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■ CHILDREN'S ORTHOPAEDICS

The cost effectiveness of potential risk factors for developmental dysplasia of the hip within a national screening programme

A. T. Poacher,
J. L. J. Froud,
J. Caterson,
D. L. Crook,
G. Ramage,
L. Marsh,
G. Poacher,
E. C. Carpenter

From Noah's Ark Children's Hospital for Wales, Cardiff, UK

Aims

Early detection of developmental dysplasia of the hip (DDH) is associated with improved outcomes of conservative treatment. Therefore, we aimed to evaluate a novel screening programme that included both the primary risk factors of breech presentation and family history, and the secondary risk factors of oligohydramnios and foot deformities.

Methods

A five-year prospective registry study investigating every live birth in the study's catchment area (n = 27,731), all of whom underwent screening for risk factors and examination at the newborn and six- to eight-week neonatal examination and review. DDH was diagnosed using ultrasonography and the Graf classification system, defined as grade IIb or above or rapidly regressing IIa disease ($\geq 4°$ at four weeks follow-up). Multivariate odds ratios were calculated to establish significant association, and risk differences were calculated to provide quantifiable risk increase with DDH, positive predictive value was used as a measure of predictive efficacy. The cost-effectiveness of using these risk factors to predict DDH was evaluated using NHS tariffs (January 2021).

Results

The prevalence of DDH that required treatment within our population was 5/1,000 live births. The rate of missed presentation of DDH was 0.43/1000 live births. Breech position, family history, oligohydramnios, and foot deformities demonstrated significant association with DDH ($p < 0.0001$). The presence of breech presentation increased the risk of DDH by 1.69% (95% confidence interval (CI) 0.93% to 2.45%), family history by 3.57% (95% CI 2.06% to 5.09%), foot deformities by 8.95% (95% CI 4.81% to 13.1%), and oligohydramnios nby 11.6% (95 % CI 3.0% to 19.0%). Primary risk factors family history and breech presentation demonstrated an estimated cost-per-case detection of £6,276 and £11,409, respectively. Oligohydramnios and foot deformities demonstrated a cost-per-case detected less than the cost of primary risk factors of £2,260 and £2,670, respectively.

Conclusion

The inclusion of secondary risk factors within a national screening programme was clinically successful as they were more cost and resource-efficient predictors of DDH than primary risk factors, suggesting they should be considered in the national guidance.

Introduction

Developmental dysplasia of the hip (DDH) is used to describe a spectrum of a morphological abnormalities of the hip in children that range ranging from mild acetabular dysplasia to complete dislocation.[1] DDH is the most common congenital hip condition that can result in significant morbidity if left untreated.[2,3] If detected early (< 12 weeks of life), DDH can be successfully managed

Type of Screening Program	Criteria for invitation to USS investigation:	Breakdown of risk factors included:	NIPE guidance
Current NIPE guidance (selective)	Abnormal exam and/or presence of a primary RF	Breech presentation at 36 weeks Family History Multiple birth (where any of the risk factors are present in one or more of the siblings)	Endorsed by NIPE and undertaken in NHS England.
Current practice within Wales (extended)	Abnormal exam, presence of primary and/or secondary RF	Oligohydramnios Foot deformities (CTCV, CTEV) Plagiocephaly Torticollis Syndromic	Not endorsed by NIPE only practiced in Wales.
Universal	All new-borns screened using USS	n/a	Not endorsed in the UK but utilised in mainland Europe.

Fig. 1

Table demonstrating the breakdown of different classification of screening programs for developmental dysplasia of the hip within the UK. CTCV, congenital talipes calcaneovalgus; CTEV, fixed congenital talipes equinovarus; NIPE, newborn and infant physical examination; RF, risk factors; USS, ultrasound.

Table I. Table demonstrating the positive predictive value, odds ratio with 95% CI, and whether there was a significant relationship between the risk factor and DDH that required treatment (n = 141), either in the form of conservative abduction harness therapy, surgical intervention, or both.

