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GUIDELINE

Congenital nasolacrimal duct obstruction: clinical guideline

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Abbreviations

CDC	Congenital dacryocystocele
CNLDO	Congenital nasolacrimal duct obstruction
CQ	Clinical question
CT	Computed tomography
MINDS	Medical information network distribution service
MRI	Magnetic resonance imaging
PICO	Population, intervention, comparison and outcomes
RCT	Randomized controlled trial
SR	Systematic review

Preface

Congenital nasolacrimal duct obstruction (CNLDO) is the membranous obstruction of the opening of the nasolacrimal duct into the nasal cavity (Hasner valve) [1]. It occurs in 6–20% of newborns and is the most frequent lacrimal passage disease in infants [1]. It tends to spontaneously resolve by itself, with 96% of patients recovering spontaneously by the age of 1 year [2]. The standard treatment approach advocates initial application of conservative measures, with surgical intervention (probing) reserved for instances whenever there is no spontaneous resolution, except in cases of acute dacryocystitis or prolonged blepharitis.

Recently, a randomized controlled trial (RCT) [3] and a Cochrane systematic review [4] investigated the timing of probing, which highlighted the need to review treatment policies. In Japan, dacryoendoscopy has enabled visualization during dacryoendoscope-assisted probing in CNLDO cases [5]. Conventional dacryoendoscopes involve a straight-type probe, but in Japan, a bent-type probe has been developed, which improves probe treatment performance [5, 6]. Moreover, dacryoendoscope-based testing and treatment are reimbursed by national health insurance in Japan. However, there are no guidelines on the use of dacryoendoscopy for treatment, timing of surgical treatment, and the treatment options for cases of unsuccessful initial blind probing.

The Committee, organized by the Japanese Society of Lacrimal Passage and Tear Dynamics, was tasked with examining the current state of clinical diagnosis and treatment for CNLDO and congenital dacryocystocele (CDC), utilizing the Medical Information Network Distribution Service (Minds) format.

In 2019, Japanese Society of Lacrimal Passage and Tear Dynamics established the Committee for Congenital Nasolacrimal Duct Obstruction Clinical Guideline, which published Congenital Nasolacrimal Duct Obstruction: Clinical Guideline in Nippon Ganka Gakkai Zasshi, 2022;126(11):991-1021 (in Japanese). This is the English version of that Guideline. The original work is at https://www.nichigan.or.jp/Portals/0/resources/member/guideline/nasolacrimal_obstruction.pdf.

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		Summary of this guideline	
No of CQ	CQ	Summary and recommendation	Strength of recommendations
Important clinical issue 1: conservative treatment options			
1	Is lacrimal sac massage recommended?	Lacrimal sac massage may promote resolution as the a pressure massage pushes the lacrimal sac contents toward the lower end of the nasolacrimal duct (Crigler method). There is no sufficient proof of its effectiveness, but it can be done at home; thus, there are no costs involved. Moreover, there are no reports of clear negative effects; its implementation is suggested, whenever possible.	Implementation suggested
2	Is topical antibiotic administration recommended in conservative treatment?	The topical administration of antibiotics does not promote resolution; it alleviates ocular discharge and mucopurulent secretion. However, there is a potential for the emergence of resistant bacteria; thus, whereas long-term use should be avoided, its administration should be recommended only when necessary.	Implementation suggested
Important clinical issue 2: Spontaneous resolution rate and timing of surgical treatment			
3	Is surgical intervention recommended for patients with congenital nasolacrimal duct obstruction (CNLDO) aged 6–15 months?	Probing under local anesthesia of patients aged around 6–9 months rather than waiting until after 1 year of age and then probing under general anesthesia is proposed for surgical intervention for unilateral CNLDO. It was impossible to determine which timing was better for bilateral cases.	Implementation suggested.
Important clinical issue 3: indications for dacryoendoscope as a surgical instrument			
4	Is a dacryoendoscope recommended for the treatment of CNLDO?	The use of dacryoendoscope is proposed for the probing of CNLDO. However, considering the high spontaneous resolution rate of CNLDO and the extremely limited number of facilities where dacryoendoscopy can be conducted on children, its use is proposed depending on the situation.	Implementation suggested
Important clinical issue 4: treatment options for unsuccessful initial blind probing			
5	Is additional blind probing (regardless of anesthesia method) recommended for patients with an unsuccessful initial blind probing?	It is suggested that additional blind probing (regardless of anesthesia method) should not be conducted in patients with an unsuccessful initial blind probing.	Non-implementation suggested
Important clinical issue 5: amblyopia risk of CNLDO			
6	Should consideration be given to the risk of amblyopia in patients with CNLDO?	It was not possible to judge whether CNLDO was a factor in amblyopia, hence, it is uncertain whether special attention should be given to amblyopia; however, it is recommended that comprehensive ophthalmic examinations be conducted to the extent possible, keeping in mind the possibility of amblyopia.	Implementation recommended
Important clinical issue 5: Congenital dacryocystocele (CDC) diagnosis and treatment			

