The natural history of developmental dysplasia of the hip after early supervised treatment in the Pavlik harness

A PROSPECTIVE, LONGITUDINAL FOLLOW-UP

J. P. Cashman, J. Round, G. Taylor, N. M. P. Clarke

From Southampton General Hospital, England

Between June 1988 and December 1997, we treated 332 babies with 546 dysplastic hips in a Pavlik harness for primary developmental dysplasia of the hip as detected by the selective screening programme in Southampton. Each was managed by a strict protocol including ultrasonic monitoring of treatment in the harness. The group was prospectively studied during a mean period of 6.5 ± 2.7 years with follow-up of 89.9%. The acetabular index (AI) and centre-edge angle of Wiberg (CEA) were measured on annual radiographs to determine the development of the hip after treatment and were compared with published normal values.

The harness failed to reduce 18 hips in 16 patients (15.2% of dislocations, 3.3% of DDH). These required surgical treatment. The development of those hips which were successfully treated in the harness showed no significant difference from the normal values of the AI for the left hips of girls after 18 months of age. Of those dysplastic hips which were successfully reduced in the harness, 2.4% showed persistent significant late dysplasia (CEA <20°) and 0.2% persistent severe late dysplasia (CEA <15°). All could be identified by an abnormal CEA (<20°) at five years of age, and many from the progression of the AI by 18 months.

Dysplasia was considered to be sufficient to require innominate osteotomy in five (0.9%). Avascular necrosis was noted in 1% of hips treated in the harness.

We conclude that, using our protocol, successful initial treatment of DDH with the Pavlik harness appears to restore the natural development of the hip to normal. We suggest that regular radiological surveillance up to five years of age is a safe and effective practice.

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The Pavlik harness has become widely accepted as an efficient and satisfactory treatment for infants with developmental dysplasia of the hip (DDH) within the first three months of life. Despite its popularity, there have been few prospective long-term reports of the results of its use in relation to development of the hip. Fujioka et al reported a series of 380 patients with a follow-up rate of 33% more than 20 years later. They reported severe dysplasia in 19% of treated hips. Tucci et al studied a group of 61 patients with congenital dislocation of the hip treated by the Pavlik harness, with a mean follow-up at 12 years of 57%. They noted that all hips had normal radiological appearances at three and five years of age, but at the final follow-up 17% had radiological changes of severe acetabular dysplasia (Severin grade 3), although the consequences of this could not be determined. They recommended that all such patients should be followed up until skeletal maturity. Although these studies have been useful, their retrospective nature and poor follow-up rates have compromised the conclusions.

In this prospective study the outcome of treatment using the Pavlik harness was based on a series of patients with DDH, all of whom had been treated according to a standardised protocol. The aims were to determine the natural history of acetabular development after treatment in the harness, to ascertain the incidence of late dysplasia in those infants who were initially thought to have been successfully treated and to determine the minimum period necessary for effective radiological follow-up.

Patients and Methods

The series comprised all infants with DDH born in the Southampton area (population about 500 000) between June 1988 and December 1997 who had been identified by our selective ultrasound screening programme (Fig. 1). and treated using the Pavlik harness. Those referred from the surrounding regions during the same period who mat-
ched our criteria were also included. Infants were excluded if they had multiple congenital abnormalities, presented after 90 days of age, had had prior treatment in other centres, or showed teratological dislocations. The last were defined as fixed dislocation of the hip in association with either a recognised syndrome or a neurological disorder.

A total of 337 infants fulfilled the above criteria and formed the basis of the study. The details of the standardised protocol by which patients were managed have been described in previous publications reporting the short- and medium-term results of the earlier recruits to this series and are summarised in Figure 2. The rate of treatment in the harness was approximately 4.4 per 1000 live births. Ultrasonography was used both to diagnose and subsequently to monitor the progress of each child in the harness. All ultrasound scans were reviewed by the senior author (NMPC) at the commencement of treatment and were thus assessed consistently, but not independently.

