Screening Strategies for Hip Dysplasia: Long-term Outcome of a Randomized Controlled Trial

WHAT'S KNOWN ON THIS SUBJECT: Only 2 randomized controlled trials have addressed effects of ultrasound screening for developmental hip dysplasia. Both concluded that adding universal or selective ultrasound to routine clinical examination gave a nonsignificant reduction in rates of late presenting cases, but higher treatment rates.

WHAT THIS STUDY ADDS: This maturity review assesses long-term outcome of one of these trials. Rates of radiographic findings indicating acetabular dysplasia and degenerative change were similar across the 3 screening groups in young adulthood. Increased treatment rates were not associated with avascular necrosis.

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abstract

OBJECTIVE: Screening for hip dysplasia is controversial. A previous randomized controlled trial revealed that adding universal or selective ultrasound to routine clinical examination gave a nonsignificant reduction in rates of late presenting cases, but with higher treatment rates. This study assesses differences in outcome at skeletal maturity for the 3 newborn screening strategies in terms of radiographic markers of acetabular dysplasia and early degenerative change and avascular necrosis (AVN) secondary to neonatal treatment.

METHODS: From the initial trial including 11 925 newborns, a population-based sample of 3935 adolescents was invited for follow-up at age 18 to 20 years. A standardized weight-bearing anteroposterior view was obtained. The outcomes evaluated were the radiographic findings of dysplasia (center-edge angle, femoral head extrusion-index, acetabular depth-width ratio, Sharp's angle, subjective evaluation of dysplasia) and degenerative change (joint-space width). Signs of AVN were documented.

RESULTS: Of the 3935 subjects invited, 2038 (51.8%) attended the maturity review, of which 2011 (58.2% female patients) were included: 551, 665, and 795 subjects from the universal, selective, and clinical groups, respectively. Rates per group of positive radiographic findings associated with dysplasia or degenerative change varied depending on radiographic marker used. No statistically significant differences were detected between groups. No AVN was seen.

CONCLUSIONS: Although both selective and universal ultrasound screenings gave a nonsignificant reduction in rates of late cases when compared with expert clinical programs, we were unable to demonstrate any additional reduction in the rates of radiographic findings associated with acetabular dysplasia or degenerative change at maturity. Increased treatment rates were not associated with AVN. *Pediatrics* 2013;132:492–501

Developmental dysplasia of the hip (DDH) represents an important health issue and is the underlying cause of 1 in 4 total hip replacements in patients under the age of 40.[1] The reported prevalence varies from 0.15% to 4% according to definition used, age, ethnicity, and method of ascertainment.[2–5] Clinical neonatal screening with early treatment of those testing positive was introduced ∼6 decades ago. It has, however, not been as efficient in reducing the rates of late presenting cases and their need for surgery as first expected,[6–8] due perhaps to poorly organized screening programs, inexperienced examiners, and/or insufficient follow-up.[9,10] This led to the widespread use of hip ultrasound throughout Europe, with implementation of universal or selective ultrasound screening before 6 weeks of age, associated with treatment rates as high as 7.7% after universal ultrasound.[11–15] The rate of late presenting DDH is commonly used as outcome measure in the evaluation of a screening program. However, the age definition of a "late case" ranges from 4 weeks of age to 6 months of age and more, making the interpretation of the literature difficult. Screening policies have been influenced by a number of studies, including 2 randomized controlled trials (RCTs), which both advocate a selective ultrasound approach, in addition to high-quality clinical screening.[16,17] One of the RCTs, performed at our institution,[16] evaluated the effect of 3 different ultrasound screening strategies for DDH in newborns. It demonstrated a nonsignificant reduction in the rates of late presenting (ie, after 4 weeks of age) subluxated or dislocated DDH in the universally and selectively screened groups as compared with the group receiving clinical examination alone (P = .11), but also higher treatment rates for the universal group (P < .001) (Table 1).

Results from a maturity review of a population-based sample drawn from the initial RCT have previously shown

TABLE 1 Rates of Abduction Treatment, Ultrasound Follow-up and Late Detected Cases by Screening Group During the Initial RCT in 1988–1990 Comprising 11 925 Newborns

Variable	Universal Ultrasound Screening (n = 3613)	Selective Ultrasound Screening (n = 4388)	No Ultrasound Screening (n = 3924)	Prestudy Period 1983–1987
Treatment rate (%)	123 (3.4)	89 (2.0)	71 (1.8)	2.0
Ultrasound follow-up rate (%)	470 (13.0)	78 (1.8)	—	14–20[a]
Rate of late cases[b] (per 1000)	1 (0.3)	3 (0.7)	5 (1.3)	2.6

[a] Pelvic radiograph at 4.5 months.
[b] Subluxated or dislocated hips.

that the prevalence of radiographic findings associated with hip dysplasia in young adulthood (based on at least 1 affected hip) ranged from 1.7% to 20% depending on the radiographic measurement and on their corresponding cutoff values used.[18] This wide range highlights the challenge of defining acetabular dysplasia. Based on the original RCT, we hypothesized that at skeletal maturity there would be no difference between the 3 trial groups in the rates of radiographic findings associated with acetabular dysplasia or early degenerative change. Avascular necrosis (AVN) of the femoral head described as a medial flattening of the femoral head was documented for the 3 groups as a potential adverse effect of neonatal treatment.