		Summary of this guideline	
7	Is surgical treatment indicated for CDC?	CDC should be carefully monitored in the early postnatal period because although the majority of cases can spontaneously resolve, serious complications such as acute dacryocystitis, cellulitis, and respiratory and breastfeeding problems are possibilties. Early surgical treatment should be considered if serious complications are observed; this treatment may involve transnasal marsupialization, probing, or a combination of the two.	Implementation suggested

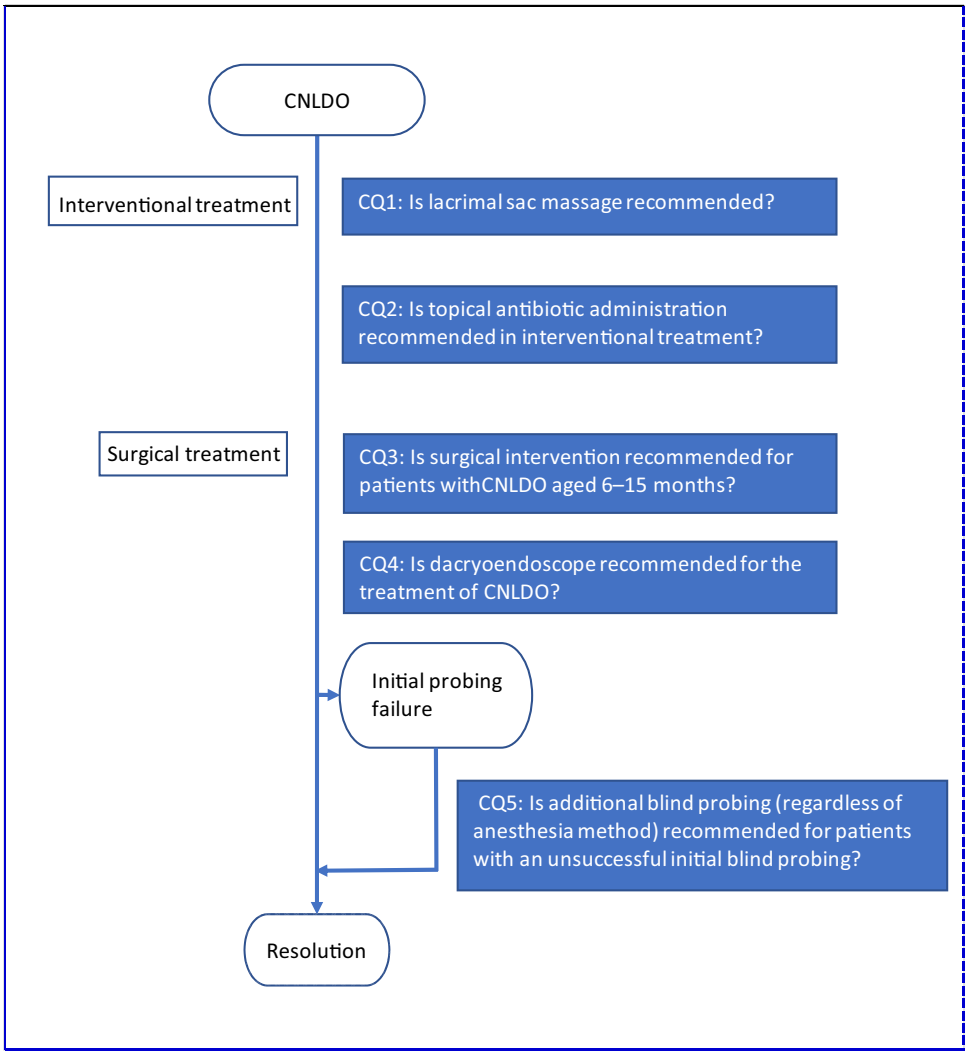
Chapter 1

How to read recommendations and explanations

Overall guideline

In these clinical guidelines, we aimed to present recommendations using evidence based on the Medical Information Network Distribution Service (Minds) format [7]. We addressed the recommendations in the form of CQs and presented the recommendations based on SRs (see below). Important issues not suitable for SRs were presented as reviews based on literature search.

Clinical algorithm



CQ

CQs are based on important clinical issues. In these guidelines, a total of seven CQs were set: five items related to treatment and one each on amblyopia risk and CDCs as a related disease.

Recommendations The recommendations are responses to the CQs, prepared based on the SR results, considering the strength of evidence regarding both the outcomes and the balance between benefits and possible damage. The two critical outcomes in the treatment were the resolution rate and complications.

Strength of recommendation The strength of each recommendation was determined by the clinical guidelines' establishment group. As a rule, the following four implementation categories were used: (1) implementation recommended, (2) implementation suggested, (3) non-implementation suggested, and (4) non-implementation recommended.

Strength of evidence for CQs

The evaluated evidence strength for each outcome (body of evidence) was consolidated, and a summary of the body of evidence for the CQ is presented. Overall strengths of the evidence were established in relation to the treatment outcomes:

A (Strong): Strong confidence
B (Moderate): Moderate confidence
C (Weak): Limited confidence
D (Very weak): Almost no confidence

Explanation