Risk factor	Adjusted odds ratio (95% CI)	p-value	Risk difference (95% CI)	Positive predictive value (95% CI)
Breech presentation	3.10 (2.03 to 4.63)	< 0.0001	1.69 (0.94 to 2.45)	2.13 (1.44 to 3.02)
Family history	4.99 (3.13 to 7.71)	< 0.0001	3.57 (2.06 to 5.09)	4.02 (2.65 to 5.84)
Oligohydramnios	6.74 (1.93 to 18.1)	< 0.0001	8.95 (4.81 to 13.10)	9.42 (5.68 to 14.48)
Foot deformity	10.0 (5.18 to 18.2)	< 0.0001	11.00 (3.00 to 19.00)	11.1 (9.50 to 14.59)

CI, confidence interval; DDH, developmental dysplasia of the hip.

conservatively.[2] However, late (12 to 24 weeks of life) and missed (> 24 weeks of life) presentation is more likely to require surgical intervention, and carries an increased risk of long-term complications, such as abnormal gait, joint deformity, and arthritis.[3]

The epidemiology of DDH and its risk factors is still being refined and controversy surrounds the subject of which screening methodology is most appropriate.[4-8] Current national guidance in the UK recommends a 'selective' ultrasound screening programme that uses primary risk factors (Figure 1) to guide invitation to ultrasound screening.[9] The primary risk factors of first-degree family history, breech presentation, or multiple gestation where one sibling is of breech birth have established association with a significantly increased risk of hip dysplasia.[10-13] Currently, UK government guidance advises that only those with these primary risk factors or an abnormal hip examination should be invited for ultrasound investigation.[14,15] However, additional risk factors are used variably throughout the UK, including and expanding upon those set out by the Newborn and Infant Physical Examination (NIPE) programme. For example, in Wales, an extended screening programme has been developed that also invites those with secondary risk factors, such as foot deformities, oligohydramnios, plagiocephaly, and torticollis to undergo ultrasound screening for DDH (Table I). There is much debate within the literature as to the efficacy and inclusion of these secondary risk factors within a national screening programme.[10,16,17] Therefore, through the design and implementation of a national extended screening programme for DDH, we have examined the epidemiology of DDH and its risk factors in our population to information related to the cost-effectiveness of individual risk factors.

Methods

Study design. A cohort study following live births recorded in our population in the catchment of a single tertiary centre (Noah's Ark Children's Hospital for Wales, UK) between 2016 and 2020 (n = 27,731) (Figure 2). For
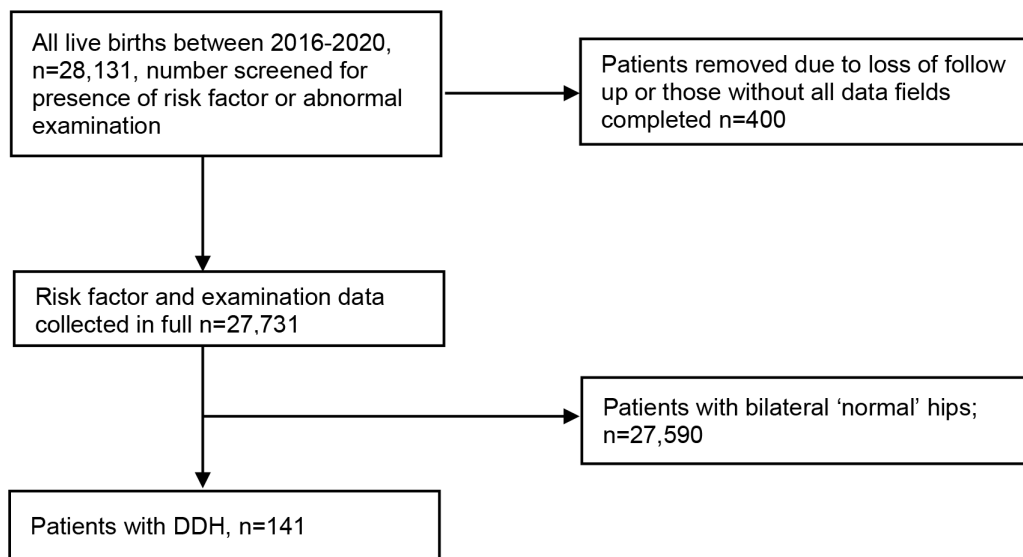
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┌─────────────────────────────┐          ┌─────────────────────────────┐
│ All live births between      │          │ Patients removed due to loss │
│ 2016-2020, n=28,131, number  │─────────▶│ of follow up or those without│
│ screened for presence of     │          │ all data fields completed    │
│ risk factor or abnormal      │          │ n=400                        │
│ examination                  │          └─────────────────────────────┘
└─────────────────────────────┘
              │
              ▼
┌─────────────────────────────┐
│ Risk factor and examination  │          ┌─────────────────────────────┐
│ data collected in full       │─────────▶│ Patients with bilateral      │
│ n=27,731                     │          │ 'normal' hips;               │
└─────────────────────────────┘          │ n=27,590                     │
              │                            └─────────────────────────────┘
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│ Patients with DDH, n=141     │
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Fig. 2

