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Consensus-based guideline for the supportive anthroposophic therapies to treat children with pseudocroup (stenosing laryngotracheitis)

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ABSTRACT

Purpose: Supportive anthroposophic therapies are used to treat children with pseudocroup by pediatricians in outpatient and inpatient settings. Anthroposophic treatment comprises forms of creative therapies, external applications as well as remedies, which production is based on the knowledge of the human being, nature and substances. A scientifically based guideline for these therapies is lacking. Due to insufficient study situation, we developed a consensus-based guideline to make therapy decisions more transparent and facilitate clinical routine.

Methods: An online Delphi process with 67 anthroposophic pediatricians was conducted. Recommendations were accepted when reaching more than 75 % of expert agreement; otherwise, recommendations were revised and assessed by the experts once again.

Results: Recommendations for general interventions and for anthroposophic remedies (Bryonia/Spongia comp.; Larynx/Apis comp.) as well as for external applications (embrocation with lavender oil) were developed. Recommendations have a consensus of 96.4 % or more.

Conclusion: The consensus-based guideline provides practical recommendations for the supportive anthroposophic therapies for pseudocroup. The implementation and practicability of this guideline has to be investigated.

1. Introduction

Pseudocroup (also known as stenosing laryngotracheitis) is characterized by symptoms such as barking cough, hoarseness, stridor and respiratory distress. In most cases, children develop upper respiratory signs and symptoms as well as fever in the days before [1]. Pseudocroup mostly has a viral cause, whereby parainfluenza viruses (type 1,2, and 3) are responsible for 75 % of cases [2].

Symptoms occur suddenly and mostly in the night, with high prevalence in the autumn and winter months [2,3]. Due to the occurrence of abrupt and impressive symptoms, most parents are very concerned and therefore pseudocroup is a frequent reason for a physician or emergency visit [4,5]. In fact, only 1.5 - 8 % need hospital admission [1,2,6].

In total, the twelve-month prevalence in German children suffering from pseudocroup from 0 - 10 years is 6.6 % and the prevalence in children younger than 7 years was twice as high as in schoolchildren. Boys (8.4 %) are more affected than girls (4.6 %) [7].

The diagnostic is based on clinical findings of characteristic symptoms. Further diagnostic testing is not necessary for typical courses [8].

However, differential diagnostics such as acute epiglottis, bacterial tracheitis and inhalation of foreign bodies should be considered [2].

Standard therapy for pseudocroup comprises treatment with glucocorticoid (e.g. dexamethasone, budesonide) or adrenaline. Beneficial effects are demonstrated in several clinical studies [2,9]. Intubation is required in fewer than 5 % of inpatients. The clinical effects of humidification or exposure to cold air, which is often used, are insufficiently investigated [2,6].

In German anthroposophic pediatric hospitals, such as the *Gemeinschaftskrankenhaus* (Engl.: community hospital) *Herdecke* and *the Filderklinik*, children with pseudocroup receive supportive anthroposophic therapies in addition to conventional treatment. Anthroposophic medicine is an integrative medicine approach considering the whole human being in diagnostic and therapy. Therapy comprises specific remedies as well as non-medication therapies (e.g. eurythmy). Anthroposophic

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Table 1
ESPEN classification for the strength of consensus (Table modified from [14]).

Agreement of experts	Assessment
> 90 %	Strong consensus
> 75–90 %	Consensus
> 50–75 %	Majority agreement
< 50 %	No consensus

therapies can be combined or used as monotherapy to supplement conventional medicine [10]. Anthroposophic remedies are produced of plant, animal and mineral substances in accordance to a certain procedure considering the anthroposophic knowledge of the human being, nature and substances. There are several pharmaceutical companies producing anthroposophic remedies, for example Weleda (Switzerland), WALA Heilmittel (Germany) or Abnoba (Germany) [11]. Scientifically based recommendations or guidelines for the anthroposophic therapies for pseudocroup are not available. Although AM is a very personalized medical approach, guidelines are needed to make it more transparent for physicians, patients and other persons from the healthcare sector. Therefore, we developed a consensus-based guideline for the supportive anthroposophic therapies for pediatric pseudocroup.

2. Methods

2.1. Pool of experts

In total, 67 experts with at least one year's expertize in pediatric and anthroposophic medicine were invited to join the Delphi process. The expert pool consists of physicians working in one of the two anthroposophic hospitals, the *Gemeinschaftskrankenhaus Herdecke* and the *Filderklinik*, as well as outpatient physicians. Latter ones are either members of the GAÄD (Gesellschaft Anthroposophischer Ärzte und Ärztinnen in Deutschland, engl.: Physicians' Association of Anthroposophic Medicine in Germany) or regularly use anthroposophic medicine for children and adolescents in their daily work routine. Outpatient physicians did not receive specialized training by one of the participating hospitals. Currently the participating hospitals do not use standard operating procedures (SOPs) for the anthroposophic treatment of pseudocroup. Physicians prescribe anthroposophic therapies based on the recommendations of experienced physicians or of guidebooks (e.g. Vademecum of anthroposophic remedies). In addition to German pediatrician, we invited some German-speaking pediatricians from other European countries (Austria n = 1, Hungary n = 1, Netherlands n = 1, Spain n = 1, Switzerland n = 2).

