Treatment for developmental dysplasia of the hip using the Pavlik harness

LONG-TERM RESULTS

From the Chiba University, Chiba City, Japan

We reviewed the medical records of 115 patients with 130 hips with developmental dysplasia with complete dislocation in the absence of a neuromuscular disorder, spontaneous reduction with a Pavlik harness, and a minimum of 14 years’ follow-up. The mean age at the time of harness application was 4.8 months (1 to 12) and the mean time spent in the harness was 6.1 months (3 to 12). A total of 108 hips (83.1%) were treated with the harness alone and supplementary surgery for residual acetabular dysplasia, as defined by an acetabular index > 30°, was performed in 22 hips (16.9%).

An overall satisfactory outcome (Severin grade I or II) was achieved in 119 hips (91.5%) at a mean follow-up of 16 years (14 to 32) with a follow-up rate of 75%. Avascular necrosis of the femoral head was noted in 16 hips (12.3%), seven of which (44%) underwent supplementary surgery and nine (56%) of which were classified as satisfactory. The acetabular index was the most reliable predictor of residual acetabular dysplasia.

In 1950, Pavlik1-3 developed a functional harness for the management of developmental dysplasia of the hip (DDH). Since then, the Pavlik harness has gained widespread acceptance, with several reports showing favourable rates of reduction and a low incidence of complications, such as avascular necrosis (AVN) of the femoral head. The reported rate of reduction ranges from 70% to 99% and the incidence of AVN from 0% to 28%.4-16 These discrepancies seem to be partly due to a lack of clear criteria for the definition of subluxation and dislocation. Johnson et al15 reported a reduction rate of 99% and incidence of AVN of 0%, but their study included subluxation. Mubarak et al17 reported that the incidence of AVN was higher when the harness was used to treat dislocation rather than subluxation or acetabular dysplasia. Therefore, the results for dislocation should be distinguished from those for subluxation.

There have been few reports of the long-term outcome on skeletal maturity of treating complete dislocation with the Pavlik harness.18-22 The reported satisfactory outcome ranges from 53% to 83%. Residual acetabular dysplasia was one of the most influential factors leading to a poor outcome, although these studies only included patients who were treated conservatively and excluded those treated by supplementary surgery. Salter23 suggested that early surgical correction of residual hip dysplasia was necessary in patients over the age of 18 months. We believe that the long-term outcome of patients treated with additional surgery should be included in the assessment of harness treatment.

The purpose of this retrospective review was to clarify the long-term results of harness treatment at skeletal maturity, including supplementary surgery for complete dislocation in DDH, to evaluate the incidence of AVN following the treatment, and to identify predictors of residual acetabular dysplasia.

Patients and Methods

The medical records of 221 patients who were treated with a Pavlik harness (Nihan Gishusokuseizo Co., Tokyo, Japan) for DDH at Chiba University Hospital and Chiba Children’s Hospital between 1972 and 1991 were reviewed. The criteria for inclusion in the study were: 1) complete dislocation in the absence of a neuromuscular disorder. This was diagnosed clinically by a positive Ortolani sign,24 or radiologically by lateral and cephalad displacement of the proximal end of the femur, accompanied by interruption of Shenton’s and Perkin’s lines;25 2) the harness was applied as an initial treatment and successfully reduced the dislocation; 3) radiological follow-up until at least 14 years of age. We excluded 23 patients with subluxations. Seven patients suffering from neuromuscular disorders (cerebral...
TREATMENT FOR DEVELOPMENTAL DYSPLASIA OF THE HIP USING THE PAVLIK HARNESS 231

Protocol for the initial treatment of developmental dysplasia of the hip.

- Pavlik harness
  - Reduced
  - Unreduced
  - Continuous harness treatment
  - Radiological evaluation at a mean age of 4.9 years (3 to 7)
  - Acetabular index < 30°
    - Acetabular index ≥ 30° (residual acetabular dysplasia)
  - Outpatients follow-up
    - Harness-only group n=108 (83.1%)
    - Supplementary group n=22 (16.9%)