A flow chart demonstrating the inclusion/exclusion and relevant numbers of participants. 'Normal' hips were defined as: an initial scan demonstrating type I hips or IIa with no regression of disease and type I hips on first follow up ultrasound (n = 3,747), or no missed presentation of developmental dysplasia of the hip (DDH) after between 24 and 94 months of follow-up (n = 23,843). DDH hips were defined as dislocated hips (Graf type III/IV), instability (Graf type IId), or critical range dysplasia (which were those defined on ultrasound Graf type 2b and above and those with type 2a disease that progressed to true dysplasia (type ≥ 2b) or required treatment secondary to regression of alpha angle by ≥ 4° after four weeks of follow-up) (n= 141). Of the 141 cases of DDH, 129 were identified by ultrasound screening, and 12 were identified as missed cases after 24 to 96 months of follow-up.

all children, data was prospectively gathered relating to demographic variables, family history, intra-uterine position, gestational age at birth, birth weight, presence of foot deformities, oligohydramnios, and other gestational and medical history, through GP and paediatric services, the findings of which were documented via standardized neonatal hip ultrasound referral forms filled out for each infant. Data was collected without incentive and stored on a secure database.

Diagnosis of DDH. All newborns were screened using the traditional clinical assessment at the newborn and six to eight week examinations, at both these time points neonates were also screened for the presence of any risk factors relating to DDH and underwent risk factor assessment with their general practitioner or allied health professional. An abnormal examination was one in which there was evidence detected of positive Ortolani or Barlow test, clicky hips, asymmetrical hip creases, or asymmetrical leg length. Children with an abnormal examination or the presence of a primary or secondary risk factor (Figure 1) underwent ultrasonographic screening. Ultrasounds were graded using the Graf classification system.[18],[19] This study has provided an analysis of all hips with DDH (n = 141), defined as dislocated hips (Graf type III/IV), instability (Graf type IId), or critical range dysplasia (which were those defined on ultrasound Graf type 2b and above and those with type 2 a disease that progressed to true dysplasia (type ≥ 2b) or required treatment secondary to progression of alpha angle by ≥ 4° after four weeks of follow-up).[20]

Missed cases of DDH were defined as children presenting with clinical and radiological evidence of DDH, demonstrated on anteroposterior pelvic plain radiograph after age 24 weeks that required clinical intervention. Data relating to all missed case referrals and their management were collected prospectively by the senior author (EC), and checked by LM and AP as part of the department's quality improvement processes. This data was audited, and each case was reviewed annually both locally and nationally to ensure there were no missing data.

