We report the six-year results of a prospective, controlled demographic trial of developmental dysplasia of the hip (DDH) treated in the Pavlik harness using ultrasound supervision. Our aim was to assess the value of ultrasound and its role in monitoring reduction in the harness, in terms of progression or failure of reduction at an early state.

From 1988 to 1994, a total of 221 patients with 370 ultrasonographically abnormal hips was treated in the Pavlik harness. This represents a treatment rate for the Southampton district of 5.1 per 1000 live births. Sixteen hips in 12 patients were not reduced in the harness and required surgical treatment; 95.7% were successfully reduced. One case of mild avascular necrosis (0.3%) was identified in those treated by harness alone. Of the 221 patients 87.8% remain under radiological review, with 3.2% of affected hips showing continued, mild acetabular dysplasia.

We conclude that ultrasound monitoring has led to an acceptably low level of intervention, a high reduction rate and minimal iatrogenic complications. The trial is continuing.


Pavlik developed his ‘functional method’ for treatment of congenital dislocation of the hip because of the high rates of ‘aseptic necrosis’ that he had observed from the use of ‘passive mechanical methods’. His method is now widely used, but recent reports quote rates of aseptic necrosis of from 0% to 28%. There is also a considerable range in the reported rates of failure to achieve reduction, from 3% to 16%. The reasons for these wide variations are not clear. The problems include uncertainty in the selection of patients for treatment, the method of monitoring in the harness and the indications for abandoning this treatment. Apart from the risk of avascular necrosis during prolonged treatment for failed reduction, there is concern about the possible damage to the development of the acetabulum.

In the longer term, it is still uncertain how long review should be continued to assess late acetabular dysplasia. For these patients, the long-term prospective results of a ‘defined population’ are still required to identify early predictive features.

There are few studies of the screening and treatment for developmental dysplasia of the hip (DDH) using ultrasound, that of Vedantam and Bell being the only one of a defined population. We describe a considerably larger cohort with a longer follow-up, which allows an assessment of ‘late acetabular dysplasia’. To assess acetabular development, radiological review will continue until all the children reach skeletal maturity. We now report the medium-term results of our study.

PATIENTS AND METHODS

Children were recruited into the trial from the Southampton DDH screening clinic. They were referred from the Southampton district (population approximately 500 000) as a result of the neonatal and community clinical screening programme and the selective ultrasound screening programme. Additional cases were referred from other districts. We report the results of all children treated for DDH in the Pavlik harness between June 1988 and December 1994.

Children were excluded if they had multiple congenital deformities, prior treatment by a different method, ‘teratological dislocations’ or had presented late. For the purpose of our study, teratological dislocation was defined as a fixed dislocation of the hip in association with either a recognised syndrome or neurological disorder. Late presentation was defined as ‘more than 90 days’ at the first clinic visit, although the diagnosis may have been made earlier. Thir-
teen children who met this criterion were treated in the Pavlik harness and 11 were not, based on the clinical assessment of the senior author (NMPC) at the initial appointment.

Children referred shortly after birth were examined; those with unstable hips were nursed in double nappies and an appointment was made for two weeks later. Children referred for ‘risk factors’ were seen at approximately six weeks postpartum.

At the first clinic appointment a standard history was taken and clinical examination performed. Static and dynamic ultrasound assessments in two planes for both hips was then performed or supervised by the senior author and graded as ‘normal’, ‘displaced’ or ‘dislocated’. The displaced category included those with minor subluxation but marked instability on imaging. On the basis of this primary assessment a decision was made as to whether to treat in the Pavlik harness or to maintain the child in double nappies and review with ultrasound for one or two weeks. If the latter method resulted in no improvement then ‘delayed’ application of the harness was carried out. In all cases, the Pavlik harness was fitted and adjusted weekly by a dedicated physiotherapist.

Weekly, static ultrasound imaging, in two planes, was performed with the baby in the harness (Fig. 1) and on this basis the position of the hip was observed and recorded. No dynamic assessment was performed after treatment had started. In children whose hips failed to reposition satisfactorily, the harness was abandoned at between four and six weeks, unless progressive improvement in the position had been shown. Removal of the harness was begun when the hip was concentrically reduced, initially for one hour each day and gradually increasing until it was used only at night. After reduction and weaning the children were reviewed at 6 and 12 weeks and then at 6 and 12 months. When the ossific nuclei had been established radiography was used to assess hip development. The children remain under yearly radiological review until maturity. If there is a failure to attend the clinic a fresh appointment is made. For persistent failure, the general practitioner is contacted by letter. This treatment programme is summarised in Figure 2.