Fig. 1

Treatment protocol (Fig. 1). The harness was applied in the outpatient clinic to patients who were more than three months old or who weighed more than 6 kg. The baby lay supine on a flat, semi-rigid bed and was free to roll and turn. Parents were instructed to cradle the baby in their arms whenever the baby cried. We examined the movement of the lower legs every few days during the first two weeks and established whether the dislocation was reduced either clinically or radiologically. Ultrasound screening was only adopted from 1990, so the majority of patients were monitored clinically and radiologically. As a result we did not evaluate the ultrasound images in the few patients examined by ultrasound. If reduction could not be obtained within the first two weeks, the harness was discontinued and closed reduction under general anaesthesia was attempted after three weeks of preliminary horizontal traction. If the hip was still unstable, open reduction was considered. The harness was worn full-time during the first four weeks after spontaneous reduction, and then part-time for a further five months. During part-time wearing, the harness was removed only for bathing. The parents were instructed in the management of the harness. This schedule followed the original method described by Pavlik.1,2

The medical records regarding the Ortolani sign24 were complete for only 108 of the 191 hips. Of the 108 hips, 92 were Ortolani positive and reducible and 16 were Ortolani negative and irreducible. Reduction using the harness was successful in 66 of the Ortolani-positive hips (72%) and 13 of the Ortolani-negative hips (81%).

Of the 38 hips that failed to respond to harness treatment, 31 required closed and seven open reduction.

Radiological follow-up was carried out every 6 to 12 months after the initial treatment and the plain radiograph taken a mean age of 4.9 years (3 to 7) was used to evaluate the indications for additional surgery. The acetabular index (AI)26,27 was used as the basic indicator of residual acetabular dysplasia. Periodic examination was continued for patients with an AI < 30° (harness-only group), and additional surgery was indicated for those with an AI of 30° or more (supplementary group) (Fig. 1). The operative method depended upon the state of the joint and the surgeon’s preference. The centre-edge angle of Wiberg28 and the centre-head distance discrepancy29 in unilateral cases, were also measured on the radiographs taken at a mean age of 4.9 years (3 to 7).

The Severin classification system30 was used to evaluate the result at the end of follow-up. Classes I and II were considered satisfactory and classes III, IV, V and VI were unsatisfactory. AVN was classified by the method of Kalamchi and MacEwen.31 Type I AVN was excluded from the statistical analysis because of its good prognosis. Types II, III and IV were considered significant.

Statistical analysis. Overall results of the harness treatment. We evaluated whether reducibility (Ortolani sign positive or negative) affected outcome. Two-by-two contingency tables32 were computed to tabulate the incidence of AVN and long-term outcome (satisfactory or unsatisfactory). Separate tables were computed for the reducibility. Fisher’s exact probability test was applied. A p-value < 0.05 was considered significant.

Long-term results of the harness-only and the supplementary groups. Two-by-two contingency tables were computed to tabulate long-term outcome. Separate tables were computed for the incidence of AVN (absence and presence of AVN in the harness-only group or the supplementary group). Fisher’s exact probability test was applied. A p-value < 0.05 was considered to be significant.

Indicators of residual acetabular dysplasia. Correlation analysis between AI and centre-edge angle and between AI and...
centre-head distance discrepancy at around five years of age was performed using Spearman’s coefficient. A p-value < 0.05 was considered significant. This study protocol was approved by our institutional review board.

Results

Overall results of the harness treatment. Patients were followed-up for a mean of 16 years (14 to 32). At final follow-up 119 of 130 hips (91.5%) were considered satisfactory (Severin classes I and II). AVN was identified in 16 hips (12.3%), seven type II, four type III, and five type IV. However, a satisfactory outcome was obtained in nine of these (56%) with AVN. We excluded type I AVN, which occurred in seven hips, all of which were classified as Severin Ia.

At a mean age of 4.9 years (3 to 7), 108 of the 130 hips (83.1%) showed an AI of less than 30° and were treated only in the harness (harness-only group). However, 22 hips (16.9%) showed residual acetabular dysplasia, defined by an AI of 30° or more, and underwent supplementary surgery (supplementary group), which included 13 Salter innominate osteotomies, 33 four combined procedures of Salter innominate osteotomy and femoral varus osteotomy, and three Pemberton osteotomies. 34 Of the 79 hips reduced by the harness, 66 were reducible (Ortolani positive) and 13 were irreducible (Ortolani negative). Of the 66 reducible hips, 61 (92%) were classified as Severin I/II and AVN was noted in six (9%). All of the 13 irreducible hips (100%) were classified as Severin I/II, and AVN was noted in one (8%). There was no statistically significant difference between reducibility and outcome.

In 30 of the 38 hips treated by closed or open reduction the patient had reached at least 14 years of age. Of these 30 hips, 25 were Severin I/II (83%) despite AVN in eight (27%).