Risk factor evaluation. All newborns were screened for the presence of a primary or secondary risk factor at their initial newborn examination and the six- to eight-week infant check. Those with a primary risk factor breech (defined as a breech presentation at > 36 weeks of gestation) and family history, and/or secondary risk factors; oligohydramnios (defined as the deepest vertical pool of amniotic fluid index under the fifth percentile for amniotic fluid volume') and foot deformities (defined as the presence of congenital calcaneovalgus (CTCV), congenital equinovarus (CTEV)). Multivariate odds ratios (ORs) were calculated to establish significant association, and risk differences were calculated to provide quantifiable risk increase with DDH, positive predictive value was used as a measure of predictive efficacy. The side of abnormality on examination was collected prospectively in the database and compared with the diagnosis of DDH, an abnormal examination was only considered diagnostic if the side matched the side of DDH.

Table II. A table demonstrating prevalence, estimated cost of inclusion in initial screening per 1,000 live births in a population, and the estimated cost of inclusion of each risk factor per DDH case detected. Figures are shown to the nearest single pound (January 2021).

Risk factor	Prevalence, %	Estimated cost of inclusion in initial screening per 1,000 population, £	Estimated cost of inclusion per case of DDH detected, £
Breech Presentation	5.44	13,654	11,409
Family history	2.48	6,224	6,276
Oligohydramnios	0.25	602	2,260
Foot deformities	0.69	1,831	2,670

Cost analysis. Costings were calculated from NHS tariffs and are based just on the average initial screening costs for each patient in secondary care, i.e. the initial clinic appointment and ultrasound scan (January 2021).[21] Each patient was prospectively recorded at each secondary care appointment until a diagnosis of DDH or bilateral normal Graf type I hips was made. Until a diagnosis was made the total number of appointments and ultrasound scans/plain radiographs/other investigations, were calculated for every child with each risk factor and divided by the number of cases of DDH detected secondary to an invitation to ultrasound screening due to that specific risk factor. Cost of treatment, follow-up, outpatient appointments, and imaging once a diagnosis of DDH had been made were not included as these are not part of the screening programme. Furthermore, the cost of treatment of DDH was not evaluated within this study, which was designed to evaluate the cost-effectiveness of individual risk factors in detecting DDH for the service.

Exclusion criteria. Patients who were lost to follow-up secondary to death or migration out of the area and/or whose data set was incomplete due to uncompleted prospective documentation of risk factors, or examination findings within the registry were excluded from the study (n = 400) (Figure 2).

Data were analyzed for correctness and missingness. The presence of missing data was assumed to be non-differential. Therefore, a decision was made to remove any participants with missing data from the final analysis. Treatment versus non-treatment was treated as the outcome variable. Unadjusted ORs were calculated using logistic regression for individual risk factors. For significant risk factors, adjusted ORs were calculated using multivariate logistic regression, adjusting for the presence of any other risk factor (including abnormal examination) or multiple other risk factors, and sex. 95% confidence intervals (CIs) are also given.

Statistical analysis. Statistical analysis was performed using R (R Foundation for Statistical Computing, Austria).[22] The 'glm' function was used for multivariate logistic regression. Null and residual deviance were compared, as well as Akaike Information Criterion, to assess quality of model. Cook's distance was used to identify any significant outliers.

Ethical approval was not required as this study fell under the scope of routine clinical governance work in keeping with the aim of service evaluation and quality improvement.

Results

Overview. The incidence of DDH without our population was 5/1,000 live births (141/27,731 live births). The presence of any risk factor in a child with a normal examination diagnosed 57.4% (81/141) of DDH, and the presence of a secondary without a primary risk factor and a normal examination diagnosed 13.5% (19/141). Over the duration of the extended screening programme, the rate of missed cases of DDH was 0.43/1000 live births (12/27,731).