We used a special proforma to collate information from the case notes and collect it on a computer database. All radiographs for each patient were measured for acetabular angles and the height of the ossific nucleus. The centre-edge angle was recorded after the age of five years. Avascular necrosis was assessed using the method of Kalamchi and McEwen. Persistent dysplasia, as defined by Tönnis, was diagnosed from the acetabular angle in children under five years of age and the centre-edge angle in those over five years, using the most recent radiograph. Age and gender were taken into account when diagnosing dysplasia.

RESULTS

Between June 1988 and December 1994, a total of 221 children was recruited, 190 from the Southampton district and 31 from outside the area. There were 187 girls and 34 boys. There was no significant variation in the number referred in each year of the study, the sex ratios or the method or overall results of ultrasound assessment of the affected hips. All the babies had either clinically dislocated or unstable hips, or ultrasound evidence of hip displacement.

To date 27 patients (12.2%) have been lost to review for more than 18 months. The mean age at review is 3.64 years for the remainder.

Ultrasound grading. At the initial clinic visit a number of children were seen with ‘minor’ abnormalities of the hip such as ‘excessive’ laxity and ‘mild’ acetabular dysplasia. They were regularly observed by ultrasound, seen to improve and discharged without treatment.

Within the treated group of 221 children, 149 had hips which were considered to be bilaterally sonographically abnormal; 72 children were unilaterally affected. The treated group therefore consisted of 442 hips affected as follows: normal 72 (16.3%); displaced 291 (65.8%); and dislocated 79 (17.9%).

There was no variation between left and right sides. Of the 16 hips that failed to reduce in the harness, 14 were dislocated at presentation.

Time to reduction. The median age at the time of primary treatment was 19.5 days (1 to 166). A small proportion had ultrasound for one or two weeks before treatment in the harness. The hips which failed to reduce presented slightly later than the others at a mean of 47.5 days compared with a mean of 31.2 days.

The mean time in the harness before reduction as assessed sonographically varied with the initial ultrasound grading: for dislocated hips it was 3.2 weeks (1 to 12) and for displaced hips 2.3 weeks (1 to 10). The mean time in the harness for those hips failing to reduce and requiring treatment...
other treatment was 6.3 weeks (3 to 17) compared with a mean of 6.7 weeks (4 to 19) to weaning in the successful group.

**Failure of treatment.** Sixteen hips in 12 patients failed to reduce in the Pavlik harness and required further treatment, giving a failure rate of 4.3%. These hips have so far required 20 surgical procedures: open reduction (9), closed reduction (7), Salter osteotomy (3) and varus osteotomy (1).

One hip showed asymptomatic, grade-1 avascular necrosis, recognised by a marginal deterioration in the homogeneity of the ossific nucleus. This abnormality has now resolved radiologically. There were no other complications of treatment in the Pavlik harness.

**‘Late’ dysplasia.** Seven hips in seven patients (3.2%), with a mean age 5.6 years (2.6 to 6.9), showed low-grade acetabular dysplasia at the time of latest review. Five hips in four patients were mildly dysplastic on CE angle. The patient affected bilaterally is 6.8 years of age. The other three had ‘slight dysplasia’ on measurement of their acetabular angles. None is considered to require a further acetabular procedure at present. Figure 3 shows a typical example.

**Late presentation.** During our study, seven children from the Southampton district and six from outside it presented beyond the arbitrary 90 days and were treated in the Pavlik harness. Of the Southampton patients, five were diagnosed within the 90-day period, but were delayed in attending the clinic. The other two were first seen at 130 and 166 days, respectively. They are included as late presentations in separate screening data, but both were successfully treated in the harness without complications. One child from the Southampton group and one from outside the district failed to reduce and required open operation.

In addition to these seven cases, 11 Southampton-born children presented late between 1988 and 1995 because of...
delayed diagnosis and were not considered suitable for harness treatment. Table I gives the distribution of these cases. All were treated by surgery when the ossific nucleus of the affected side was radiologically visible.