METHODS:

Study Population and Design

The current study is a maturity review of a population-based sample drawn from the initial RCT.[16] The original RCT study included 11 925 infants born during January 1988 to June 1990 at the maternity hospital in Bergen, Norway. The infants studied were assigned to universal ultrasound screening (n = 3613), selective ultrasound screening (n = 4388), or clinical screening alone (n = 3924). The "1989 Bergen Birth Cohort Hip Study" was defined as all newborns from 1989 included in the initial RCT except those whose mother lived outside the hospital catchment area (n = 296) (Fig 1). Of these, 3935 were invited by postal letter

to participate in this review (Fig 1), performed at the pediatric radiology department between March 2007 and March 2009.

Original RCT Performed During 1988–1990

This RCT[16] was published in 1994 and is described in detail in the Appendix. All newborns were assessed for known risk factors for DDH (breech presentation and/or family history of DDH). All infants had a clinical assessment, including hip stability (Barlow/Ortolani tests).[19,20] In addition, high-risk infants (ie, at least 1 risk factor, and/or clinical hip instability) from the selectively screened group and all infants from the universally screened group were offered a single examiner hip ultrasound (Rosendahl's method) at birth (Fig 2).[21] Rates of abduction treatment, ultrasound follow-up, and late detected (ie, after 4 weeks) cases by screening group are shown in Table 1. There were 6 late detected subluxated hips and 3 late detected dislocated hips among the original 11 925 participants. All 9 received traction followed by cast and/or orthotic treatment: the 3 dislocated hips also had a closed (2) or open (1) reduction. None of the 3 dislocated cases had had an ultrasound performed: 2 came from the clinical screening group, and 1 was classified low-risk from the selectively screened group. Of the 6 cases with subluxation, 5 were low-risk cases from the clinical (3) and the selectively screened (2) groups, and thus did not have a newborn hip ultrasound. The final case was low-risk
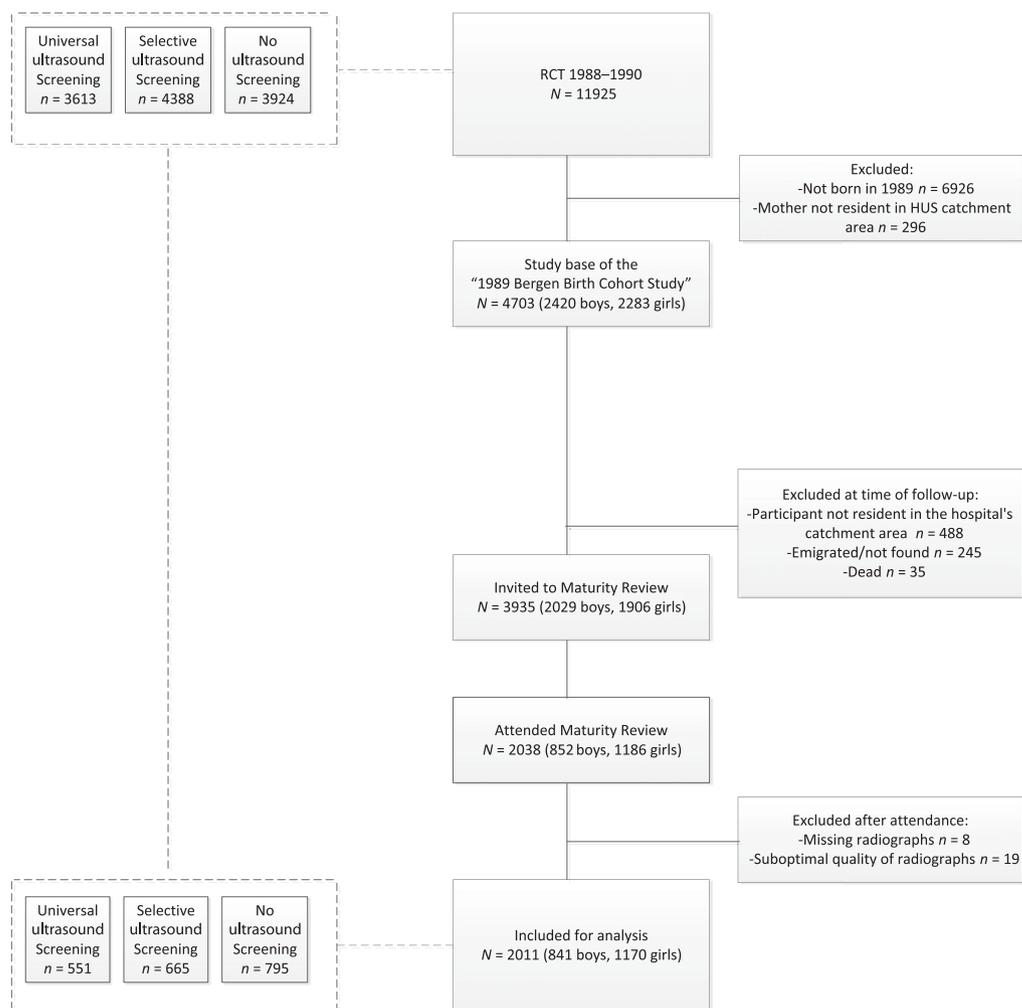
FIGURE 1
Flowchart of participants included in the original RCT (1988–1990) and who later attended the maturity review (2007–2009).
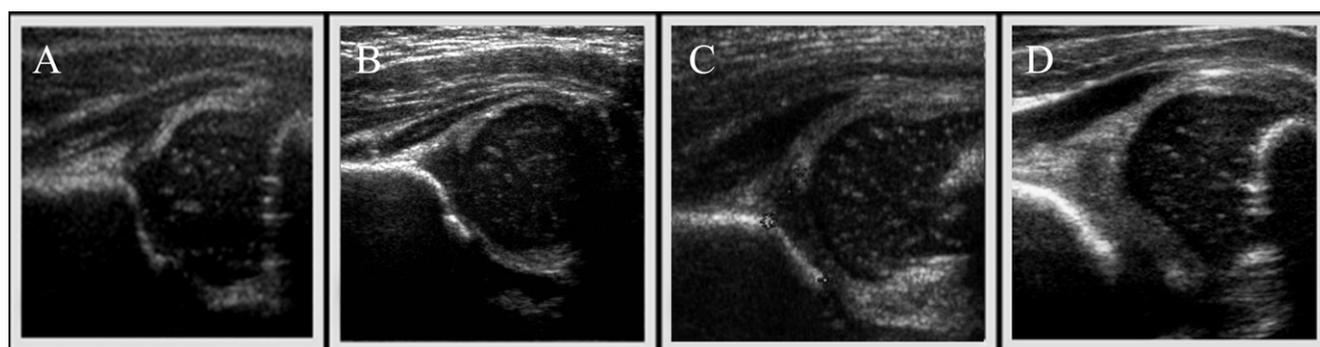
FIGURE 2
Graf's coronal standard section through the midacetabulum revealing normal (A), immature (B), mild (C), and severe dysplasia (D) in a newborn hip.