2.2. Delphi process

The Delphi process is an accepted and well-described procedure to develop consensus-based guidelines in the medical field [12,13]. Our Delphi process was conducted between May and October 2023, using the online survey tool UniPark (https://www.unipark.com/). In the first round, the experts were asked to give detailed information about therapy options. Using the quantitative data analyzing software MAXQDA, answers were clustered to the following aspects:

1. General behavioral measures.
2. Anthroposophic medical therapies.
3. Anthroposophic external applications.

All responses given to these three topics were presented to the experts in the second round. Experts decided by "drag and drop" function, which answer options are applicable. These data were quantitatively analyzed, and we phrased recommendation statements by considering responses which were chosen by ≥ 50 % of experts. These statements were sent to the experts, who were required to agree or disagree. In the case of disagreement, they had to state their reasons. Statements need more than 75 % consensus of experts to be accepted.

2.3. Consensus classification

Consensus was evaluated by the ESPEN consensus classification of consensus strength [14] (Table 1).

2.4. Data analysis

Content analyses of open questions were qualitatively analyzed by using the MAXQDA standard 2020 software. Coding and interpretation of responses were performed by two independent reviewers. In case of discrepancies, a third reviewer was involved in the process. Quantitative analysis of "drag and drop" questions was performed by Excel 2016.

3. Results

3.1. Response rate

The response rate varied between 24.6 % and 43.1 % (Table 2). In the first two rounds, the ratio of physicians working in hospital and in practice was balanced. In the third round, more physicians working in a hospital joined the survey. Almost all participant were German. In the first and second round, only one non-German pediatrician was recorded.

3.2. Consensus assessment

All recommendations reached strong consensus (>90 %) in the initial vote. All experts agreed to the general behavioral recommendations and to the statements (e.g. indication, dosage) for the use of the anthroposophic remedy Bryonia/Spongia comp. The recommendations for the anthroposophic remedy Larynx/Apis comp. and for the external applications obtained 94.6 % consensus (26/27 experts).

3.3. Experts' objections to recommendation

One expert disagreed with the recommendations for Bryonia/Spongia comp. because he had no experience with it, and additionally he stated that a symptom complex was missing which differs from that of

Table 2
Response rate and expert characteristics.

	Round 1	Round 2	Round 3
Response rate	N = 20; 30.8 %	N = 16; 24.6 %	N = 28; 43.1 %
Physicians…			
working at a hospital	N = 9; 45.0 %	N = 7; 43.7 %	N = 18; 64.3 %
working in a practice	N = 10; 50.0 %	N = 9; 56.3 %	N = 6; 21.4 %
working at a hospital and in a practice	N = 0; 0.0 %	N = 0; 0.0 %	N = 1; 3.6 %
working somewhere else in the medical field	N = 1; 5.0 %	N = 0; 0.0 %	N = 3; 10.7 %
working in Germany	N = 19; 95.0 %	N = 15; 93.8 %	N = 25; 100.0 %
working in another European country	N = 1; 5.0 %	N = 1; 6.3 %	N = 0; 0.0 %

Spongia sp. (another anthroposophic remedy).

Regarding the recommendation of external applications, one expert considered that lavender oil should only be used as prophylaxes and not in acute situation because of the essential oils.

3.4. Clinical recommendation

In the following, we present the statements for the different topics of our clinical recommendation for the supportive anthroposophic therapies for pediatric pseudocroup. Appropriate consensus assessments are stated.

3.4.1. General behavioral recommendation for the treatment of pseudocroup (100 % consensus)

- Calm the child and take the fears away
- Supply cool air to the child, e.g., by opening the windows or by taking a walk. Please ensure that the child is kept warm.
- Moreover, humid air can provide relief, e.g., by letting the hot water of the shower run (NB: Risk of scalding!)

3.4.2. Recommendation of anthroposophic drug therapy

Bryonia/Spongia comp. (100 % consensus).

(Active substances: Apis mellifica Dil. D3, Belladonna Dil. D3, Bryonia Dil. D3, Spongia Dil. D3; distributed by Weleda [15]).

The anthroposophic remedy Bryonia/Spongia comp. is recommended as acute medication as well as a prophylaxis for the treatment of pseudocroup particular for symptoms such as hoarseness, cough and stridor. In acute situations, the following dosages are recommended:

Infants: 3 drops diluted in a little water.

Young children: 5 drops diluted in a little water.

School children: 5 - 10 drops in a little water.

Remedy should be administered every 15 min up to hourly.

As preventive therapy 10–30 drops of Bryonia/Spongia comp. diluted in a glass of water can be drunk during the day.

Larynx/Apis comp. globuli (96.4 % consensus).

