Ultrasonography in the diagnosis and management of developmental hip dysplasia (UK Hip Trial): clinical and economic results of a multicentre randomised controlled trial

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Summary

Background Clinical screening aims to identify and treat neonatal hip instability associated with increased risk of hip displacement, but risks failures of diagnosis and treatment (abduction splinting), iatrogenic effects, and costs to parents and health services. Our objectives were to assess clinical effectiveness and net cost of ultrasonography compared with clinical assessment alone, to provide guidance for management of infants with clinical hip instability.

Methods Infants with clinical hip instability were recruited from 33 centres in UK and Ireland and randomised to either ultrasonographic hip examination (n=314) or clinical assessment alone (n=315). The primary outcome was appearance on hip radiographs by 2 years. Secondary outcomes included surgical treatment, abduction splinting, level of mobility, resource use, and costs. Analysis was by intention to treat.

Findings Protocol compliance was high, and radiographic information was available for 91% of children by 12–14 months and 85% by 2 years. By age 2 years, subluxation, dislocation, or acetabular dysplasia were identified by radiography on one or both hips of 21 children in each of the groups (relative risk 1·00; 95% CI 0·56–1·80). Fewer children in the ultrasonography group had abduction splinting in the first 2 years than did those in the no-ultrasonography group (0·78; 0·65–0·94; p=0·01). Surgical treatment was required by 21 infants in the ultrasonography group (6·7%) and 25 (7·9%) in the no-ultrasonography group (0·84; 0·48–1·47). One child from the ultrasonography group and four from the no-ultrasonography group were not walking by 2 years (0·25; 0·03–2·53; p=0·37). Infants in the ultrasonography group incurred significantly higher ultrasound costs over the first 2 years (£42 *vs* £23, mean difference £19, 95% CI 11–27); total hospital costs were lower for those infants, but the difference was not significant.

Interpretation The use of ultrasonography in infants with screen-detected clinical hip instability allows abduction splinting rates to be reduced, and is not associated with an increase in abnormal hip development, higher rates of surgical treatment by 2 years of age, or significantly higher health-service costs.

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Introduction

Developmental dysplasia of the hip (DDH)[1] refers to a range of developmental hip disorders that includes part or complete displacement of the femoral head from the acetabulum—ie, developmental displacement of the hip, previously called congenital dislocation of the hip (DDH/CDH)—and acetabular dysplasia with or without displacement. Normal growth and development of the hip might be impaired as a consequence of DDH/CDH, which could lead to gait abnormalities and premature degenerative changes in the hip joint.[2] A national screening programme that uses the Ortolani-Barlow test was introduced in the UK in 1969.[3] This test aims to identify infants with neonatal hip instability who are at increased risk of hip displacement in order to allow early treatment with abduction splinting to stabilise the hip. However, uncertainty exists about which infants identified by screening should receive such treatment because hips will often stabilise spontaneously, there is no diagnostic test for DDH/CDH, and the effectiveness of abduction splinting has never been assessed in a randomised trial.[4] This uncertainty is associated with potential overtreatment of infants with false-positive screening results, as well as with failures of diagnosis and treatment of those with true-positive screening results.[5] Abduction splinting is not without risks: avascular necrosis can arise in the contralateral hip.[6–8] Splints also impede daily care, and might therefore interfere with the relationship between babies and their parents. There are also financial costs for parents and the health services. Accurate identification of babies whose hip or hips will stabilise without treatment could reduce these risks and costs, which will have implications for the cost-effectiveness of screening strategies.[9]

Since the mid-1980s there has been an increase in use of dynamic and static ultrasonography of hips of newborn infants.[10] Imaging might be offered to all newborn babies in the context of primary screening, or only to those selected on the basis of risk factors or clinically detected hip instability. Neither clinical nor ultrasonographic screening programmes have been satisfactorily assessed.[4,11,12] Results of observational studies of the effects of screening are inconsistent,[13,14] and some investigators have suggested that the prevalence of DDH has increased.[15]

Because of these concerns about screening, particularly about that with ultrasonography, a UK Department of

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Health and Medical Research Council working party was formed to review the performance of current screening programmes in the UK, the role of ultrasonography, and the subsequent management of children identified through screening. The working party planned three complementary strategies. The first, reported elsewhere,[10] comprised epidemiological studies to establish current screening practices and to estimate the number of infants per 1000 livebirths who are treated with abduction splinting[4] and the number who have a first operative procedure related to DDH/CDH before age 5 years per 1000 children.[13] We report the second strategy, which is to assess the clinical and psychosocial effects, and cost-effectiveness of ultrasonography in the diagnosis and management of children with neonatal hip instability with a randomised trial. The third strategy was to synthesise existing data to investigate the effectiveness and efficiency of various primary screening strategies, including primary screening with ultrasonography.[16]

Results from a previous trial suggest that ultrasonography could reduce the number of newborns with unstable hips treated with abduction splinting by as much as 70%.[17] However, the apparent advantages of such screening could be outweighed by an increase in the need for late treatment and poorer long-term function. However, this previous trial included only 79 children in a single centre and had the statistical power to identify only a very large adverse effect with any confidence. These features of the study left questions: is it safe not to splint hips that were clinically suspect but seemed normal during ultrasonography? And are these results generalisable? We planned our trial to have enough statistical power to answer these questions.