After the appearance of the ossific nucleus in the capital epiphysis, radiography was used to assess development of the hip. Such radiological follow-up was requested every four months for 12 months and every six months for a further 24 months. Annual radiographs were taken thereafter. For those patients failing to attend for follow-up, explanatory letters together with a further appointment were sent to their parents. The respective general practitioners were notified and their records were checked to ensure that the postal address had remained unchanged.

The initial sonographic status and subsequent radiological measurements were recorded for both hips of each patient. The acetabular index (AI) was recorded until the pelvic triradiate cartilages fused and the centre-edge angle of Wiberg (CEA) was also recorded for all radiographs taken after the age of five years. The ossific nuclear height was recorded on all radiographs. Normal values for the AI and CEA as defined by Tönnis were accepted as were the limits of acceptable pelvic rotation and inclination. Avascular necrosis was assessed using the criteria of Kalamchi.

![Diagram showing summary of the protocol for selective ultrasound screening.](image1)

![Diagram showing the algorithm for treatment in the Pavlik harness.](image2)
and MacEwen. Patients were deemed to have been lost to follow-up if they failed to attend the most recent two successive appointments so that radiological assessment was not possible.

Two independent observers undertook the radiological measurements. An observer variation study of radiological measurements was done by asking each of the investigators to measure independently the AI, CEA and the ossific nuclear height of five different radiographs on three separate occasions. In order to compare our results with previously published data, the findings were expressed in terms of intraobserver error as determined by the range of two standard deviations from the mean of the recordings.

The patients’ data were collated prospectively from the hospital notes on a customised proforma and entered into a computer database and spreadsheet for subsequent analysis.

Results

Five of the 337 children were excluded. Two had cerebral palsy, two teratological disorders and the fifth a muscular dystrophy.

This left 332 infants in the study, 42 of whom had been referred from outside our region. There were 57 boys and 275 girls (ratio 1:4.8). The mean follow-up was 6.5 ± 2.7 years (2.1 to 11.8). The follow-up rate was 89.9%; 37 patients were lost to follow-up for more than two years. Ultrasonography identified DDH in 546 hips (82.2%) the severity of which is shown in Table I. Figure 3 shows the distribution of sonographically-detected DDH in the right and left hips. Our findings regarding the incidence of bilateral dysplasia are consistent with those of other reports of hip dysplasia when using ultrasound diagnosis.

The observer variation study of radiological measurements showed that more than 98% of both AI and CEA readings were within 2° of the mean, with respect to both inter- and intraobserver variation. This was validated by comparison with other authors’ published data.

Treatment in the Pavlik harness failed to reduce 18 hips in 16 patients; 15.2% of all complete dislocations or 3.3% of all hips with DDH, and these required surgery. The radiological measurements for such patients were included in our analysis up to the time of surgery and excluded thereafter.

In order to allow comparison of our series of over 10 000 radiological measurements with other published data, we categorised the readings into those age bands described by Tönnis and shown in Figure 4. The mean AI, together with the positive and negative two standard deviation values for each category of age group, were then plotted against time to demonstrate the pattern of acetabular development in each of the age groups. These were compared with the normal values. The pattern of development of the CEA is similarly represented, with the 15° and 20° thresholds of dysplasia (Fig. 4).

After categorisation of our radiological measurements into the above age groups, the mean for each age group was analysed using a z test of the null hypothesis that there was no difference between the values of the AI of the study population and those of the normal population as determined by Tönnis. The results are shown in Figures 4 and 5. Despite ultrasonically proven hip dysplasia, we noted that the mean AI appeared to be greater in the normal population than in the study group (Figs 4 and 5). These differences were not statistically significant (p < 0.94) and merely reflect the small number of radiographs taken of our patients before seven months of age.

