

Guideline on the diagnosis and treatment of primary idiopathic clubfoot

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Abstract — A delegation of 6 pediatric orthopedic surgeons from the Dutch Orthopedic Association (NOV) and 2 members of the board of the Dutch Parents' Association for children with clubfoot created the guideline “The diagnosis and treatment of primary idiopathic clubfoot” between April 2011 and February 2014. The development of the guideline was supported by a professional methodologist from the Dutch Knowledge Institute of Medical Specialists.

This evidence-based guideline process was new and unique, in the sense that the process was initiated by a parents' association. This is the first official guideline in pediatric orthopedics in the Netherlands, and to our knowledge it is also the first evidence-based guideline on clubfoot worldwide.

The guideline was developed in accordance with the criteria of the international AGREE instrument (AGREE II: Appraisal of Guidelines for Research and Evaluation II). The scientific literature was searched and systematically analyzed. In the second phase, conclusions and recommendations in the literature were formulated according to the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) method. Recommendations were developed considering the balance of benefits and harms, the type and quality of evidence, the values and preferences of the people involved, and the costs.

The guideline is a solid foundation for standardization of clubfoot treatment in the Netherlands, with a clear recommendation of the Ponseti method as the optimal method of primary clubfoot treatment. We believe that the format used in the current guideline sets a unique example for guideline development in pediatric orthopedics that may be used worldwide. Our format ensured optimal collaboration between medical specialists and parents, and resulted in an important change in clubfoot care in the Netherlands, to the benefit of medical professionals as well as parents and patients.

In this way, it is possible to improve professional collaboration between medical specialists and parents, resulting in an important change in clubfoot care in the Netherlands that will benefit medical professionals, parents, and patients. The guideline was published online, and is freely available from the Dutch Guideline Database (www.richtlijndatabase.nl).

Clubfoot (talipes equinovarus) is a well-known deformity in children. The disorder consists of 4 entities: cavus, equinus, varus, and adductus, not spontaneously correcting with growth. There are no specific data on the incidence of clubfoot in the Netherlands, but this incidence can be estimated based on data obtained in nearby countries with similar population characteristics. Based on the incidence of clubfoot in Sweden of 1.4 per 1,000 newborns (Wallander et al. 2006), it is estimated that 200–300 children with 1 or 2 clubfeet are born in the Netherlands every year.

Starting around 1990, the popularity of the non-surgical treatment of clubfoot with the Ponseti method increased worldwide. Today, the Ponseti treatment of clubfeet is considered to be the first choice of primary treatment in most parts of the world, but some feet are still first treated surgically. For patients and their parents, and also for medical professionals, the choice between these treatment modalities was not an obvious one. For the non-surgically based treatment, unwanted variation resulted in different outcomes in children who were treated, leading to an urgent need for scientifically based guidance.

The Dutch Parents' Association for children with clubfoot organized a forum discussion in 2011, which resulted in the development of the Dutch guideline on primary treatment

of clubfoot supported by the Dutch Orthopedic Association (NOV). The guideline was developed in collaboration with the Dutch Knowledge Institute of Medical Specialists and was co-developed by the Dutch Parents' Clubfoot Association. The initiation by and participation of a parents' association represents a new concept for guideline development in the Netherlands.

The Dutch clubfoot guideline on primary treatment of clubfoot has recently been approved by the general assembly of the NOV. The NOV already has a long history of multidisciplinary reviews leading towards evidence-based guidelines. Also, in the Nordic Orthopaedic Federation the importance of guideline development to improve care is emphasized. These guidelines serve as a standard in specific treatments used by professionals to rule out unwanted variance and to provide guidance for professionals and patients. Guidelines cover the optimal applied care that an orthopedic surgeon should provide. Deviations from a guideline are allowed—and are sometimes even required—to ensure optimal care of an individual patient, but only if they are justified and properly documented and agreed upon together with the patient (or legal representative). In a research setting, deviations from guidelines are also allowed, but only after proper authorization by an ethics committee. Guidelines from the NOV are always developed together with professional guideline developers to guarantee an optimal, methodologically sound, process. A properly developed evidence-based guideline makes it easier caregivers to treat according to a well-balanced standard.