but in the universally screened group, with a reportedly normal ultrasound at birth. There were no signs of AVN at the conclusion of the original RCT at a minimum 27 months of age.

Data Collection at Maturity Review

The follow-up study aimed to assess radiographic and clinical features related to acetabular dysplasia and early degenerative change at skeletal maturity. The participants were asked about weekly hours of physical activity and self-reported hip discomfort in either hip during the preceding 3 months. The clinical assessment included height,

weight, and hip range of motion in all planes. All examiners were unaware of the original screening group. Exclusion criteria were radiographs of suboptimal technical quality, including excessive pelvic rotation as assessed by a foramen obturator index beyond the range 0.6 to 1.8,[22] or missing radiographs (uncertain pregnancy status or examination refused). Searches within the database of our hospital and of the only other orthopedic hospital in the area detected no additional cases of late presenting DDH or of surgery among the nonresponders. At follow-up, baseline characteristics from the original RCT including gender, birth weight, positive clinical findings (Barlow/Ortolani), positive family history, and breech presentation were compared between the 3 sample groups.

The weight-bearing, anteroposterior view (Fig 3) was obtained according to a standardized protocol, by 1 specifically trained radiographer. All radiographs were obtained with a low-dose digital radiography technique (Digital Diagnost System, version 1.5, Philips Medical Systems, Best, Netherlands). The film/focus distance was 1.2 m and centered at 2 cm proximal to the symphysis. A tube containing a contrast medium was placed in the radiograph field to give the true horizontal level for leg length measurement. The radiographer ensured that hips were kept in a neutral abduction-adduction position with toes pointing forward.[5,23] All male patients were offered gonadal shields. The radiographs were measured in the digital measurement program "Adult DDH" (University of Iowa Hospitals and Clinics, Iowa City, IA),[24] by 3 of the authors (Drs Laborie, Engesæter, and Lehmann), unaware of original screening group. Detailed descriptions of the digital measurement program, of its accuracy and of the measurements included have been reported previously.[25,26] The following measurements were performed digitally. Markers for acetabular dysplasia (Fig 4 A–D): The center-edge (CE) angle of Wiberg,[27] the femoral head extrusion index (FHEI),[28] the acetabular depth-width ratio (ADR),[29] and Sharp's angle.[30] Minimum joint space width (JSW) as a marker for early degenerative change was measured digitally at 3 locations: laterally, centrally, and medially (Fig 5).[31,32] There is no clear consensus on the definition of acetabular dysplasia at skeletal maturity.[18] To perform a group comparison of acetabular dysplasia as a long-term outcome, we chose to assess the most common radiographic measurements and findings associated with acetabular dysplasia. For the CE angle, we also calculated the rates of the often used borderline group, for detection of differences at a level in between normal and dysplastic hips. As the definition of acetabular dysplasia is unclear, we also created an individual variable corresponding to ≥1 positive dysplasia finding based on categorization of the angle measurements. We then compared the results at a group level. All angle measurements were performed digitally. Subjectively assessed findings and leg length discrepancy were not part of the digital program and thus assessed manually in the IMPAX (Agfa IMPAX Web1000, version 5.0, Agfa Gaevert, Mortsel, Belgium). The shape of the lateral acetabular roof, namely the subchondral bony condensation known as the "sourcil" was evaluated subjectively as normal, immature, or mildly

FIGURE 3
A weight-bearing anteroposterior radiograph of a study participant at skeletal maturity, revealing bilateral moderate dysplasia.
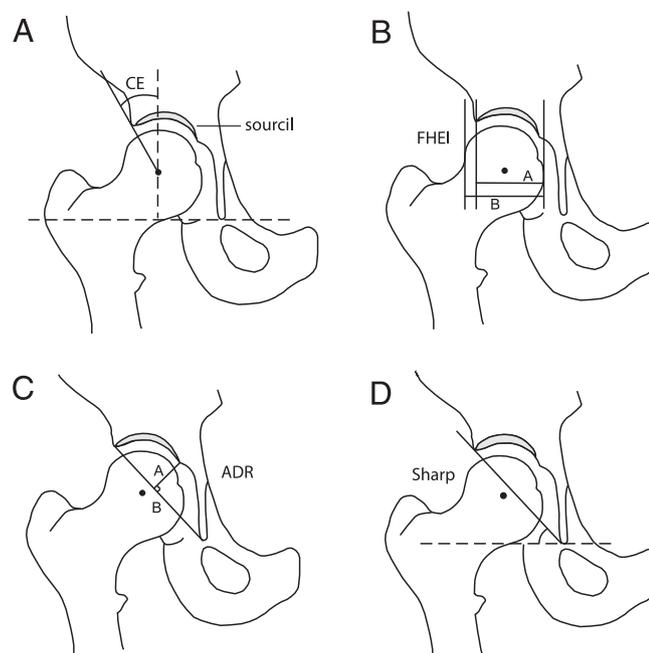
FIGURE 4
Measurements describing the position of the femoral head relative to the acetabular cavity: CE angle of Wiberg (A) and FHEI (B). Measurements describing the acetabular anatomy: ADR ([A/B]*1000) (C) and Sharp's angle (D).
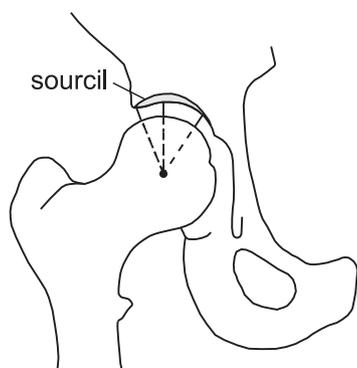
FIGURE 5
JSW at the medial, central, and lateral position in the hip joint.

or moderately dysplastic.[33] This subjective assessment of dysplasia was performed by a musculoskeletal radiologist with more than 25 years of experience (Dr Rosendahl), and was included as an alternative and complementary assessment of acetabular dysplasia. Subjective evaluation of medial flattening of the femoral head indicative of AVN as a possible complication of treatment was also performed by the senior author (Dr Rosendahl).[34] Leg length discrepancy was measured manually by one author (Dr Laborie), by drawing a true horizontal line through the tube at the 2 top levels of liquid contrast (Fig 3), and thereafter measuring perpendicularly down to the top of the caput on each side. A difference of >5 mm was considered a positive finding.

Ethics

The research protocol, including analyses of the nonresponders, was approved by the Regional Ethical Committee for Medical and Health Research (number 018.06). All participants of the follow-up study gave written informed consent according to the 1964 Declaration of Helsinki.