Long-term results of the harness-only and the supplementary groups. In the harness-only group 100 of 108 hips (93%) were considered satisfactory (Severin class I or II) at final follow-up and 19 of 22 hips (86%) in the supplementary group (Table I). Of the 16 hips with AVN, nine were treated conservatively, and seven showed residual acetabular dysplasia and underwent supplementary surgery. There was no incidence of AVN after supplementary surgery.

In the absence of AVN in the harness-only group, 96 hips were satisfactory and three unsatisfactory; in the presence of AVN, four hips were satisfactory and five unsatisfactory (Table II). There was a significant difference between hips with AVN and those without AVN in the long-term results of the harness-only group (p < 0.0001). In the absence of AVN in the supplementary group, 14 hips were satisfactory and one was unsatisfactory; in the presence of AVN, five hips were satisfactory and two were unsatisfactory. There was no significant difference between hips with and without AVN in the long-term results of the supplementary group.

Indicators of residual acetabular dysplasia. The mean AI at a mean age of 4.9 years (3 to 7) was 22.6° (12° to 34°) in the harness-only group and 33.9° (30° to 43°) in the supplementary group. There was a predictably significant difference between these groups (p < 0.0001). The mean centre-edge angle at a mean age of 4.9 years (3 to 7) was 17.7° (-3° to 31°) in the harness-only group and 3.4° (-30° to 12°) in the supplementary group. The mean centre-head distance discrepancy was 3.0% (-6.6% to 17%) in the harness-only group and 8.5% (0% to 26.6%) in the supplementary group. Correlation between AI and centre-edge angle at a mean age of 4.9 years (3 to 7) was shown by a strong negative Spearman’s correlation coefficient of -0.85 (95% CI -0.89% to -0.79%). Correlation between AI and centre-head distance discrepancy was shown by a moderate Spearman’s correlation coefficient of 0.40 (95% CI 0.21% to 0.55%).

Discussion

The long-term results of the Pavlik harness used for dislocation only in this study were satisfactory compared with previous reports. Fujioka et al22 reported a 78% satisfactory outcome with 23.6 years of follow-up, but included both dislocation and subluxation. Mubarak et al17 reported that if subluxation was considered a type of dislocation, the results were better. We believe that one reason for our favourable long-term results was that additional surgery for residual acetabular dysplasia was performed when indicated on the radiograph at a mean age of 4.9 years (3 to 7) (Fig. 2). Mitani et al21 reported a satisfactory outcome in only 67% of patients treated with the harness and no addi-

**Table I.** Long-term results (Severin classification20)

<table>
<thead>
<tr>
<th>Group (number of hips)</th>
<th>Satisfactory</th>
<th>Unsatisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harness-only (108)</td>
<td>ls ib Ia Ib</td>
<td>IIa III Iva</td>
</tr>
<tr>
<td>Total (%)</td>
<td>100 (92.6)</td>
<td>8 (7.4)</td>
</tr>
<tr>
<td>Supplementary (22)</td>
<td>8 6 3 2 1</td>
<td>3 13.6</td>
</tr>
<tr>
<td>Overall (130)</td>
<td>71 39 4 5 3</td>
<td>8 3</td>
</tr>
<tr>
<td>Total (%)</td>
<td>119 (91.5)</td>
<td>11 (8.5)</td>
</tr>
</tbody>
</table>

**Table II.** Relationship between long-term results and avascular necrosis (AVN)

<table>
<thead>
<tr>
<th>Group (number of hips)</th>
<th>Satisfactory</th>
<th>Unsatisfactory</th>
<th>Significance *</th>
</tr>
</thead>
<tbody>
<tr>
<td>Harness-only (108)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVN absent (%)</td>
<td>99 96 (97)</td>
<td>3 3</td>
<td>p &lt; 0.0001</td>
</tr>
<tr>
<td>AVN present (%)</td>
<td>9 4 (44)</td>
<td>5 3 (56)</td>
<td></td>
</tr>
<tr>
<td>Supplementary (22)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>AVN absent (%)</td>
<td>15 14 (93)</td>
<td>1 7</td>
<td>NS</td>
</tr>
<tr>
<td>AVN present (%)</td>
<td>7 5 (71)</td>
<td>2 29</td>
<td></td>
</tr>
</tbody>
</table>

* Fisher’s exact probability test; NS, not significant
tional surgery for residual acetabular dysplasia. Tucci et al.\textsuperscript{18} reported a satisfactory outcome in 83\% of patients followed up for 12 years, but excluded those who required a supplementary operation for acetabular dysplasia. Our long-term results include both the harness-only group and the supplementary surgery group.

