at ~2 week intervals to monitor hip position and provide Pavlik harness adjustments. Weaning regimes and total length of harness duration varied among centers according to local guidelines. There were 32 left and 16 right hips, including 7 patients with bilateral D/I hips. Of the 48 D/I hips, 27 were treated successfully in Pavlik harness (56.3%). Total time in Pavlik harness ranged from 43 to 106 days. Intercentre variation exists in duration and weaning regimes, though all centers started with full time wear (23 or 24 h/d). Some patients received continued treatment in a Rhino Cruiser brace beyond their time in Pavlik harness. The remaining 21/48 hips (43.7%) failed Pavlik harness treatment, requiring alternative management to achieve reduction. Two patients (3 hips) had Pavlik harness abandoned due to femoral nerve palsy (that subsequently resolved with harness removal) and the remainder due to failure to achieve reduction. Pavlik treatment in this group was abandoned early due to risk of avascular necrosis (AVN) and acetabular wear from persistently dislocated hips in harness. However, in one case continued sonographic improvement was demonstrated and Pavlik treatment was continued for 69 days. Subanalysis according to laterality, contralateral hip status, sex, and age is stratified below.

Patient Demographics

Patients successfully treated by Pavlik (27 hips) were a mean of 1.2 months old at diagnosis (range, 0.1 to 4.0) while those failing Pavlik (21 hips) were a mean of 1.6 months (range, 0.1 to 4.0). This age difference in age was not statistically significant ($P = 0.22$). Likewise, patient sex had no bearing on the chance of successful Pavlik treatment ($P = 0.61$).

Affected Hip Laterality

Laterality had a statistically significant effect on outcome. Specifically, 22/32 left D/I hips were successfully concentrically reduced by Pavlik harness treatment (68.8%). In contrast, only 5/16 right hips (31.2%) were comparably reduced ($P = 0.01$).

Contralateral Hip Status

The contralateral hip was abnormal in 20/41 patients (48.8%), 7 of whom had bilateral D/I hips (14 hips). These 7 patients were all treated by Pavlik harness. Successful reduction was achieved in both hips of 2 patients, the left hip of 1 patient, and in neither hips of 4 patients. These 9 persistently dislocated hips were treated with closed or open reductions.

The contralateral hip was involved to a lesser degree in another 13 patients. Specifically, 8 contralateral hips were reducibly dislocated (D/R), 2 were dislocatable, and 3 were dysplastic.

Contralateral hip status did not appear to be correlated with successful reduction in Pavlik harness ($P = 0.32$). Subanalysis of the bilateral D/I hips in comparison with those patients with a normal or lesser affected contralateral hip trended toward a difference in treatment success; however, larger numbers will be needed to demonstrate significance of this result ($P = 0.07$).

Management Following Failed Pavlik Treatment

In total, 21 D/I hips failed Pavlik harness treatment. Alternative braces were subsequently used to treat 5 hips, all unilateral. One patient had a Denis-Browne brace applied which achieved reduction. The remaining 4 patients were switched to a Rhino brace, achieving reduction in one case. The 19 hips that failed all harness treatment (Pavlik/Rhino) were subsequently successfully treated with closed (7 hips) or open (12 hips) reduction. The average age at surgery was 7.5 months (range, 3.2 to 11.7) and the average time between brace abandonment and surgery was 4.0 months (range, 0 to 11.0). All surgical decision making was by the treating surgeon, using their own techniques, under general anesthetic. All procedures were performed by pediatric orthopaedic surgeons whose subspeciality is DDH. Subanalyis of these outcomes is beyond the scope of this paper.

Patient Follow-up

All hips included in this study had at least 20 months of clinical and radiographic follow-up from diagnosis (median, 25.9 mo; range, 20.0 to 58.0). All hips were radiographically classified by IHDI grade at final follow-up, with 53/59 hips IHDI grade 1 and 6/59 IHDI grade 2.[8] A higher acetabular index (AI) was found in hips failing to reduce in Pavlik [mean, 26.0 degrees; range, 10 to 40 degrees, 95% confidence interval (CI), 23.2-28.7] compared with those successfully treated (mean, 20.0 degrees; range, 12 to 25 degrees; CI, 18.6-21.4). No difference was found in comparison with those treated by alternative methods (mean, 24.5 degrees; 95% CI, 20.9-28.2). No patient had subsequent surgery for residual acetabular dysplasia within the follow-up period.