Statistical Analysis

Data for the radiologic outcome measures were summarized by using mean and SD, or number and percentage, as appropriate. The radiographic measurements were compared as continuous variables, and also categorized as normal or dysplastic, based on previously published gender-specific cutoff values (CE angle <21°/<20°, Sharp's angle >46°/>47°, FHEI <74%/<73%, and ADR <235‰/<233‰ for male and female patients, respectively).[26] In addition, an intermediate borderline group (<25°) for the CE angle as a categorical variable was calculated.[18] A categorical variable corresponding to at least 1 positive radiographic marker was created, consisting of the CE angle (dysplastic values only), FHEI, ADR, and Sharp's angle. Subjective evaluation of the sourcil was a categorical variable. JSW was assessed both as a continuous variable and also categorized as normal or pathologic, defined as minimum JSW ≤ 2 mm in at least 1 position.[5,35]

A general regression model was performed, adjusted by side, gender, family history, and breech and taking into account clustering of hips within a subject to compare the 3 screening groups. Univariate (crude) and multivariate (adjusted) P values are presented. No correction for multiple comparisons was performed. All P values were 2-tailed. To adjust for nonresponders when comparing the 3 screening groups we calculated inverse probability weights[36] based on a logistic regression model including gender, ultrasound performed at birth (yes/no), and DDH treatment received (yes/no) as covariates. Statistical analyses were performed in IBM SPSS Statistics, version 20.0 (Armonk, NY) and in Stata Statistical Software (Release 11, Stata Corp, College Station, TX).

RESULTS

Of the 3935 subjects invited, 2038 (51.8%) attended the follow-up, of which 2011 (1170 [58.2%] female participants) were included for further analyses, predominantly ethnic Norwegians.

This population-based sample of 2011 participants represented equal proportions of the 3 original RCT screening groups: 551/3613 (15.3%), 665/4388 (15.2%), and 795/3924 (20.3%) subjects originated from the initial universal ultrasound, selective ultrasound, and clinical only screening groups, respectively (Fig 1). Mean age was 18.6 years (SD 0.6, range 17.2–20.1 years) for both genders. The 3 groups were similar at time of follow-up with respect to gender distribution ($P = .56$), BMI (kg/m^2) ($P = .83$), weekly hours of physical activity ($P = .80$), leg length discrepancy ($P = .85$), and hip range of motion in all planes (all P values > 0.20). Hip discomfort during the preceding 3 months were similarly distributed between groups for right and left side ($P = .81$ and $P = .75$, respectively). The 3 groups also demonstrated similar baseline characteristics from the RCT with respect to birth weight, positive clinical findings (Barlow/Ortolani), and positive family history ($P = .37$, $P = .44$, $P = .57$, respectively). Similar to the initial universal group, breech presentation was slightly higher in the corresponding follow-up group as compared with the 2 other groups (6.4% vs 3.6% and 3.7% at follow-up, $P = .03$). Among the 2011 subjects who attended the follow-up, 39/551 (7.1%), 33/665 (4.9%), and 30/795 (3.8%) had received abduction treatment in the universal, selective, and no ultrasound screening groups, respectively.

Radiologic Outcome Measures

The rates per screening group of radiographic findings associated with left- or right-sided acetabular dysplasia varied depending on the measurement used: The CE angle, FHEI, ADR, Sharp's angle, and subjective evaluation of the sourcil shape. Dysplastic rates based on the 4 angle measurements ranged from 1.1% (FHEI in the universal group) to 3.4% (CE angle in the no ultrasound group). The total rate when including those with at least 1 positive dysplastic findings

based on the 4 categorical angle measurements ranged from 5.7% to 7.6% for the left side, and from 5.4% to 7.6% for the right side. Rates based on a borderline CE angle <25° ranged from 9.3% to 13.3% on left and right side separately. No statistically significant differences in acetabular dysplasia, as assessed by the CE angle, FHEI, ADR, Sharp's angle, or subjective evaluation of the sourcil shape could be found between the 3 groups at skeletal maturity (Tables 2 and 3).

On subjective evaluation of the sourcil shape, 6 hips (4 girls) were classified as moderate dysplasia (Fig 3). Two left (0.25%) and 3 right (0.38%) hips (1 unilateral and 2 bilateral cases) came from the no ultrasound group and 1 left (0.15%) hip from the low-risk arm (ie, no ultrasound) of the selective group (Table 3). The 1 unilateral case from the clinically screened group had a late detected left dislocated hip and received a closed reduction in infancy. One of the persons from the no ultrasound group, with bilateral moderate dysplasia as assessed both subjectively and by the angle measurements, was referred to an orthopedic surgeon.

The rates of a positive minimum JSW as an indicator for early degenerative change ranged from 3.1% to 4.7% and from 1.9% to 3.0% for left and right side, respectively, without any detectable differences between groups (Table 4). None of the study participants had a flattening of the medial aspect of the femoral head interpreted as a sign of AVN.