After authorization by the relevant medical societies and patient organizations, guidelines are published in the Dutch Guideline Database (Richtlijndatabase; richtlijndatabase.nl/en/). In this database, guidelines are organized in separate modules with each module addressing a specific clinical question. Instead of revising complete guidelines every 5 years, the guideline database allows for regular updates at the level of individual modules according to need. New modules can easily be added, and modular revisions ensure that guidelines in the guideline database remain up-to-date. This avoids rigidity in guidance and stimulates new scientific initiatives. As part of the guideline development process, knowledge gaps are identified and research questions formulated. These research questions are published on the guideline database together with the guideline, and are used by professional societies to provide guidance for future clinical research in the Netherlands.

This guideline covers the primary diagnosis and treatment of idiopathic clubfoot in children presenting with the deformity in the first 6 months after birth. This cohort has been studied because it has not been biased by previous treatments. The current guideline does not cover the treatment of clubfeet after delay or in children with residual deformities. At a later stage the guideline might be extended to these patient groups. To our knowledge, this is the first evidence-based guideline on clubfoot.

Methods: see [Supplementary data](#).

Results of literature review and analysis: see [Supplementary data](#).

Guideline recommendations according to the following clinical questions:

Clinical Question 1: What is the optimal treatment for clubfoot?

- Treat primary clubfoot with the standard Ponseti method;
- Do not use plaster casting according to the Kite method;
- Do not use synthetic plaster casts but Plaster of Paris for the Ponseti method;
- Do not use foot orthotics in follow-up treatment, but use a foot abduction brace;
- If possible, the Achilles tendon tenotomy is to be carried out under local anesthetics;
- Only carry out surgery for primary treatment for idiopathic clubfoot as described in the standard Ponseti method.

Clinical Question 2: What is the importance of brace compliance and other patient-related factors in the successful treatment of clubfoot?

- Inform the parents of children with a severe clubfoot because of an increased risk of a higher number of plaster changes and recurrences;
- Motivate the parents strongly so that they succeed with high compliance in the after-treatment with a Dennis Browne-type foot abduction brace up to the age of 4, in order to minimize the chance of recurrences;
- Register and document all factors that could possibly be related to the outcome of the Ponseti treatment on a regular basis for evaluation of the long-term follow-up.

Clinical Question 3: What is the optimal method to be used for the diagnosis and classification of a clubfoot?

- Use physical examination to establish a clubfoot diagnosis;
- Do not use standard radiological examination; radiological examination should only be used when there are doubts about the diagnosis, or when there is a lack of progression of the foot correction, or if there is a recurrence;
- Use both the Diméglio and the Pirani score as classification systems in order to obtain sufficient long-term data for both classification systems.

Clinical Question 5: With respect to organization of care, what are the preconditions for optimal treatment of patients with clubfoot?

- Refer pregnant mothers, when there is suspicion of clubfoot pathology in their unborn children, to a specialized member of a clubfoot treatment team;
- Refer newborns with a clubfoot without previous suspicion—preferably on the first working day—to a local ortho-

pedic surgeon who can take care of referral to a clubfoot center, preferably within 48 hours but not more than one week after delivery;

- The orthopedic surgeon of the clubfoot center should be responsible for the correct diagnosis, initiation of the correct treatment, and the logistic pathway;
- The treatment itself (plaster treatment, tenotomy, brace fitting, and follow-up) must be carried out by adequately trained and qualified members of the specialized team;
- During the primary treatment, the child should be seen on a weekly basis. After the primary process until wearing of the brace starts, there must be frequent contact with the child and parent between 3 and 6 months;
- In the first year, routine physiotherapy is not advisable.
- Clubfoot treatment and the aftercare should be performed in appointed centers with a specialized clubfoot treatment team. Also, extended operations on clubfeet should be performed in specialized centers;
- The treating team should consist of at least 2 trained orthopedic surgeons, 2 trained plaster physicians, and, if necessary, a technician;
- The Dutch Orthopedic Society yearly the centers on an annual basis according to the recommendations in the guideline, and publishes the results;
- A clubfoot center must use a website with adequate and up-to-date information;
- Prenatal counseling should be provided.

