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


Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The use of ultrasonography in the diagnosis and management of developmental hip dysplasia.

Type of intervention
Secondary screening.

Economic study type
Cost-effectiveness analysis.

Study population
The study population consisted of babies aged less than 43 days, who had been initially diagnosed with neonatal hip instability by a senior doctor, and whose parent gave consent. Infants were excluded if they had had prior ultrasonographic imaging of their hips, had indication of immediate splinting, had a hip click but no signs of instability, and if their hips were deemed to be clinically normal by the Ortolani-Barlow test.

Setting
The setting was secondary care. The economic analysis was carried out in Oxford, UK (using data from throughout the UK).

Dates to which data relate
The effectiveness data were collected from a randomised controlled study between December 1994 and January 1998. Year 2000 prices were used.

Source of effectiveness data
The effectiveness data were gathered from a single prospective study.

Link between effectiveness and cost data
The costing was undertaken prospectively on the same group as that used in the effectiveness study.

Study sample
Power calculations to determine the sample size were reported. Centres were eligible to participate in the trial if they were within reach of appropriate ultrasonography facilities. A range of centres was chosen so that the results could be generalised throughout the UK NHS. Seven hundred children would be needed to detect a doubling of the risk of late treatment from 6 to 12% with 80% power. The patients were enrolled from 33 centres in the UK and Ireland. The participants were recruited from maternity units and paediatric or orthopaedic outpatient clinics. The central service
allocated infants to one of two groups using minimisation (with a probabilistic element) to ensure that key prognostic factors were balanced within both groups.

A total of 629 infants were enrolled in the study, of which 314 were randomly allocated to the ultrasonography group and 315 to the control group. At baseline, the clinical characteristics were similar between the groups. The median age at entry was 4 days (interquartile range: 1 - 19) in the ultrasonography group versus 6 days (interquartile range: 1 - 20) in the control group. Most of the infants were female, 70% (ultrasonography) versus 75% (control), and 29% of the children had a diagnosis that warranted early prophylactic splinting (30% ultrasonography group versus 28% control group).

**Study design**
This was a randomised controlled trial. Treatment guidelines were given to centres for the use (or no use) of ultrasonography. There was no potential bias from the patients. An independent panel of radiologists, who were blinded to the centre, allocation, treatment status and local report, reviewed copies of radiographs and classified them. The baseline and outcome data were recorded at entry, 8 weeks, 12 - 14 months and 24 months. Missing numbers for each clinical measure were reported. Protocol compliance was high. Radiographic information (the primary outcome measure) was available for 91% of children by 12 - 14 months and for 85% by 2 years. The information was missing for 56 patients (18%) in the ultrasonography group and 39 patients (12%) in the no-ultrasonography group.

**Analysis of effectiveness**
The basis of the analysis was intention to treat. The primary health outcome was the appearance on hip radiographs by 2 years as a best proxy for functional impairment in life. The secondary health outcome included the amount of hip treatment required, the number of abduction splints, and the child's level of independent mobility after the first year of life.

**Effectiveness results**
By age 2 years, there were 4 (1%) abnormal appearances on the radiograph for the ultrasonography group and 6 (2%) for no ultrasonography, (relative risk, RR=0.67, 95% confidence interval, CI: 0.14 - 2.83; p=0.75). Borderline appearances were 17(5%) for ultrasonography and 15(15%) for no ultrasonography, (RR 1.14, 95% CI: 0.58 - 2.24; p=0.85).

Fewer children in the ultrasonography group had abduction splinting in the first 2 years than did those in the no-ultrasonography group, (RR 0.78, 95% CI: 0.65 - 0.94; p=0.01).

Surgical treatment was required by 21 infants (6.7%) in the ultrasonography group and 25 (7.9%) in the no-ultrasonography group, (RR 0.84, 95% CI: 0.48 - 1.47; p=0.65).

One child from the ultrasonography group and 4 from the no-ultrasonography group were not walking by 2 years, (RR 0.25, 95% CI: 0.03 - 2.53; p=0.37).

**Clinical conclusions**
The use of ultrasonography in infants with screen-detected clinical hip instability allows abduction splinting rates to be reduced. It is not associated with an increase in abnormal hip development, or higher rates of surgical treatment by 2 years of age.

**Measure of benefits used in the economic analysis**
There was no summary benefit measure. Thus, a cost-consequences analysis was conducted.