DISCUSSION

The wide variety of management strategies used for DDH reflects our poor understanding of its natural course and the short- and long-term effects of different treatment and follow-up programs. To date, only 2 RCTs addressing these issues have been performed; both concluded that universal and selective ultrasound screening tended to reduce the rates of late cases during infancy and

TABLE 2 Radiographic Findings (Mean [SD]) at Time of Follow-up of the 2011 Participants, According to Newborn Screening Group During the RCT

Variable	Screening Strategy			P	
	Universal Ultrasound (n = 551), Mean (SD)	Selective Ultrasound (n = 665), Mean (SD)	No Ultrasound (n = 795), Mean (SD)	Crude	Adjusted[a]
CE angle of Wiberg (°)					
Left	31.8 (5.9)	31.8 (5.9)	32.3 (6.0)	.12	—
Right	31.3 (6.0)	31.2 (6.1)	31.7 (6.2)	.25	.28
FHEI (%)					
Left	86.7 (6.3)	86.6 (6.5)	87.1 (6.4)	.24	—
Right	85.4 (6.3)	85.6 (6.6)	86.0 (6.5)	.21	.40
ADR (‰)					
Left	300.0 (35.4)	296.8 (34.7)	299.9 (34.6)	.17	—
Right	297.2 (34.4)	295.3 (35.5)	296.6 (36.1)	.63	.25
Sharp's angle (°)					
Left	40.1 (3.5)	39.8 (3.7)	39.9 (3.8)	.25	—
Right	39.9 (3.6)	40.0 (3.7)	39.8 (3.6)	.73	.56

[a] Estimated by using a general regression model, adjusted by side, gender, family history and breech, and taking into account clustering of hips within a subject.

early childhood but at the cost of higher treatment rates. Ultrasound is able to identify newborns with dysplastic hips in need of early treatment, thus reducing the number of late subluxed or dislocated cases in early childhood. Its ability to prevent acetabular dysplasia at skeletal maturity, however, has not been demonstrated. Several authors have emphasized the need for outcome studies at skeletal maturity for the different screening policies.[37–39]

Our study confirms that in a Norwegian population, all 3 screening programs studied resulted in similar rates of all radiographic findings associated with acetabular dysplasia or early degenerative change at skeletal maturity. Offering universal hip ultrasound, and treating those testing positive, had thus no additional impact at a group level at skeletal maturity. A universal strategy with higher treatment rates did not seem to cause higher rates of AVN even though abduction treatment may place hips at risk. We have previously shown that based on existing cutoff values the prevalence of acetabular dysplasia (ie, at least 1 hip) ranges from 1.7% to 20% in this cohort,[18] with the lowest value based on the subjective assessment of the sourcil shape, and the highest value based on the borderline CE angle. The

prevalence based on the dysplastic CE angle was 3.3%. These previous findings confirm the challenge in diagnosing acetabular dysplasia. Assessment of acetabular dysplasia at skeletal maturity is important as it is associated with early onset hip osteoarthritis.[5,40] Several radiographic measurements are used to describe and define the condition, with presumably varying clinical validity as to which extent they are indicators for early degenerative change. Significant relationships between radiographic osteoarthritis discriminators including minimum JSW, and dysplasia discriminators including the CE angle, FHEI, and ADR were shown in a Danish study.[5] We chose to assess the most common quantitative measurements (ie, CE angle, FHEI, ADR, and Sharp's angle), and also a subjective evaluation of dysplasia.[18]

The strengths of our study include a large original RCT (11 925 infants) as the basis for this follow-up study, with standard protocols that remained unchanged throughout the whole RCT period. This maturity review also followed a highly standardized radiographic protocol. One specifically trained radiographer performed all the radiographs and ensured correct posture to avoid pelvic tilting and rotation.[41] Moreover, each of the 3

TABLE 3 Radiographic Findings (N [%]) at Time of Follow-up of the 2011 Participants, According to Newborn Screening Group During the RCT

