EFORT open reviews

PAEDIATRICS | 7:7 | 498–505

Treatment of centered developmental dysplasia of the hip under the age of 1 year: an evidence-based clinical practice guideline - Part 1

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- Despite the high incidence of developmental dysplasia of the hip (DDH), treatment is very diverse. Therefore, the Dutch Orthopedic Society developed a clinical practice guideline with recommendations for optimal and uniform treatment of DDH. This article summarizes the guideline on centered DDH (i.e. Graf types 2A–C).
- The guideline development followed the criteria of Appraisal of Guidelines for Research and Evaluation II. A systematic literature review was performed to identify randomized controlled trials and comparative cohort studies including children <1 year with centered DDH. Articles were included that compared (1) treatment with observation, (2) different abduction devices, (3) follow-up frequencies, and (4) discontinuation methods. Recommendations were based on Grading Recommendations Assessment, Development, and Evaluation, which included the literature, clinical experience and consensus, patient and parent comfort, and costs.
- Out of 430 potentially relevant articles, 5 comparative studies were included. Final guideline recommendations were (1) initially observe 3-month-old patients with centered DDH, start abduction treatment if the hip does not normalize after 6–12 weeks; (2) prescribe a Pavlik harness to children <6 months with persisting DDH on repeated ultrasonography, consider alternative abduction devices for children >6 months; (3) assess patients every 6 weeks; and (4) discontinue the abduction device when the hip has normalized or when the child is 12 months.
- This paper presents a summary of part 1 of the first evidence-based guideline for treatment of centered DDH in children <1 year. Part 2 presents the guideline on decentered DDH in a separate article.

Keywords

- DDH
- guideline
- abduction treatment

EFORT Open Reviews
(2022) **7**, 498–505

Introduction

Developmental dysplasia of the hip (DDH) is a very common disorder in young children. In the Netherlands, the incidence is 3.7% in children up to 6 months of age (1). The vast majority of these cases represent centered dysplasia. DDH may lead to pain, functional limitations and early hip osteo-arthritis, and has huge societal impact (2).

www.efortopenreviews.org
https://doi.org/10.1530/EOR-21-0125

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The diagnosis of DDH is based on ultrasound or radiographs. Different classification systems exist. One of the most frequently used ultrasound methods is from Graf (3), which is the current standard in the Netherlands and other countries. In this classification, types 2A/B and C represent centered dysplasia.

Despite the high incidence of centered DDH, its treatment is very diverse among hospitals and health-care systems. Even in a small country like the Netherlands, there is controversy on the optimal treatment and follow-up. Some pediatric orthopedic surgeons provide immediate treatment with an abduction device upon diagnosis of centered DDH, while others initially observe according to a 'wait-and-see' policy (2). The choice of abduction device also varies considerably, as well as the clinical follow-up schedule. Finally, once the hip has normalized, the question remains whether the abduction device should be discontinued directly or gradually.

Therefore, a clinical practice guideline for treatment of DDH under the age of 1 year was developed under the auspices of the Dutch Orthopedic Society in cooperation with other relevant medical professionals and the Dutch hip patient association. The aim was to provide recommendations for the best possible and uniform treatment of DDH. Part 1 of this guideline, as described in the current article, focuses on treatment of centered DDH. Part 2, as described in a separate article, focuses on decentered and dislocated hips (4).

Materials and methods

Guideline development

A multidisciplinary guideline committee was composed in 2018. The committee consisted of representatives of all relevant medical professionals involved in the care of children with DDH, as well as the Dutch hip patient association, under support of the Dutch Knowledge Institute of the Federation of Medical Specialists (KiMS). The Dutch hip patient association is the largest association for parents and children with hip disease in the Netherlands. A board member of the association was included as a member of the DDH guideline committee and was involved in all guideline development phases. The target group consisted of all health-care providers for children with DDH, including (pediatric) orthopedic surgeons, radiologists, pediatricians, general practitioners, and youth health-care physicians.

The guideline was developed in accordance with the criteria of the international AGREE instrument (Appraisal of Guidelines for Research and Evaluation II (AGREE II)) (5). In the preparatory phase, the committee discussed and prioritized key issues, in consultation with all relevant stakeholders, including the Dutch hip patient association. High-priority issues were defined to compose clinical guideline questions and relevant outcome measures in the Patient, Intervention, Comparison, Outcome (PICO) format (6).