**Direct costs**
The cost/resource boundary of this analysis was that of the hospital. However, the original study measured the costs incurred by families. The direct costs were for ultrasonographs, radiographs, outpatient visits, home visits, days in hospital and associated surgery, splints and other treatments. The means and standard deviations (SDs) were reported for the costs and the quantities for the cost categories. The unit costs are reported on the Lancet website [http://image.thelancet.com/extras/01art1227webtable.pdf](http://image.thelancet.com/extras/01art1227webtable.pdf). The unit costs were obtained from participating centres, national data sources, financial returns of UK NHS trusts and other studies. Discounting was not carried out since the follow-up period was less than two years. The costs per patient were reported at 2000 prices. Complete cost data were available for only 573 (89%) infants.

**Statistical analysis of costs**

For cost data, the means and SDs were shown with mean differences and 95% CIs. A regression analysis was used to control for variation in prognostic variables.

**Indirect Costs**

No indirect costs were included.

**Currency**

UK pounds sterling (£).

**Sensitivity analysis**

No sensitivity analysis of the costs was carried out.

**Estimated benefits used in the economic analysis**

Not applicable.

**Cost results**

The cost analysis was based on available data. Infants in the ultrasonography group incurred significantly higher ultrasound costs over the first 2 years (£42) than those in the control group (£23). The mean difference was £19 (95% CI: 11 - 27).

In all other resource-use categories, the resources used per patient were slightly lower in the ultrasonography group, but no other statistically significant differences were detected.

The main elements of cost were outpatient visits and days in hospital. Outpatient visits cost £322 in the ultrasonography group versus £327 in the no-ultrasonography group (mean difference £4, 95% CI: -41 to -33). Days in hospital cost £267 (ultrasonography) and £365 (no ultrasonography), respectively (mean difference £97, 95% CI: -289 to -95).

The total costs averaged £724 (SD £1,178) per patient in the ultrasonography group and £827 (SD £1,585) in the control group. This represented a non significant saving of £102 per patient (95% CI: -£331 to -£127). When variations in prognostic variables were taken into account, this difference changed slightly to £106 per patient, but remained non significant.

**Synthesis of costs and benefits**

Not applicable.

**Authors' conclusions**

The use of ultrasonography in infants with clinical hip instability allows abduction splinting rates to be reduced. It is not
associated with higher abnormal hip development, or higher rates of surgical treatment or significantly higher health-service costs.

CRD COMMENTARY - Selection of comparators
Clinical assessment alone was justified as the comparator on the grounds that it was the natural alternative. You should consider whether this is a widely used technology in your own setting.

Validity of estimate of measure of effectiveness
The internal validity of the study was high. The study had adequate power to answer its primary question. The study sample was representative of the study population. The patient groups were shown to be comparable at analysis, so for those variables confounding should be low. Selection bias was likely to have been low due to randomisation. Measurement bias should have been low because the independent panel was appropriately blinded. The compliance rates were high so performance bias is likely to be low. The authors justified the assessment of radiological appearance of hips at 2 years, when most children are walking, as being a meaningful surrogate measure of whether a hip is likely to remain functionally unimpaired throughout life. Adequate details of the methods used to estimate effectiveness were given.

Validity of estimate of measure of benefit
There was no summary measure of benefit.

Validity of estimate of costs
The perspective adopted for the economic analysis was not clearly stated, but it is likely to have been that of the UK NHS. The indirect costs were not included and this may affect the authors' conclusions. The mean costs and quantities were reported separately, while the unit costs were reported elsewhere. A statistical analysis of the quantities was performed, whereas a statistical analysis of the prices was not. Discounting was unnecessary since all the costs were incurred over 24 months.

Other issues
The authors presented their results thoroughly. The study enrolled infants with clinical hip instability and this was reflected in the authors' conclusions. The authors made comparisons of their findings with those from the Bristol trial (Gardiner et al, see Other Publications of Related Interest). The authors acknowledged that the external validity of their trial is difficult to assess, but they noted that various features of their study design made the effects observed generalisable.

Implications of the study
According to the authors, the effects of the two diagnostic policies should be assessed from skeletal maturity onwards. Further, a large multicentre trial of abduction splinting is needed. In particular, to inform treatment decisions in infants who show borderline abnormalities on ultrasonography, but who have hips that are clinically stable.

Source of funding
Funded by the Department of Health and Medical Research Council.

Bibliographic details
PubMedID
12504396

Other publications of related interest


Indexing Status
Subject indexing assigned by NLM

MeSH
Costs and Cost Analysis; Female; Great Britain; Hip Dislocation, Congenital /economics /surgery /ultrasonography; Humans; Infant; Infant, Newborn; Male; Splints /economics

AccessionNumber
22003008020

Date bibliographic record published
31/10/2003

Date abstract record published
31/10/2003