Variable	Screening Strategy			P	
	Universal Ultrasound (n = 551), n (%)	Selective Ultrasound (n = 665), n (%)	No Ultrasound (n = 795), n (%)	Crude	Adjusted[a]
CE angle of Wiberg					
Left borderline	57 (10.3)	73 (11.0)	74 (9.3)	—	—
Dysplasia	10 (1.8)	15 (2.3)	16 (2.0)	.83	—
Right borderline	73 (13.3)	77 (11.6)	84 (10.6)	—	.54
Dysplasia	10 (1.8)	20 (3.0)	27 (3.4)	.28	.20
FHEI					
Left	6 (1.1)	14 (2.1)	12 (1.5)	.36	—
Right	10 (1.8)	20 (3.0)	18 (2.3)	.38	.71
ADR					
Left	13 (2.4)	22 (3.3)	12 (1.5)	.08	—
Right	10 (1.8)	18 (2.7)	24 (3.0)	.38	.44
Sharp's angle					
Left	16 (2.9)	20 (3.0)	25 (3.1)	.97	—
Right	12 (2.2)	19 (2.3)	18 (2.3)	.69	.70
Dysplasia score[b]					
Left ≥1 positive findings	36 (6.6)	50 (7.6)	45 (5.7)	.36	—
Right ≥1 positive findings	30 (5.4)	50 (7.6)	55 (6.9)	.34	.36
Subjectively assessed dysplasia					
Left normal	491 (89.1)	597 (89.8)	716 (90.1)	—	—
Immature	55 (10.0)	55 (8.3)	70 (8.8)	—	—
Mild	5 (0.9)	12 (1.8)	7 (0.9)	—	—
Moderate	—	1 (0.15)	2 (0.25)	.52	—
Right normal	491 (89.1)	594 (89.3)	721 (90.7)	—	—
Immature	56 (10.2)	61 (9.2)	64 (8.1)	—	.15
Mild	4 (0.7)	10 (1.5)	7 (0.9)	—	.26[c]
Moderate	—	—	3 (0.38)	.30	—

[a] Estimated by using a general regression model, adjusted by side, gender, family history and breech, and taking into account clustering of hips within a subject.
[b] Dysplasia score based on positive CE (dysplastic), FHEI, ADR, and Sharp values.
[c] Combined P value for mild and moderate score, due to few cases of moderate dysplasia.

TABLE 4 Minimum Joint Space Width (Mean [SD] and N [%]) Indicating Early Degenerative Change at Time of Follow-up of the 2011 Participants, According to Newborn Screening Group During the RCT

Variable	Screening Strategy			P	
	Universal Ultrasound, n = 551	Selective Ultrasound, n = 665	No Ultrasound, n = 795	Crude	Adjusted[a]
JSW, mean (SD), mm					
Lateral left	5.3 (1.1)	5.3 (1.1)	5.3 (1.1)	.87	—
Right	5.4 (1.1)	5.4 (1.2)	5.5 (1.1)	.29	.31
Central left	3.6 (0.9)	3.6 (0.9)	3.5 (0.8)	.53	—
Right	3.7 (0.8)	3.7 (0.8)	3.7 (0.8)	.57	.88
Medial left	4.4 (1.3)	4.5 (1.4)	4.5 (1.4)	.44	—
Right	4.4 (1.2)	4.5 (1.3)	4.4 (1.3)	.82	.53
JSW, n (%)[b]					
Left	26 (4.7)	31 (4.7)	25 (3.1)	.23	—
Right	13 (2.4)	20 (3.0)	15 (1.9)	.38	.12

[a] Estimated by using a general regression model, adjusted by side, gender, family history and breech, and taking into account clustering of hips within a subject.
[b] Less than or equal to 2 mm in at least 1 position.

groups had a similar participation rate at follow-up.

We acknowledge several limitations to our study. We have only reviewed 2038 young adults, corresponding to 17% of the 11 925 included in the original RCT. This weakens the power of the study as the original trial was not designed to detect such differences between the 3 groups at time of follow-up. An undetected difference (type II error) can therefore not be excluded. Based on the population-based sample invited, there was a moderate follow-up rate of 51.8%. Previous analyses based on height and weight measured at birth, 7 and 19 years of age revealed no differences between the responders and the nonresponders except for the gender distribution.[42] The treatment rate for each group was higher in the maturity sample than in the original RCT, most likely due to a selection bias reflecting that those who received treatment of DDH were more prone to participate at follow-up. We therefore calculated inverse probability weights taking into account gender, hip ultrasound at birth, and treatment of DDH to adjust for nonresponders when comparing the 3 screening groups.

CONCLUSIONS

Although both selective and universal ultrasound screenings gave a nonsignificant

reduction in the rates of late cases in infants and young children when compared with expert clinical programs, we were not able to demonstrate any additional reduction in rates of radiographic findings associated with acetabular dysplasia or early degenerative change at maturity, thus confirming our hypothesis. Increased treatment rates were not associated with AVN.