Guideline questions

Based on the prioritization of key issues, the following guideline questions on treatment of children <1 year with centered DDH were formulated:

1. What are the outcomes of observation compared to abduction treatment with regard to residual dysplasia, complications, and subsequent surgery?
2. What are the outcomes of treatment with a Pavlik harness compared to treatment with another abduction device with regard to residual dysplasia, complications, and subsequent surgery?
3. Does the frequency of monitoring affect the outcomes of stable DDH with regard to residual dysplasia, complications, and subsequent surgery?
4. What are the outcomes of immediate discontinuation compared to 'weaning' the abduction treatment of normalized DDH with regard to residual dysplasia, complications, and subsequent surgery?

Relevant outcome measures

The guideline committee considered residual dysplasia as a *critical* outcome measure for decision-making. Complications and surgical treatment were as regarded *important* outcome measures. The outcome measures were defined as follows: residual dysplasia according to the acetabular index (AI) of Tönnis and Brunken (7), complications as described in the studies (e.g. avascular necrosis, femoral neuropathy), and any surgical procedure for DDH.

Search strategy and study selection

In the development phase, a systematic review of the literature was performed based on the PICO format. The databases Medline (via OVID) and Embase (via Elsevier) were searched with relevant search terms from 1980 until September 25, 2019. Detailed search strategies are depicted in Appendix 1.

Two committee members (CvB and MF) independently selected studies for the guideline questions, based on the following criteria: randomized controlled trials and comparative cohort studies including children with centered DDH (Graf types 2A/B and C) under 1 year, comparison of abduction devices with other abduction devices or with observation, assessment of frequency of follow-up, and comparison of different discontinuation methods. The language was limited to English and Dutch. All reference lists of included articles were checked manually in search of additional relevant articles. A PRISMA flow diagram of the selection process is presented in Fig. 1.

Formulation of literature conclusions and guideline recommendations

The scientific evidence was summarized into literature conclusions. Conclusions and recommendations in the literature were formulated according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method (8). Levels of evidence were assigned to each conclusion with use of the GRADE methodology. GRADE classifies the scientific evidence as high, moderate, low, or very low, based on both the scientific certainty and clinical considerations. Thus, in formulating the recommendations, the guideline committee also took considerations into account that were not reflected in the literature, including potential harm of the interventions, patients' and parents' values and preferences, costs, and organization of care. Finally, recommendations were formulated to answer the guideline questions, based on available scientific evidence and the clinical considerations.

Commentary phase and authorization

A concept guideline was generated and presented to 19 Dutch societies involved in the care of children with DDH. The committee discussed the comments and constituted the final version of the guideline. The final version was presented to the involved societies and was formally authorized on January 11, 2021 (https://richtlijnendatabase.nl/richtlijn/ddh_dysplastische_heupontwikkeling_bij_kinderen_onder_n_jaar).

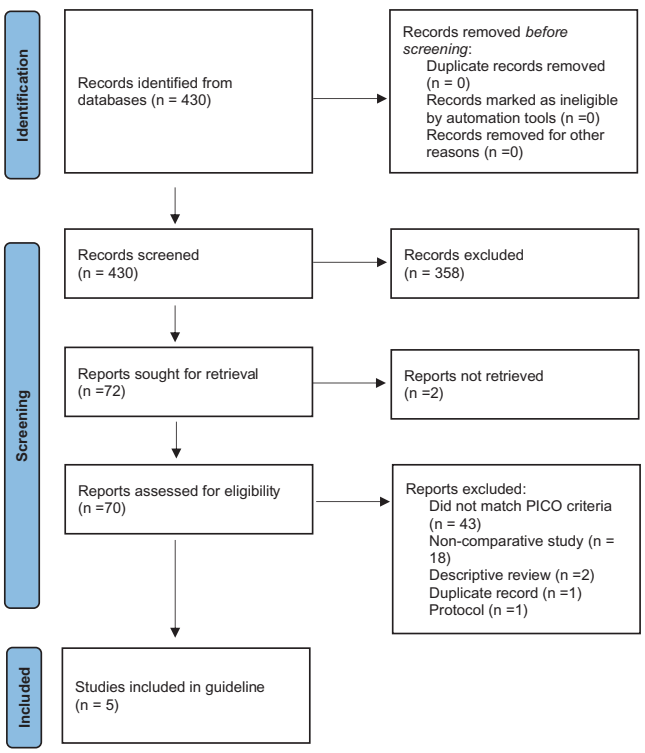

Figure 1
PRISMA flow diagram. PICO, patient, intervention, comparison, outcome.