(Active ingredients: Apis mellifica ex animale toto Gl Dil. D16, Bryonia cretica ferm 33b Dil. D14, Larynx bovis Gl Dil. D16, Levisticum officinale e radice ferm 33c Dil. D14, Nervus laryngeus recurrens bovis Gl Dil. D16, Nervus laryngeus superior bovis Gl Dil. D16, Nervus vagus bovis Gl Dil. D16; distributed by WALA Heilmittel [16]).

The anthroposophic remedy Larynx/Apis comp. are recommended as acute medication as well as a prophylaxis for the treatment of pseudocroup, particularly for symptoms such as hoarseness, cough and stridor. In acute situations, the following dosages are recommended:

Infants: 3 globuli.

Young children: 5 globuli.

School children: 5 −10 globuli.

Remedy should be administered every 15 min.

As preventive therapy, Larynx/Apis comp. globuli can be given 3 - 5 times daily.

3.4.3. Recommendation for anthroposophic non-drug therapy

External application (96.4 % consensus).

For external application, embrocation of the chest with lavender oil is recommended.

4. Discussion

For a long time, it was assumed that guidelines and the personalized fundamental idea of AM did not fit. However, here we demonstrated again that the development of consensus-based guidelines is also possible in AM. We have already developed guidelines for the anthroposophic therapies to treat gastroenteritis and bronchitis in children[17,18]. The symptom-related use of specific anthroposophic remedies and external applications facilitates the development of general therapy recommendations. This is reflected by the high consensus ratings obtained in our Delphi process. Interestingly, despite a large variety of different available anthroposophic remedies only two remedies were selected for recommendation. In the first round of the Delphi process experts also mentioned the anthroposophic remedies Aconit globuli, Bronchi Plantago globuli, Anis-Pyrit tablets, Cuprum aceticum, Bryonia/Aconitum globuli, Bryonia/Stannum globuli, Infludoron globuli, Infludo drops and Tartarus stibiatus as therapy option. However, in the second round only Bryonia/Spongia comp. and Larynx/Apis comp. were selected by at least 50 % of experts as recommendable remedies (Supplemental figure 1) and so fulfilled our criteria to be included in the draft of the recommendation, to which experts had to agree or reject. The reasons for the selection might be that they are the most effective remedies but the present clinical study situation does not allow us to draw any conclusions. More studies are necessary to address this issue and to develop an evidence-based guideline for the anthroposophic therapies to treat pseudocroup. Nevertheless, consensus finding processes such as the Delphi process are a common method for presenting expert opinions in the medical field, as is used for the development of S2k guidelines [13].

Moreover, at this point, for us it is a concern to underline that individual therapy decision according to the concept of AM should be preserved and that our guideline should supplement and not replace conventional therapy approaches.

As limitation of our guideline, we have to mention that it only reflects the opinion of a selected pool of physicians and that clinical study data investigating efficiency and safety of recommended therapies are lacking [19]. Also, clinical study data are insufficient for the recommended general interventions, e.g. breathing cold air [2,6]. In addition, most of the experts are German, so the availability of recommended drugs in other countries might be limited.

To sum up: for the first time we have successfully developed a consensus-based guideline for the anthroposophic therapies in children with pseudocroup. Nevertheless, more clinical studies are urgently necessary to investigate safety and efficiency of AM therapies for pseudocroup. As a first step, we are carrying out case series studies in two German anthroposophic children' hospitals to assess feasibility and efficiency of recommended AM therapies.

Ethics approval

This study was performed in line with the principles of the Declaration of Helsinki.

The ethics application for this survey was approved by the ethics commission of the University of Witten/Herdecke (179/2016).

Author Contributions

All authors contributed to the study conception and design. The Delphi process was conducted and analyzed by Melanie Schwermer. Data were checked on completeness and correctness by Tycho Zuzak and Alfred Längler. The first draft of the manuscript was written by Melanie Schwermer, and all authors commented on previous versions of the manuscript. All authors read and approved the final manuscript.

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Author statement

All authors confirm that they have seen and approved the final version of the manuscript "Consensus-based guideline for the supportive anthroposophic therapies to treat children with pseudocroup (stenosing

laryngotracheitis)".

The authors ensure that the article is the authors' original work, has not received prior publication and is not under consideration for publication elsewhere.

Moreover, the authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

CRediT authorship contribution statement

Tycho Zuzak: Writing – review & editing, Project administration, Methodology, Funding acquisition, Conceptualization. **Alfred Längler:** Writing – review & editing, Supervision. **Melanie Schwermer:** Writing – original draft, Methodology, Investigation, Formal analysis, Conceptualization.

Declaration of Competing Interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing interests: Tycho Zuzak reports financial support was provided by Mahle Foundation. Tycho Zuzak reports financial support was provided by Christophorus Foundation. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supporting information

Supplementary data associated with this article can be found in the online version at doi:10.1016/j.ctim.2024.103072.

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