The process preceding the presentation of the recommendation, overview of SR reports, and summary were based on the CQ. The references consulted during the preparation are described. The selected references only include a small number of randomized controlled trials (RCT), whereas other references are also incorporated. A quantitative SR was determined to be difficult owing to the small number of RCTs; instead, qualitative SRs were created.

Concerning treatment, four categories: resolution rate, complications, cost-effectiveness, and "patient preference are described. The level of evidence and risk of bias of the papers incorporated in the SR are explained. The strength of evidence on overall outcomes for CQs was evaluated.

Chapter 2

Preparation policy and process

I. Preparation policy

These clinical guidelines were created to assist medical professionals, patients, and other parties involved in the decision-making process during the management of congenital nasolacrimal duct obstruction (CNLDO) in both diagnosis and treatment. Guideline preparation followed the Minds format [7] to the extent possible, with attention given to impartiality, rigor, and transparency throughout the guidelines' preparation process.

II. Precautions

These guidelines are intended to support the decision-making of healthcare professionals in clinical practice but do not oblige them to follow the recommendations. Actual decisions should be made jointly by the attending physician and patient, considering the deployment status of medical equipment, experience of the physician, patient's condition, and costs.

The recommendations in the guidelines do not guarantee that patient outcomes will necessarily improve if medical decisions are made following them. Additionally, these guidelines are not intended to be used for medical lawsuits, and the committee for CNLDO clinical guidelines bears no responsibility whatsoever for the results of any decisions made in medical practice based on these recommendations.

III. Organizational structure

The Supervisory Board for CNLDO Clinical Guidelines consists of four ophthalmologists nominated by the directors and board of the Japanese Society of Lacrimal Passage and Tear Dynamics.

CNLDO Clinical Guideline Preparation Team consists of seven ophthalmologists (including the four supervisory board members) selected by the CNLDO clinical practice guideline's supervisory board.

SR Team: Comprising 12 ophthalmologists (including the aforementioned 7 members) selected by the CNLDO clinical practice guidelines' supervisory board.

IV. Preparation Process

1. Main entities and implementation schedule

The SRs were conducted by an SR team.