Results

The systematic literature search resulted in 430 potentially relevant articles. Seventy-two studies were initially selected based on title and abstract screening. After reading the full texts, the authors excluded 67 of these studies. Most excluded studies did not meet the guideline questions or were not comparative. The five remaining studies were included in the guideline (Table 1).

Guideline question 1: Observation compared to abduction treatment

Wood *et al*. (9) performed a prospective cohort study in 44 children aged 2–6 weeks with dysplastic stable hips, either treated with a Pavlik harness or observed with clinical and ultrasound examination. After 2 years of follow-up, treatment with a Pavlik harness resulted in a mean AI of 21.6° and observation resulted in a mean AI of 23.5° ($P = 0.2$).

Rosendahl *et al*. (10) performed a randomized controlled trial in newborns with mildly dysplastic hips (α-angle 43°–50°). The intervention consisted of immediate abduction treatment for at least 6 weeks using a Frejka pillow splint with sonographic follow-up. The control consisted of active sonographic surveillance but no treatment before 6 weeks of age. In case of persistent hip dysplasia after 6 weeks of observation, patients received an abduction splint; this was reported in 47%. AIs at 1 year follow-up were not statistically significantly different between both groups ($P = 0.7$).

Brurås *et al*. (11) described the long-term outcomes of the study of Rosendahl *et al*. They reported no statistically significant differences between intervention and control groups after 6 years of follow-up.

Kim *et al*. (12) performed a prospective cohort study in infants diagnosed with stable dysplasia. Treatment with a Pavlik harness resulted in a mean AI of 20.9° (S.D. 4.7°) and observation resulted in a mean AI of 22.1° (S.D. 3.5°) after 2 years of follow-up ($P = 0.2$) (see Table 1).

Guideline question 2: Pavlik harness compared to other abduction devices

There were no comparative studies that examined different abduction braces in children with DDH and reported relevant outcome measures.

Guideline question 3: Frequency of monitoring

There were no comparative studies that examined the frequency of monitoring treatment in children with DDH.

Table 1 Summary of included studies.

Study	Study characteristics		Number of		Follow-up	Loss to follow-up†	Outcomes	
	Type/intervention/control		Patients	Hips			Residual dysplasia (AI)	Complications
PICO 1: observation compared to abduction treatment								
Wood *et al.* (9)	PCS				2 years	18 (41%)		
	Intervention	Pavlik harness	25	38			21.6°	No AVN
	Control	Observation	19	25			23.5°; $P = 0.2$	No AVN
Rosendahl *et al.* (10); Bruras *et al.* (11)	RCT*							
	Intervention	Frejka pillow splint	64		6 years	22 (35%)	14.5° ± 4.0° (right), 13.6° ± 3.2° (left)	No AVN; surgery: one pelvic osteotomy
	Control	Observation	64		6 years	23 (36%)	14.9° ± 3.9° (right), 13.3° ± 3.7° (left); $P = 0.9$	No AVN; no surgery
Kim *et al.* (12)	PCS							
	Intervention	Pavlik harness		65	29 ± 4.9 months	21 (32%)	20.9° ± 4.7°	
	Control	Observation		42	29 ± 4.9 months	15 (36%)	22.1° ± 3.5°; $P = 0.2$	
PICO 4: immediate discontinuation compared to 'weaning' the abduction treatment								
Westacott *et al.* (13)	RCCS							
	Intervention	Weaning of the Pavlik harness over a 4-week period upon ultrasonic hip normalization	80	120	24 months (range: 12–45)	25 (31%)	23.7° (range:16°–42°)	AVN: 4 (9%)
	Control	Immediate discontinuation of the Pavlik harness upon ultrasonic hip normalization	48	65	19.2 months	21 (44%)	24.8° (range: 19°–42°)	AVN: 1 (4%)

*Blinded; †*n* (%) of patients.
AI, acetabular index; AVN, avascular necrosis; PCS, prospective cohort study; RCCS, retrospective cross- center study; RCT, randomized controlled trial.