Albinana et al.\textsuperscript{35} have shown that AI is a reliable indicator of acetabular development. They concluded that an AI > 30˚ four years after closed or open reduction was associated with an 80\% probability of developing a Severin grade III/IV hip. On the other hand, Murakami and Katada\textsuperscript{19} reported that a minimum centre-edge angle of 10˚ at five or six years of age may be a reasonable threshold of normality. However, Kim et al.\textsuperscript{27} reported that the centre-edge angle is only useful in children over the age of five years because the...
centre of the femoral head is difficult to define in a younger child with an eccentrically-located ossific nucleus. Ogata et al. reported that it was sometimes difficult to distinguish precisely the lateral edge of the acetabulum because of the indistinct shadow of the sourcil. Chen et al. demonstrated that centre-head discrepancy was the most significant correlative factor in predicting the outcome of acetabular development, and Kim, Kim and Yoo reported that a centre-head distance discrepancy > 6% and the upward orientation of the sourcil at four or five years of age were indications for additional surgery. However, centre-head distance discrepancy can only be used in unilateral cases. Because AI correlated with centre-edge angle and centre-head distance discrepancy, and satisfactory results of 86% were obtained in the supplementary group, we believe that an AI > 30˚ around five years of age is the most useful predictor of residual acetabular dysplasia and an indicator for additional surgery.

Severin stated that a follow-up study that does not include the majority of patients originally treated is incomplete. We believe that our follow-up rate is higher than those previously reported. Cashman et al. reported a prospective study with 89.9% follow-up, but their mean follow-up period was only 6.5 years. This is not enough to clarify the long-term results of DDH because the Severin classification is different in those between six and 13 years of age and over 14 years of age. Furthermore, Koizumi et al. reported that Kalamchi type II AVN may not be recognised until after ten years of age. We experienced such a case (Fig. 3) and emphasise the importance of follow-up until at least skeletal maturity. The reported incidence of AVN in complete dislocation ranges from 7.3% to 14% at skeletal maturity.

Our use of the harness followed Pavlik’s original method. He used the harness for all patients with dislocation up to the age of one year. Viere et al. recommended a trial of the harness in patients with a typical dislocation up to the age of seven months, even if the dislocation could not be reduced by the Ortolani manoeuvre. In our series there was no statistically significant difference in reducibility (as assessed by the Ortolani sign) or outcome. On the other hand, Mostert, Tulp and Castelein suggested that the harness should not be used in Graf type IV hips, as in their hands it was successful in only 50% of such hips. The incidence of AVN in this study was higher in hips which failed harness treatment and required closed or open reduction than in those that responded to harness treatment. However, it is still unclear whether wearing the harness for even a short time affects the occurrence of AVN.

Herring suggested that the harness has a screening role. Hips which failed to respond to harness treatment were recalcitrant, at risk of failure with other types of treatment, and required a cautious approach. The influence on AVN of further treatment should not be ignored. We never forcibly reduced dislocated hips with the harness and never continued to use it unless spontaneous reduction occurred within two weeks. Takahashi reported that spontaneous reductions were observed as early as three to four days, and usually within a week after application of the harness. Harris et al. also suggested that the treatment should be abandoned if the hip could not be reduced after two to four weeks of treatment.

In the harness-only group there was a significant difference in outcome between those with AVN and those without, but there was no significant difference between those with and without AVN in the supplementary group. We suggest that supplementary surgery may improve the outcome in AVN with residual acetabular dysplasia.

Since 1991 we have modified the use of the Pavlik harness to reduce the incidence of AVN, based on the studies by Grill et al. and Ramsey et al. Small pillows are placed under the knees of supine babies to allow their abduction within a safe zone a few days after reduction, when they do not want to move their legs. We start the application routinely at about 70˚ of flexion and increase it slowly, as babies and their hips need time to adapt to the therapeutic position of the harness. We repeatedly explain the procedure to parents by means of our brochures to promote a better understanding of the treatment. Spontaneous reduction is monitored using ultrasonography via an anterior approach. In a recent short-term study, the incidence of AVN was reduced to 0%.

The incidence of AVN was nil in the group initially reduced with the Pavlik harness in Chiba Children’s Hospital. The initial treatment of developmental dysplasia of the hip is important if AVN of the femoral head is to be avoided.

References