Our primary aim was to assess whether ultrasonography can reduce the likelihood of children with neonatal hip instability being splinted without a doubling of the risk of late treatment. As a secondary aim, we investigated whether the extra financial costs associated with diagnosis with ultrasonography will be balanced by a reduction in other costs. We focus on clinical outcomes and hospital costs.

Methods

Participants

Clinical centres from teaching or district general hospitals were eligible to participate in the trial if they were within reach of appropriate ultrasonography facilities. Participants were recruited from maternity units and paediatric or orthopaedic outpatient clinics. A range of centres was chosen so that our results could be generalised throughout the UK National Health Service. Local research ethics committees at participating centres gave ethics approval for the study.

Babies aged less than 43 days were eligible for the trial if they had been diagnosed with neonatal hip instability by a senior doctor, and if written parental consent had been obtained. We excluded babies who had already had ultrasonographic imaging of their hips, those for whom the attending clinician was certain that immediate splinting was indicated, and those with a hip click but no signs of instability. Babies with recognised risk factors for subsequent dislocation but whose hips were deemed to be clinically normal by the Ortolani-Barlow test were also excluded. However, babies whose hips were initially judged to be unstable but which had stabilised by the time of recruitment were eligible if the recruiting doctor was convinced that hip instability had been present on initial examination.

Procedures

The local clinician telephoned a central randomisation service to confirm eligibility, to provide clinical details at the time of trial entry, and to ensure that all babies recruited could be identified for later follow-up. The central service allocated babies to one of two groups—diagnosis and management with ultrasonography or diagnosis with clinical examination alone—using minimisation (with a probabilistic element) to ensure that key prognostic factors were balanced within both groups. These prognostic factors included clinical centre, unilateral or bilateral hip instability, age of baby (<4 weeks or ⩾4 weeks), level of clinical suspicion (enough to warrant prophylactic splinting or to refer for specialist assessment), and clinical diagnosis of the worse hip under four headings (previous instability, dislocatable or subluxatable, dislocated but reducible, and dislocated but irreducible).

Babies allocated to the ultrasonography group received an ultrasound examination of the hips when they were aged 2 weeks or older. We took a static view of acetabular development in the standard coronal plane, and a dynamic test of joint laxity in the transverse plane.[18,19] Results were recorded on a standardised report form that can be seen at http://image.thelancet.com/extras/01art12270webappendix1.pdf. We showed methods of ultrasonographic scanning at workshops and in a video distributed to centres. We also provided centres with a flow chart which showed agreed guidelines for treatment pathways (figure 1). These guidelines recommended that treatment for babies in the ultrasonography group be delayed until ultrasonographic images were available to guide the decision-making process. If ultrasonography showed significant hip displacement or instability, we recommended immediate splinting. Minor displacement or instability were to be monitored with ultrasonography, and treated at the discretion of the clinician responsible for care. Hips were to be splinted if the abnormality remained at 8 weeks of age.

Decisions about treatment for the babies allocated to the no-ultrasound group were to be on the basis of clinical examination only. In the trial guidelines, we recommended that these decisions should depend on the

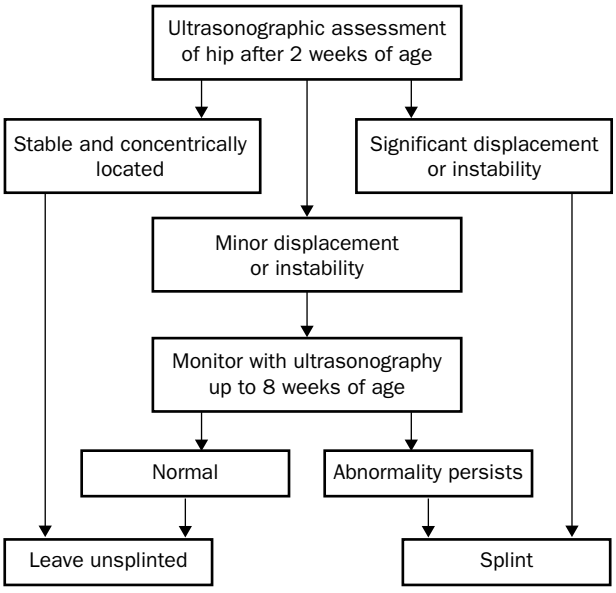

Figure 1: **Treatment guidelines for ultrasonography group**