Guideline question 4: Immediate discontinuation compared to 'weaning' the abduction treatment

Westacott *et al.* (13) performed a retrospective cross-center study in children diagnosed with DDH at less than 6 months of age to investigate clinical and radiological outcomes and complication rates of different abduction device discontinuation regimes, after hip normalization on ultrasonic follow-up. The intervention consisted of weaning the harness treatment over a 4-week period (−1 h/day during the first week, −2 h/day during the second, −4 h/day during the third, and −8 h/day during the final week), after which the harness was removed. The control consisted of discontinuing the harness immediately, that is, without a weaning period. After 1 and 2 years of follow-up, AIs were not statistically significant. Four children (9%) in the weaning group and one child (4%) in the control group suffered from avascular necrosis ($P = 0.5$).

Conclusions and recommendations

The GRADE conclusions and recommendations of the guideline are presented in Table 2. The recommendations are based on the included literature, clinical experience and consensus, taking into consideration the patient and parent comfort and costs (see 'Discussion' section). The recommendations as formulated in this clinical practice guideline resulted in the treatment flowchart presented in Fig. 2.

Discussion

This paper presents a summary of the recently developed Dutch guideline on the treatment of centered DDH under the age of 1 year. To the best of our knowledge, this is the first official evidence-based guideline on DDH in the literature (https://g-i-n.net; https://guideline.gov). It was developed by a diverse group of experts from all relevant backgrounds, including orthopedic surgery, youth health care, radiology and patient association, with support of the Knowledge Institute of the Federation of Medical Specialists.

The first guideline recommendation is to initially observe 3-month-old patients with centered DDH. This recommendation is based on the systematic literature evaluation with a GRADE moderate level of evidence, together with the experience of the committee, suggesting that centered DDH may normalize without treatment in the very young (9, 10, 11, 12). Although these studies included slightly different populations (e.g. different age and definitions of mild/stable DDH), they provide relevant information with regard to the recommendation. In addition, an important randomized clinical trial was published after the systematic literature review of this guideline. Pollet *et al.* (14) investigated 104 children,

Table 2 Conclusions and recommendations.

Guideline question	Conclusions	Recommendations[1]	GRADE
1: observation compared to abduction treatment	There is probably no difference in residual dysplasia, complications or the number of subsequent surgeries at 1–6 years follow-up between treatment with an abduction brace compared to observation in patients <1 year with centered DDH (9, 10, 11, 12).	Initially observe 3-month-old patients with centered DDH. Consider starting abduction treatment if the hip does not normalize after 6–12 weeks.	Moderate[2]
2: Pavlik harness compared to other abduction treatment	There were no comparative studies identified about the effectiveness of different abduction braces in patients with centered DDH <1 year that reported relevant outcome measures.	Prescribe a Pavlik harness to children <6 months with centered DDH on repeated ultrasonography. Consider another abduction device for children >6 months.	Not applicable
3: frequency of monitoring	There were no comparative studies identified about the frequency of monitoring treatment in patients with centered DDH <1 year.	Assess patients <1 year with centered DDH in the outpatient clinic and with imaging every 6 weeks.	Not applicable
4: Immediate discontinuation compared to 'weaning' the abduction treatment	It is unclear whether weaning of the Pavlik harness compared to discontinuing the harness is associated with residual dysplasia, complications or the number of subsequent surgeries at 2 years follow-up in patients <1 year with normalized centered DDH (13).	Discontinue the abduction device when the hip has normalized or when the child is 1 year old.	Very low[3]

DDH, developmental dysplasia of the hip; GRADE, Grading Recommendations Assessment, Development, and Evaluation (8).
[1]Recommendations are based on the literature conclusions as well as the clinical considerations as described in the text. [2]The GRADE level of evidence was downgraded by one level because of imprecision. [3]The GRADE level of evidence comes from an observational study and therefore starts low. This was downgraded one level because of study limitations (bias due to inadequate follow-up).

aged 3 months, with Graf types 2B and 2C. Fifty-five children were randomized to Pavlik harness treatment and 49 children to observation. No difference in ultrasonic α-angle was found after 6 and 12 weeks of follow-up. Ten patients (20%) of the observation group received Pavlik harness treatment after 6 or 12 weeks because of persistent DDH. Radiographs at a mean age of 10 months and 2.5 years showed no significant differences in AIs between both groups. Furthermore, a literature review in 2018 studying the natural history of 13 561 dysplastic hips under the age of 6 months confirmed these findings (15). In addition, a systematic review in 2020 identified 20 studies that described the number of centered DDH cases that resolved during the study period, reporting a mean rate of 84% (16). All these studies seem to provide sufficient evidence to support initial observation of young patients with centered DDH. This strategy reduces unnecessary treatment in 53–84% of the patients, without increased risk of persistent DDH (10, 11, 14, 16). However, the study groups are relatively small; a large randomized trial will be needed to support or confute the proposed treatment strategy.