Discussion

To our knowledge, this is the first evidence-based guideline by a national orthopedic association to be initiated by a parents' association. This initiative resulted in a scientifically based guideline with optimal support in the medical and parent/patient communities.

The guideline is aimed at providing evidence-based advice both to clinicians and to parents, in order to minimize unwarranted variation in treatment of clubfoot and to improve therapeutic compliance.

Because of the frequent lack of high-level evidence in pediatric orthopedics in general, and in clubfoot management in particular, it was essential to use the GRADE method. This is a systematic and transparent approach to collection and grading of the available evidence and to weighing the evidence together with complementary arguments, so-called considerations, relevant to the clinical question—including patient values and preferences, and resource use (costs, organization of care issues) (Guyatt et al. 2011, Schunemann et al. 2014). Guideline panels must use judgement in integrating these factors to make a strong or weak recommendation. In the GRADE approach, the strength of a recommendation reflects the extent to which the guideline panel was confident that the desirable effects of the intervention would outweigh the undesirable

effects, across the range of patients for whom the recommendation is intended. Guidelines that are produced as a result of a thorough methodological process and used in the correct manner can direct patient care in a positive way. Unwanted variance can be avoided and both caregivers and patients can use a guideline as a basis for communication. A medical professional can always deviate from the recommendations in the guideline but must justify this decision with valid arguments. As a part of a guideline one should identify lack of knowledge, leading towards new research, which can lead to revisions of the guidelines in the future. In this way, guidelines only have advantages, and should lead to positive changes in care. The Dutch Guideline Database is formatted in a modular fashion. This means that if there are new insights, it is easier to alter a particular module, so the guideline is more of a dynamic tool.

The most important clinical question addressed in the current guideline concerns the primary treatment of clubfoot—whether to use extensive surgery or a non-surgical method. A systematic analysis of the current scientific literature showed similar benefits from surgical treatment (postero-medial release) and non-surgical treatment (Ponseti). Due to the lack of high-quality comparative studies, the overall quality of the evidence was low. Despite this, the guideline panel decided on a strong recommendation of the standard Ponseti method for the treatment of primary idiopathic clubfoot, because of the higher intrinsic risk of complications in surgical treatment than with the non-surgical (Ponseti) treatment. Because of the enormous popularity and favorable results with the Ponseti treatment in idiopathic clubfoot, parents and ethical committees will not support randomized clinical trials comparing surgical release and non-surgical (Ponseti) treatment. Thus, higher levels of evidence cannot be expected in future. New studies should instead focus on optimizing the Ponseti method by determining the optimal length of brace treatment, improving compliance with brace treatment, developing diagnostic tools to identify clubfeet that are at high risk of treatment failure, and as a consequence developing optimal treatment for these clubfeet. The possibility of using hybrid methods between different non-surgical methods and physiotherapy could also be investigated. Optimal diagnostic and classification tools should also be designed. There is no evidence-based reason to only use the Pirani or the Diméglio score, so the guideline group decided to use both. In this way, we can probably solve this knowledge hiatus in the future. In a recent study to evaluate both classification systems, simultaneous use of both systems was recommended, as they are different and complement each other (Cosma and Vasilescu 2015).

This guideline was produced for idiopathic clubfoot children starting treatment within 6 months of delivery. Because of this narrow definition, the literature survey could be focused but could be a base for further guideline development in regarding clubfoot patients with residual deformities, relapses, and syndromic clubfoot. The importance of having a guideline for these specific entities, which are not covered by the present

document, must be emphasized and this should be addressed in the near future.

Supplementary data

Methods and results are available as supplementary data in the online version of this article <http://dx.doi.org/10.1080/17453674.2017.1294416>.

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ATB: chairman of guideline group and senior author. RJBS: member of guideline group; correction and judging of manuscript. HAS: co-chairman of guideline group; correction and judging of manuscript. MEHW: member of guideline group; correction and judging of manuscript; VCMZ: member of guideline group; correction and judging of manuscript. JDV: member of guideline group; correction and judging of manuscript. RAB: parent member of guideline group; correction and judging of manuscript. SDM: parent member of guideline group; correction and judging of manuscript. MCvds: correction and judging of manuscript. KNJB: senior advisor of guideline group; correction and judging of manuscript.

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