Statistical association and risk. The relationship between the primary risk factors of breech and family history, and the secondary risk factors of oligohydramnios and foot deformity, demonstrated a significant association with DDH by OR (Table I; $p < 0.0001$). Summary data used to build 2×2 tables can be found in Supplementary table i. The risk difference (RD) was calculated for individual risk factors. The primary risk factors of breech and family history increased the risk of DDH development by 1.69% (95% CI 0.93% to 2.45%) and 3.57% (95%CI 2.06% to 5.09%), respectively (Table I). The increased risk of requiring treatment from foot deformities was 8.95% (95% CI 4.81% to %13.1), and oligohydramnios 11.6% (95% CI 3.0% to 19.0%). This relationship with DDH was also reflected in the predictive value of risk factors with secondary risk factors demonstrating an increased positive predictive value (PPV) (oligohydramnios PPV 9.42, and foot deformity PPV 11.1%) compared to the primary risk factors (breech presentation PPV 2.12, and family history PPV 4.02%).

Cost of intervention. Considering risk factors individually, primary risk factors of breech and family history had a significantly higher prevalence and, therefore, total cost to service (ranging from £6,224 to £13,654/1,000 births) than the secondary risk factors (ranging from £602 to £1,831/1,000 births) (Table II). The total cost of inclusion of each secondary risk factor within the screening programme was a fraction of the cost of a primary risk factor, indicating a comparatively minimal impact on resources.

Value of intervention. The cost of detecting a case of DDH using an extended screening programme was £5,508; however, modelling for a selective screening programme (as per NIPE guidance), only including ultrasound screening for primary risk factors and an abnormal examination, would have cost £7,619 per case of DDH detected and led to an extra 19 cases presenting late. There is a clear and substantial reduction in the cost of detection of DDH between the primary and secondary risk factors. Family history was the most cost-effective primary risk factor with a cost-per-case detected of £6,276 while breech presentation demonstrated a cost-per-case detected of £11,409. The secondary risk factors foot deformities and oligohydramnios a cost-per-case detection of £2,670 and £2,260, respectively.

Discussion

Within our population, the incidence of DDH that required treatment was 5/1,000 live births, falling within the reported UK prevalence of between five and 30/1,000 births.[9,23] Furthermore, we have demonstrated a comparatively low rate of 0.43/1,000 missed presentations as a result of our extended screening programme, around a third of the 1.28/1,000 live births demonstrated by the seminal paper from Broadhurst et al.[24] Therefore, it is likely that screening for secondary risk factors reduces the rate of missed DDH across a population, reinforced by the fact that 13.5% of the cases of DDH (19/141) were detected through the presence of a secondary risk factor in the absence of a primary risk factor or an abnormal examination and would therefore have been missed by a selective screening programme.

Early detection of DDH with subsequent reduction in the rates of missed presentation provides significant public health benefit by reducing the childhood morbidity associated with radiological investigations and operative interventions.[25] Given these benefits, we must be confident in our understanding of which risk factors can establish a cost-beneficial prediction of DDH to improve the efficacy of a programme.[25–30] The primary risk factors of breech presentation and family history were demonstrated to have value in the prediction of DDH, as patients with these risk factors demonstrated significantly higher rates compared to the general population, this was expected given their well-established association within the literature.[24–31] However, our results study has contributed further understanding of the association between secondary risk factors and their association with DDH as the current evidence is of mixed quality,[10,27,32–34] demonstrating a significant association and risk increase of foot deformities which replicates similar robust studies into this area.[16,27,32,35,36] Oligohydramnios has demonstrated variable association with DDH;[4,33,34,37,38] this variation may be due to the lack of consensus on the definition of oligohydramnios, and the failure within the literature

to quantify the volume of amniotic fluid thresholds for the classification of oligohydramnios.[25,39,40] When considering oligohydramnios in the context of DDH screening, the results of this study suggest that oligohydramnios when defined as 'the deepest vertical pool of amniotic fluid index under the fifth percentile for amniotic fluid volume' is a significant predictor of DDH.