The screening figures for 1995 are included, but the results of harness treatment are not, since the radiological follow-up for these patients is too short.

DISCUSSION

Our principal aim was to determine the value of ultrasound in the assessment and monitoring of treatment in the Pavlik harness for DDH and to present this in the context of a screened population, with the relevant failure and intervention rates. Treatment in the Pavlik harness gave ‘successful’ reduction in 95.7% which agrees with the findings of other large studies.13 The rate of avascular necrosis of 0.4% is, however, considerably lower than many other published results.3 13 14 We are unable to determine to what degree the use of ultrasound has aided the achievement of such good results, but it is of the same order as those reported by Vedantam and Bell2 in a similar study of 31 children.

Ultrasound screening has been criticised as inevitably leading to an unacceptably high treatment rate.15 This is contradicted by our findings: our treatment rate averaged only 5.1 per 1000 live births over seven years. The rate of late presentation, missed by the screening programme and not treated in the Pavlik harness, was 0.26 per 1000 live births. Most published series do not include such demographic data; this makes current comparison between different treatment programmes unreliable.

In recent years there has been a tendency to advise an arbitrary ‘safe’ treatment period in the Pavlik harness of approximately six weeks before weaning. In our study, hips which failed to reduce promptly or show continuing improvement, had discontinuation of the harness a little earlier than those weaned after successful treatment. This mean figure hides the fact that there were a number of successful cases in which reduction occurred relatively slowly after a more prolonged application of the harness. The implication of this is that it is possible to distinguish between the recalcitrant and the gradually improving subluxation more reliably by ultrasound monitoring than by clinical examination alone. Thus, in some hips treatment may safely continue for longer than the arbitrary six weeks.16 17 This distinction may also account for our low rate of avascular necrosis. The method may also possibly reduce late or persistent dysplasia by avoiding damage to the acetabular anlage.6

It is important to emphasise the importance of skilled application and adjustment of the harness to prevent complications and improve compliance. All the patients in our series were supervised by one senior paediatric physiotherapist at a weekly clinic appointment, and this has undoubtedly contributed towards the success of the programme.

The varying number of dislocations, as opposed to displacements, in different series must influence success rates and possibly the incidence of avascular injury.3 18 It has

<table>
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<th>Year of birth</th>
<th>Births</th>
<th>Late presenting hips</th>
<th>Incidence per 1000 births</th>
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<tr>
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<td>5881</td>
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<td>5791</td>
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<tr>
<td>Total</td>
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</table>
been suggested that ultrasound can be used at initial presentation to exclude certain types of DDH from treatment in the harness. In our series this would have certainly led to the exclusion of a small number of successfully treated cases and prevented no morbidity, other than the inconvenience of several weeks in the harness itself.

A further factor in the success of this type of programme is the relatively low incidence of late referral, which we defined as more than 90 days before the start of treatment. Some older children were successfully treated, but these were few due to the efficiency of the local screening arrangements. Even this has not eliminated the rare presentation of DDH beyond six months of age in the district.

The remaining question is whether children treated by such a programme will be more or less likely to show persistent or late acetabular dysplasia. There is little published evidence of such a long-term review of a treated population. In our series to date, the incidence of mild acetabular dysplasia is 4.3%. It has not been possible to relate these to factors in the history, treatment or ultrasound appearance which would have been predictive at an early stage. Some hips may resolve in due course, but equally, others may develop. For this reason the project is continuing in these and children recruited after 1994; as far as possible all will be followed to skeletal maturity. The acetabular angle at less than five years of age, and centre-edge angles in children more than five years old are imperfect measures of acetabular dysplasia; they are based on data derived from a different population. Few authors have similar data from their local population; the use of standard radiographs was considered to provide an acceptable measure. The long-term success of our treatment programme depends not only on the ability to identify and reduce dislocated or displaced hips in infants, but also to improve the long-term development of the joint. In this context it is important to stress that our rates for acetabular dysplasia represent only preliminary results.

We believe that the ultrasound assessment and monitoring of treatment for DDH, irrespective of its screening value, facilitates treatment, reduces complication rates and may result in a lower rate of late acetabular dysplasia. We wish to thank Christine Ireland, senior paediatric physiotherapist, whose enthusiastic and dedicated work has contributed, in no small part, to the success of the treatment programme which forms the basis of this study.

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