Complications

Five patients experienced complications: 2 patients (3 hips) developed femoral nerve palsy in Pavlik, resulting in 2 subsequent successful closed reductions and 1 successful open reduction. Four patients developed AVN—2 managed in Pavlik and 2 managed by initial closed reduction and spica casting. AVN was diagnosed at 14 and 22 months of age in the closed reduction patients. In the patients managed by Pavlik, AVN was diagnosed at 18 months of age for 1 patient following 3 weeks of

unsuccessful Pavlik harness treatment aged 3 months and a closed reduction aged 11 months. The other patient was 24 months old when AVN was diagnosed, having had femoral nerve palsy in Pavlik harness, followed by a staged successful open reduction aged 11 months.

DISCUSSION

This study is the largest cohort of patients to date with D/I hips. This is the most severe form of DDH, but the 56.3% success rate reported here is one of the highest success rates in the literature for this particular diagnosis.[3–6] Pavlik harness treatment has been demonstrated to be a safe and sensible first-line treatment for these infants, but should be undertaken only when supported by close clinical and sonographic monitoring in experienced hands. Families should also be counselled accordingly.

Contrary to previous evidence in infants below 6 months old,[3,4,6] age has not been shown here to be correlated with success/failure. Pavlik harnesses for D/I hips were used successfully in infants up to the age of 4 months in this study, with age at harness initiation showing no statistical association with treatment success.

As an observational study, treatment was according to each practicing surgeon at each contributing center. We intended to examine all patients enrolled in the study who were diagnosed with an irreducibly dislocated hip under 6 months of age. After identifying this cohort of patients, the observation of treatment in this group was that no infant diagnosed over 4 months was initially trialled in a Pavlik harness. Two infants in this group aged between 4 and 6 months were treated with primary surgery, as per the decision of the surgeon.

Affected hip laterality did appear associated to Pavlik success ($P = 0.01$). Right hips fared worse than left, raising questions on the nature of the right hip pathology. In DDH, left hips are more commonly affected than right, most likely due to the most common intrauterine position being left occiput anterior. In this position, the left hip lies adducted against the maternal sacrum, potentially placing it at greater risk for dislocation.[10] Fetal positioning, such as the right occiput anterior position in which the right hip lies against the sacrum, may underlie the potential reason why right D/I hips are more sinister than left. This finding warrants further investigation.

This cohort contained more female than male individuals, consistent with existing literature.[2] Some authors believe that male individuals are harder to treat,[11] but the current study does not support that in the D/I hip spectrum (male vs. female Pavlik harness success rate $P = 0.61$, Table 1).

There is conflicting evidence whether bilateral dislocated hips are harder to treat than unilateral.[3,6,12] However, this study has not found statistical significance to support this belief specifically for D/I hips. For unilateral D/I cases, the status of the contralateral hip was not found to influence success rates ($P = 0.32$). This comparison held true whether the contralateral hip was reducibly dislocated, dislocatable, dysplastic, or normal. Bilateral D/I hips had a lower chance of successful reduction in Pavlik harness compared with unilateral D/I hips, though this did not reach significance ($P = 0.07$). However, numbers were small and further study is required.

Femoral nerve palsy was a reason for the Pavlik harness needing to be abandoned. Although few studies have specifically examined femoral nerve palsy in dislocated hips, one retrospective study reported that this complication is more likely in the more severe grades of DDH.[13] In addition, there is a lack of studies examining incidence of femoral nerve palsy following brace treatment specifically in dislocated hips, as Murnaghan and colleagues include hips across the entire DDH spectrum. Therefore, femoral nerve palsy incidence in dislocated hips may be an underappreciated iatrogenic complication. In this regard, 2 of 41 infants (5%) affected in this cohort may actually be a commendably low incidence in this severe DDH group.

AVN of the femoral head (Pavlik harness disease) is almost exclusively in those hips that are dislocated initially. However, the alternative to a Pavlik harness is surgical reduction. Closed reduction has invariably higher AVN rates in this patient group than the proportions observed in this paper with Pavlik harness treatment. All cases of AVN recorded in the larger study database to dae arose following either closed or open reduction. We recognize that some of these patients had previously undergone failed harness treatment, and as such, cannot discount the possibility that AVN may have been at least partially due to said harness. However, in our analyses of these surgical patient cohorts, the development of AVN did not seem to be associated with prior bracing attempts. These analyses are admittedly preliminary with small numbers and limited follow-up.