As expected, initial ultrasonic examination of the study group showed more severe dysplasia of the left hip than of the right (75 dislocations on the left, 43 on the right). After treatment in the harness, no significant difference in the mean AI was demonstrated at each age category between the right and left hip for either boys or girls. Neither were any statistically significant differences observed in the AI between girls and boys in the study group at any stage. The development of the initially most severely dysplastic group of hips within our study group (girls’ left hips) was compared with that of the normal population (Fig. 4). No significant difference was observed in the mean AI after 18 months of age. When the development of the AI of both hips of boys and the right hips of girls were compared with gender- and side-specific values from the normal population, significant differences were observed (Figs 4 and 5). No such statistical differences were noted if the comparisons of the mean AI of the study group were made, not

Table I. Severity of sonographically determined DDH in 332 infants

<table>
<thead>
<tr>
<th>Description of DDH</th>
<th>Right</th>
<th>Left</th>
<th>Total number</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Normal</td>
<td>86</td>
<td>32</td>
<td>118</td>
<td>17.8</td>
</tr>
<tr>
<td>Displaced</td>
<td>203</td>
<td>225</td>
<td>428</td>
<td>64.4</td>
</tr>
<tr>
<td>Dislocated</td>
<td>43</td>
<td>75</td>
<td>118</td>
<td>17.8</td>
</tr>
</tbody>
</table>

The distribution of sonographically selected DDH between the right and left hips of the 332 infants.
with side- and gender-specific normal values, but with those for girls’ left hips. The pattern of hip development in the study group and trend in Al were clearly seen to mirror those of the normal population, regardless of the child’s gender or side of affected hip.

To validate this observation, ten individuals were selected at random from the study group and their hip development was compared with the normal pattern for the left hips of girls (Fig. 6). This confirmed that after use of the harness the pattern of development of the dysplastic hip conformed to that of the normal hip. Within the study group, 66 hips in 44 patients initially appeared to have been successfully treated in the Pavlik harness, but subsequently developed late hip dysplasia using the criteria described by Tönnis i.e. a CEA of less than 20°. Among these were six hips in six patients whose CEA was less than 15°, the recommended lower limit of normality described by Fredensborg. These were termed severely dysplastic.

During the course of the study all these hips reverted to a normal pattern of development (CEA <20°) except for 13
hips in 11 patients whose acetabular development remained retarded (CEA <20°). This represents a finding of persistent radiological late acetabular dysplasia of 3.5% (11/316 patients) or 2.4% (13/546) of hips with DDH or 2.0% (13/664) of all hips treated in the Pavlik harness (Table II). The dysplasia in these patients was associated with a CEA of <20° at 60 months of age. Even in this group, however, not all such dysplasia could be predicted by earlier measurement of the AI alone (Fig. 7). Only four patients (five hips) in this group were deemed by the senior author to require surgical treatment (Table II). In each case a Salter innominate osteotomy was carried out. The acetabular dysplasia in this group was identifiable by the development of the AI by 18 months of age (Fig. 8).

Of the 316 patients who were initially successfully treated in the Pavlik harness, 11 underwent subsequent arthrography of their hips under anaesthesia for suspected dysplasia. In seven this was an early investigational procedure and no surgical intervention was deemed necessary. In the remaining four arthrography was carried out before a Salter osteotomy some years later, as described above. This represents a surgical intervention rate for late dysplasia of 1.3% (4/316) of patients or 0.9% (5/546) of hips with DDH or 0.8% (5/664) of all hips treated.

Within the study group we observed late-onset avascular necrosis (Kalamchi and MacEwen grade 3 or greater) in four hips of three children after initially radiological normal hip development. In the child with bilateral avascular
necrosis, only the left hip was initially sonographically dysplastic. Two other children (two hips) showed transient grade-1 changes, but remained asymptomatic and subsequently made a full recovery with no radiological sequelae. These findings are consistent with a major avascular event in 1% (3/316) of all patients or 0.6% (4/664) of all hips treated and of a transient minor event in a further 0.6% (2/316) of all patients or 0.3% (2/664) of all hips treated. Thus, the incidence of avascular necrosis was 1% (6/664) of hips treated or 1.6% (5/316) of patients treated.