APPENDIX: ADDITIONAL INFORMATION REGARDING THE ORIGINAL RCT PERFORMED DURING 1988–1990

The original study base of the RCT included 11 925 infants born during January 1988 to June 1990 at the maternity hospital in Bergen, Norway, after exclusion of those with birth weight <1500 g, with severe disease/malformations or who died within the first month after birth (n = 103).[16] The infants studied were randomly assigned to universal ultrasound screening (n = 3613), selective ultrasound screening (n = 4388), or clinical screening alone (n = 3924). The details regarding the randomization process is described in the original article presenting the RCT.[16] The maternity unit in Bergen consists of 3 equally sized nursery units, separate from the delivery ward. The 3 units received patients in a random sequence according to available beds. One of the units (unit 2) received some more women recovering from cesarean deliveries due to the availability of a few single-patient rooms, and thus a slightly higher rate of breech presentation deliveries was expected at this unit. The staff at the delivery unit did not receive any information on the ongoing trial. The general screening group represented unit 2 and half of unit 3, and the selective screening group represented the other half of unit 3, and unit 1. Infants born when ultrasound was not available comprised the clinical only group and represented all 3 units. Unavailability occurred in periods of 1 to 3 weeks

spread unsystematically throughout the year. Randomization was area-based (cluster randomization), to keep mothers separate (ie, to avoid recall bias with respect to risk factors). This decision was based on experiences from 1987, when all girls and boys at risk were offered ultrasound screening. The mothers of the participants and the ultrasound examiner were aware of group assignment when the ultrasound was performed.

The aim of the RCT was to determine more appropriate criteria for treatment and to determine whether the addition of a universal or selective ultrasound screening program resulted in a reduced prevalence of late DDH (ie, after 4 weeks of age) compared with clinical examination alone. Cases of AVN of the femoral head were also reported.

All newborns were assessed by means of known risk factors for DDH (breech presentation at delivery, and/or family history [first or second grade] of DDH) and by means of clinical hip examination, including hip stability. The infant was classified as high-risk if at least 1 risk factor and/or clinical hip instability (ie, pathological instability without dislocatability, dislocatability [positive Barlow test] and dislocation [positive Ortolani test]) were present. High-risk infants from the selectively screened group and all infants from the universally screened group were offered a single examiner hip ultrasound (Rosendahl's method).[21] The ultrasound method is based on Graf's coronal standard section through the midacetabulum, and each hip is classified according to morphology and stability, separately.[43] The ultrasound examination was thoroughly standardized before the RCT.[44] All high-risk infants with normal hips at birth had a hip-radiograph at age 4.5 months, regardless of screening group. Indications for treatment were persistent dislocatable/dislocated hips on a repeated, single-examiner clinical examination or severe, sonographic dysplasia

irrespective of clinical or sonographic stability. Hips with a mildly dysplastic morphology ($43° \leq \alpha < 50°$) were treated if they were also clinically or sonographically dislocatable/dislocated. Sonographically immature ($50° \leq \alpha < 60°$) or mildly ($43° \leq \alpha < 50°$) dysplastic but clinically stable hips had sonographic and clinical surveillance every fourth week until normalization or until treatment was instigated due to lack of improvement. Moreover, all children in Norway have clinical examinations performed regularly during their first 2 years as a part of the national health program, with referral to a specialist if any clinical suspicion of DDH is noted. Routines for abduction treatment included a Frejka's pillow splint from birth until 3 to 4 months of age. If further treatment was necessary, an age-adapted orthosis was used. Late detected cases (ie, after the first month of age) were defined as subluxated or dislocated hips and/or mildly or severely dysplastic hips on ultrasound, or as an acetabular index[45] >2 SDs above mean for age and/or femoral head position (classified as dysplasia, dysplasia with subluxated hip, or dysplasia with dislocated hip) on radiographs.[46,47] Outcome measures in the RCT were (1) rates of late detected DDH, rates of (2) ultrasound follow-up, and (3) abduction treatment.

During the years of clinical screening before the RCT, the prevalence of late detected cases was 2.6 per 1000 live births. To detect a sixfold reduction in prevalence in a group subjected to screening, the 2 groups would have to include ~3000 infants each (80% power, 5% significance level). In the original trial, differences in prevalence rates were tested by χ^2 tests. An exact test for linear trend in the prevalence of late DDH with the groups ordered according to the degree of ultrasound screening from the no-screening group to the selective group and to the universal screening group was used. All reported P values

were 2-sided. Intention-to-treat-analysis was applied.

The baseline demographic and clinical characteristics of each group are reported in the original article.[16] There were no statistically significant differences in gender distribution or in the prevalence of positive Barlow/Ortolani tests between the 3 study groups or in the total number of infants with risk factors between the 2 groups subjected to ultrasound screening. The number of infants born in the breech position and with a family history of DDH was significantly higher in the universally than in the selectively screened group.

In brief, the RCT demonstrated lower rates of late presenting subluxated or dislocated DDH in the universally and selectively screened groups as compared with the group receiving clinical examination alone (0.3 and 0.7 vs 1.3 per 1000) (P = .11, test for trend).[16] Treatment rates were, however, higher for the universally screened group as compared with the selectively or non-screening groups; 3.4% vs. 2.0 and 1.8 (P < .001). When compared with the prestudy period, the rates of late cases were significantly lower (eg, 0.3 and 0.7 per 1000 vs 2.6 per 1000 live newborns).

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