The focus of this investigation was to provide cost-value information, that can be considered when evaluating the inclusion of risk factors within a screening programme. The cost-per-case detected of the primary risk factors was £6,276 to £11,407 comparatively more than secondary risk factors, which ranged from £2,260 to £2,670. Therefore, given that a screening programme must not only beneficial to a population but also cost-effective.[41,42] Based on the results of this study, there is a very clear economic case for the inclusion of the secondary risk factors alongside their primary counterparts. Also given their minimal comparative prevalence to primary risk factors, secondary risk factors oligohydramnios and foot deformities, do not demonstrate a large burden on or resources for their inclusion within a screening programme. To our knowledge, this is the first study to provide valuable cost information surrounding these primary and secondary risk factors and, therefore, this data may be useful for future decision making and screening provision.

Secondary risk factors demonstrate a variable association with DDH in the literature, which is represented in the British Society for Children's Orthopaedic Surgery DDH consensus statement.[17] There are several reasons for this, including variable definitions of risk factors, widely variable definitions of DDH, limitations of service provision, variation in statistical evaluation methodology, and wide variations in population across the world which demonstrate significant inconsistency in rates and severity of DDH. For example, DDH incidence is reported to range from 0.06/1000 to 76.1/1000.[43] We have attempted to be transparent about our definitions of DDH and its risk factors while providing robust statistical evaluation. Furthermore, this study is an evaluation of the practical application of a service, which is an imperfect model, with limitations that include loss of follow-up, end-user error, and non-expert initial clinical examination. In the case of screening programme evaluation, seeing the variation between true original research and its application in practice can provide useful insight into the real-world cost modelling of DDH. Given this reasoning, we believe that this study provides a novel and useful insight into the application of additional risk factors into a national screening programme.

In conclusion, this study adds to and consolidates our understanding of risk factors in the context of a national DDH screening programme, by establishing significant associations, easily comprehensible evaluation of risk,

and relative cost-effectiveness of primary and secondary risk factors for DDH.

Take home message

- Secondary risk factors (foot deformities, oligohydramnios) are more cost-effective predictors of developmental dysplasia of the hip (DDH) than the primary risk factors breech and family history.
- Inclusion of secondary risk factors within our screening programme generated a low rate of missed DDH presentation in our population.
- Therefore, secondary risk factors can act as cost-effective and resource-efficient predictors of DDH and should be considered for inclusion within the national screening guidance.

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Supplementary material

Summary data of 28,131 patients identified in the study, and unadjusted odds ratios for key risk factors of developmental dysplasia of the hip.

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Author information:
- A. T. Poacher, MBBCh, BSc, Academic Foundation Doctor, Trauma Department, University Hospital of Wales, Cardiff, UK.
- J. L. J. Froud, MBBCh, BSc, Academic Foundation Doctor, Guy's and St Thomas' NHS Foundation Trust, London, UK.
- J. Caterson, MBBS, BSc, Foundation Doctor, London North West NHS Trust, London, UK.
- D. L. Crook, MBBCh, Junior Clinical Fellow, Department of Surgery, Royal London Hospital, London,, UK.
- G. Ramage, Medical Student
- L. Marsh, MBBCh, BSc, Medical Student
  Cardiff University School of Medicine, Cardiff, UK.
- G. Poacher, Technology Officer, Ability Medical Education, Cardiff, UK.
- E. C. Carpenter, BSc (Anatomy), MBBCh, MRCS (Eng), FRCS(T&O), Consultant Paediatric Orthopaedic Surgeon, Noah's Ark Children's Hospital for Wales, Cardiff, UK.

Author contributions:
- A. T. Poacher: Conceptualization, Investigation, Formal analysis, Visualization, Writing – original draft, Writing – review & editing.
- J. L. F. Froud: Investigation, Writing – review & editing.
- J. Caterson: Investigation, Writing – review & editing.
- D. L. Crook: Investigation, Formal analysis, Writing – review & editing.
- G. Ramage: Investigation, Validation, Writing – review & editing.
- L. Marsh: Investigation, Validation, Writing – review & editing.
- G. Poacher: Methodology, Data curation, Writing – review & editing.
- E. C. Carpenter: Conceptualization, Writing – original draft, Writing – review & editing.