This study is limited by having patient follow-up data to a median of only 2 years. Although no patient has required subsequent surgery for residual dysplasia, dysplasia may persist or appear beyond this age and many centers may perform this surgery, if needed, around the age of 4 to 5 years.[2] This would therefore fall beyond the timeframe of this study. Extended follow-up is required to gain a complete understanding of treatment success. However, there are early indications of promise within this group of patients. Specifically, IHDI radiograph scores at 2 years are either grade 1 or 2 and only 4 patients have an AI >30 degrees, with the highest AI being 40 degrees. Although all studies have a standardized infant position for radiographs, we recognize the difficulty in infant positioning which may increase error in measurement. The Pavlik treatment failure group was found to have a significantly higher AI at final follow-up. AVN rate is possibly under-reported as follow-up is currently too short for some growth disturbance to appear. This study is further limited by those 17 of 69 patients lost to follow-up. These were largely due to patients emigrating.

A recognized limitation of this study, consistent with the nature of multicentre observational studies, is the lack of standardized surgical technique between surgeons and across centers. We cannot control for differences in

technique between surgeons, thus all studies resulting from these data should be considered effectiveness studies not efficacy studies.

This is the largest prospective study to date on D/I hips, with a cohort of 52 patients (59 hips). However, these numbers are still small and there may be type 2 errors in all tests where no difference was found, such as with bilateral D/I hips ($P = 0.07$). We also cannot exclude the possibility of type 1 errors for the effect of hip laterality. The follow-up is insufficient to determine the long-term complication rate of any of these treatment methods; consequently, these results should be viewed as hypothesis-generating for future studies. Success rates have been compared within groups, but ideally regression analysis is required to generate true predictors of success in treatment modalities, for which much larger numbers of failed treatment are required.

Clinical examination of hip stability is not fully reliable.[14,15] This study only included patients who had radiologic confirmation of an irreducible dislocation, unlike previous studies on D/I hips.[3–6] Therefore, 18 hips (15 patients) were excluded for this reason. A further 10 hips in 9 patients were D/I on clinical examination, but were found to be reducible on ultrasound. These were also excluded and support the evidence for imperfect reliability of clinical examinations.

There are a number of studies in the DDH literature that examine the success rate of Pavlik harness treatment for hip dislocations. Typically, these studies are examining infants with a mixed spectrum of DDH severity. Irreducible dislocations have been included in some of these studies we reference in the introduction.[3–6] Therefore, there is past clinical precedent, despite an incomplete understanding of the true success/failure rate specifically in this cohort. With an orthotic, hips are held in the protective position of abduction and flexion, rather than extension. This was neatly demonstrated by Salter[16] in his porcine studies. Over time the hip can be observed to reduce. This is observed by weekly sonographic assessments and the position can be noted to improve. Failure to improve/reduce is a reason to abandon harness, and this decision is typically made in the first week or so. The specific intent behind using an orthosis as first-line management would be that if there is a potential for successful reduction, and minimal adverse effects of a failed attempt, then more complex and invasive surgical treatment can be avoided for at least some of these patients.

There still remains considerable variation in treatment strategies across and within centers treating DDH. These discrepancies make direct comparison more challenging. Hips treated by alternative methods to a Pavlik harness (11 hips) are included in this study in a descriptive manner only. On the basis of this study alone, recommendations cannot be made on these treatment methods. Furthermore, variability exists in Pavlik harness regimes. Timing of application, duration, weaning, and whether the treatment is guided by serial ultrasound or clinical examination may all have implications on management of DDH. This study does not yet have sufficient power to explore these variables in this particular patient group.

Despite these limitations, this study is the largest cohort of D/I hips to be analyzed and has stratified factors to help guide treatment. The use of Pavlik harness as a first-line management for D/I hips is supported, with success demonstrated up to 4 months of age. The right D/I hip was shown to be particularly difficult to treat and failure of Pavlik treatment is associated with higher residual AI's. Ongoing recruitment and follow-up within the multicenter database will allow further examination of this very difficult patient group.

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