The other guideline questions were less supported by the available literature. Recommendations with respect to guideline question 2 were therefore based on patient comfort, care, and costs. The Pavlik harness is the most frequently applied abduction device for young children (up to 6–9 months) in the Netherlands and abroad (14, 17). We recommend application of the Pavlik harness for 23 h/day, that is, bathing, etc., is allowed. The Pavlik is checked and adjusted at the outpatient clinic 1 week after its application and at following appointments if indicated. An advantage of this device is that the child is able to move the legs freely in the optimal plane of motion. A disadvantage is that children older than 6–9 months can become too strong and may disengage the harness. At this age, the harness is therefore often replaced by an abduction brace (14), which increases compliance in these older children.

For guideline question 3, an optimum between frequent and infrequent follow-up moments was chosen. Highly frequent follow-up involves numerous hospital visits and ultrasound investigations with accompanying costs and burden to the parents. Infrequent follow-up may unnecessarily increase the duration of treatment (in case the hip has normalized earlier) or lead to late detection of hip joint deterioration. We therefore aimed at an optimum time frame between these extremes. A 6-week term between follow-up visits seems a reasonable balance between a possible ultrasonic improvement of the hip and prolonged treatment duration. Ultrasound is the preferred imaging method but is changed to radiography once ultrasound is technically unfeasible (usually by age 9–12 months because of the growing ossification center of the femoral head).

With regard to guideline question 4, the clinical experience of the guideline committee concurs with the findings of Westacott *et al*. (13): a weaning treatment period after normalization of the hip does not seem advisable. Westacott *et al*. (13) also included some patients (17%) with α angles <43°, but these were evenly distributed between the groups. Additionally, it is the experience of the guideline committee that abduction device compliance decreases drastically when the child reaches 1 year of age, because of the child's development and walking abilities, and that ambulation improves the development of the hip joint. Discontinuation of abduction treatment at the age of 1 year is therefore recommended.