**Discussion**

DDH is commoner in girls and affects the left side more severely. In our study group, we observed no difference in the severity of dysplasia between the two sides after treatment in the Pavlik harness. Initial ultrasound scans confirmed that dysplasia was most evident in the left hip of the girls within the study group. Despite this, no significant difference in the mean AI was observed compared with Tönnis’ normal population, after 18 months of age. We believe that the correct use of the Pavlik harness allows acetabular remodelling to take place and rapidly negates the initial mechanical disadvantage of the left hip in utero which predisposes it to dysplasia. Residual dysplasia after treatment in the harness is often symmetrical and reveals the extent of the endogenous dysplastic tendency. This explains the striking similarity of the mean AI for the left and right hips in the study group, which is absent in the normal population. This supports the observations of Severin and Wilkinson and Carter who suggested that the contralateral hip may be used to predict the outcome of congenital dislocation of the hip. After treatment in the harness, an endogenous tendency to dysplasia may persist, which results in a normal pattern of hip development (Fig. 6), with a small (<4°), but statistically significant, larger
mean AI compared with the gender and side-specific values in the normal population (Fig. 5). Despite these statistical differences, the magnitude of the observed differences was less than 4° and may not be of clinical significance. Furthermore, these statistical differences are abolished if the comparison is made with the mean values of the AI for normal development of the left hip in girls, rather than the gender- and side-specific normal values. We thus suggest that successful treatment in the harness re-establishes a normal pattern of hip development, superimposed on any endogenous tendency to dysplasia.

We have observed that 3.5% (11/316) of patients in our prospective study group developed persistent late hip dysplasia, which we have defined as a CEA <20° after initial successful treatment in the harness. Of these, only four patients (five hips) required surgery (1.3%). The incidence of late dysplasia in the normal population is impossible to identify as there have been no long-term longitudinal prospective studies.

Our results suggest that the natural history and development of neonatal dysplastic hips treated successfully in the Pavlik harness, approximates to that of the normal population after 18 months of age. We noted that most of the patients with late dysplasia who required surgery, could be identified by 18 months (540 days) from the development of the AI (Fig. 8). All late dysplasias had a CEA <20° by 60 months of age. We found that before this age, the reproducibility of the CEA measurements decreased, even when using a transparent template of concentric circles to define the centre of the femoral head. Not all late dysplasias could be determined before 60 months by measurement of the AI alone, as shown in Figure 7. This finding agrees with that of other authors who have noted that the AI alone is not an adequate index of acetabular dysplasia, especially in the older child after fusion of the triradiate cartilage. Most (47/60) hips with a CEA <20° subsequently improved to a normal value. We thus agree with Fredensborg that in children under 12 years of age, a minimum CEA value of 15° may be a more reasonable threshold of normality, and that between 15° and 20° should be considered uncertain.

The only complication of splintage was that of avascular necrosis of the proximal femoral capital epiphysis. Minor transient appearances of avascular necrosis (Kalamchi and MacEwen grade I) were observed in 0.6% of children. The maximum incidence of any form of avascular necrosis within the group was 1% of hips or 1.6% of patients.

These low rates of avascular complications and late dysplasia appear at first sight to differ significantly from those of other published studies. The possible reasons for this include the retrospective nature of previous studies with limited follow-up rates. Such studies tend to self-select patients who are asymptomatic or likely to develop a poor outcome. Furthermore, indices of dysplasia and avascular necrosis and thresholds of normality vary between authors, making comparison difficult. The exclusion criteria of our study group were intended to select a uniform group of infants with primary developmental hip dysplasia. Such a group is more likely to respond well to functional bracing compared with some of the older and more heterogeneous groups which have been the subject of other studies. Our inclusion criteria have also probably resulted in a lower incidence of dislocation or severe dysplasia than in other studies based on clinical or radiological diagnoses which are less sensitive. Finally, the study group was managed by a standard protocol involving early treatment, careful ultrasound monitoring in the harness and early abandonment of the harness in the infants with failed reduction. In a similar series managed by a strict protocol and reported by Vedantam and Bell, the short-term results were very similar to our findings.

In conclusion, in our study group, successful initial treatment in the Pavlik harness appeared to restore the natural development of the hip to that of the normal population. Most patients with severe late dysplasia could be identified by the trend of the AI measured before the age of 18 months and all by measurement of the CEA at five years. We would suggest that radiological surveillance until five years of age constitutes a safe and effective follow-up after successful treatment using the harness, after which patients can be discharged from outpatient care in the knowledge that the development of the hip will be normal.

No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article.

References