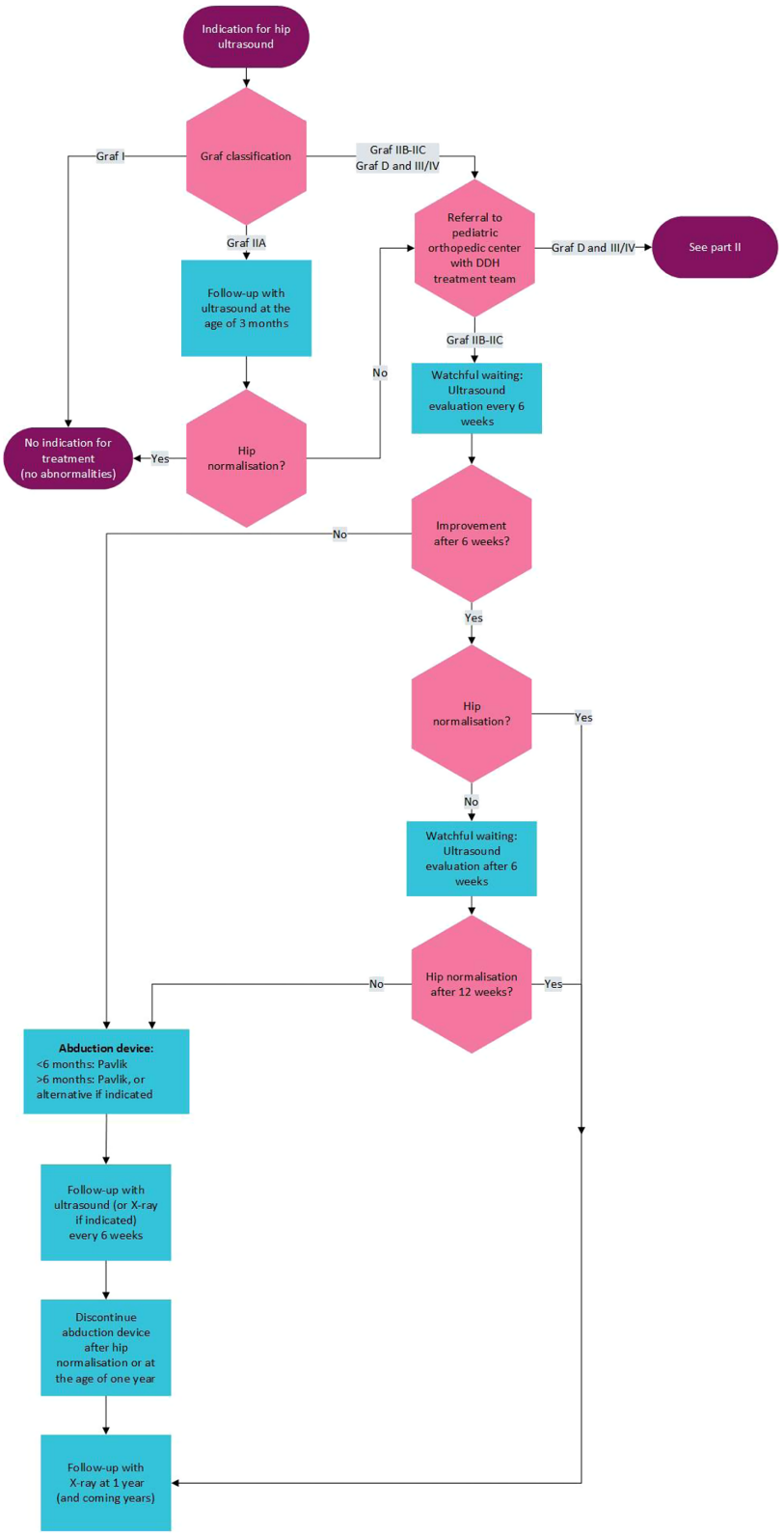

Figure 2
Flowchart guiding treatment of centered DDH.

Strengths of this guideline include the multidisciplinary background of the committee members, involvement of all relevant societies, comprehensive systematic literature review, and formulation of clear recommendations according to the GRADE approach. This approach provides a system for rating quality of evidence and strength of recommendations that is considered explicit, comprehensive, transparent, and pragmatic and is adopted by organizations worldwide (8). One of the strengths of this approach is that the recommendations are not solely based on the literature, which often has limitations. Rather, important clinical nonscientific considerations are included in the recommendations, for example, patients' and parents' values, costs, and organization. Additionally, anyone involved in the care of DDH has access to the guideline; besides the free online availability of the complete guideline (https://richtlijnendatabase.nl/richtlijn/ddh_dysplastische_heupontwikkeling_bij_kinderen_onder_n_jaar), a summary has been presented during the 2021 Dutch orthopedic association annual meeting, the 2022 EPOS annual meeting and the 2022 EFORT annual meeting. In addition, a summary in layman's language is available online (https://www.thuisarts.nl/heupdysplasie).

The guideline also has limitations. At the start of this project, a limited set of relevant questions from daily clinical practice was selected. Consequently, there are still some DDH-related issues open for debate. The part of the guideline presented in this paper only discusses centered DDH. There was no further distinction between subgroups based on age and sonographic severity. A separate paper describes the guideline for decentered and dislocated DDH (4). Another possible flaw is that only comparative studies published in English and Dutch were included, which is the standard method for Dutch guideline development. As a consequence, possibly relevant case series were excluded. Even though the recommendations in this guideline are based on best evidence from the literature, ultimately converting the evidence into recommendations was a consensus process among the committee members. This consensus process may leave room for bias, for example, the clinical experience in our country may be different from others (17). For example, in the Netherlands, selective ultrasound screening of at-risk babies is performed at the age of 3 months, while in some other countries, general screening of all newborns is performed at a younger age. Finally, the guideline is as strong as its supporting literature. The highest GRADE evidence was only moderate (question 1), and questions 2–4 had lower or even no GRADE evidence. Therefore, there is clearly a need for high-quality, large randomized controlled trials with sufficient follow-up to answer the remaining uncertainties with regard to the treatment of DDH.

In conclusion, the guideline presented in the article provides handles for uniform and evidence-based treatment of children under the age of 1 year with centered DDH. Monitoring and auditing of the guideline will be regulated by the Dutch Orthopedic Association (NOV).

Declaration of interest
The authors declare that there is no conflict of interest that could be perceived as prejudicing the impartiality of the research reported.

Funding
This work did not receive any specific grant from any funding agency in the public, commercial or not-for-profit sector.

Author contribution statement
All authors were members of the guideline committee and approved the final version of the paper. In addition, C v B selected the studies, drafted the guideline, and wrote the paper, P d W commented on the drafts, F W and B d G analyzed the included studies, M F selected the studies, and M W supervised the guideline development.

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