Literature search: May 2020 to December 2022

Literature screening: May 2020 to December 2022

Evaluation of the body of evidence and synthesis: June 2021 to December 2022

2. 2. Search for evidence

a. Evidence type

Existing SRs, meta-analyses, and individual research papers were examined in the following order of priority: RCTs, non-RCTs, observational studies, and case series studies.

b. Database

PubMed, Cochrane Library, and Ichushi Web were used. Additional references, such as cited references, were added by manual search whenever necessary.

c. Basic search policy

Literature search was conducted by The Japan Medical Library Association. Meetings were held with librarians and the clinical guideline creation group to prevent omissions. For each CQ, the essential entries were listed, and a search formula that included all the literature was created. The target languages were English and Japanese.

3. Literature inclusion and exclusion criteria

Whenever existing clinical guidelines and SR met the inclusion criteria, they were given priority. Additionally, for all CQs, an SR was conducted independently for individual research papers (de novo SR). In the SR, priority was given to RCTs that met the recruitment criteria, and observational studies were included whenever there were either no or few RCTs. Qualitative SRs were conducted for CQs for which only case series and case reports were available.

4. Evidence evaluation and integration method

The strength of the body of evidence was evaluated based on the policy of the Minds Manual for Guideline Development 2020 ver. 3.0 [7]. To summarize:

a. Conduct a systematic literature search based on PICO.

b. Compile a collection of studies based on title and abstracts (primary screening) and subsequently by secondary screening (selection according to evaluation of full text), based on explicit criteria for each combination of interventions/exposure and outcomes. Make a list of studies excluded by secondary screening, with reasons for exclusion.

c. Perform qualitative evaluation of individual studies for each outcome and compile the results of evaluation by the combination of intervention/exposure, outcome, and study design. At this time, the indirectness of PICO should be evaluated, and comments should be recorded (Qualitative SR).

d. Evaluate the body of evidence and determine the strength of evidence.

e. Compile the results of SRs in the SR report, and submit the report to the CNLDO clinical guideline preparation team.

V. Development of recommendations, finalization, and publication to post-publication

1. Development of recommendations

Recommendations were determined by the guideline preparation team. Recommendations and their strengths were decided after considering the following factors: strength of evidence, balance of benefits and drawbacks, as well as other factors, such as "parents' ethical or religious principles, preferences, and possible difficulties, and health care cost-effectiveness. In evaluating whether the net benefits outweigh the net disadvantages, the balance (possible harm, burden, and cost) will be assessed by adding the burden and the cost. Possible harm, such as adverse reactions or events, would include any negative event that occurs unintentionally. An anticipated negative event would include visiting a hospital or hospitalization, surgical operation and accompanying pain, operative scars, and loss of function. The recommendations were decided by (1) a two-thirds majority vote of the guideline members; (2) adoption results will be presented at academic meetings, and (3) the voting results will be published.

2. Finalization

In February 2023, the initial draft underwent peer review by members of the guideline preparation team. Following its completion in the same month, the draft received approval from the supervisory board. Concurrently, external evaluations were conducted using the Appraisal of Guidelines for Research & Evaluation Instrument II [8] from Minds. These evaluations, presented in an open-ended format, were sought from the external evaluation committee and the Journal of Japanese Ophthalmological Society guideline editorial committee. The objective was to assess the clinical guidelines' applicability across diverse clinical settings. Public comments aimed to incorporate the perspectives of parents and the general public were also sought. The guidelines' preparation team deliberated on the outcomes of the external evaluations and public comments, determined responses, and incorporated them in the final version.

3. Publication schedule

Following the external evaluation and responses to public comments, the clinical guidelines' supervisory board made a final decision on the publication with the approval of the chairman of the Japanese Society of Lacrimal Passage and Tear Dynamics.

4. Post-publication activity

A questionnaire survey on usage and evaluation at related societies (Japanese Society of Lacrimal Passage and Tear Dynamics and Japanese Association of Pediatric Ophthalmology etc.) was planned. The next revision is scheduled for 5 years from 2024.

The method for the next revision will be decided based on the evaluation of the present guidelines. A partial interim revision will be considered if important evidence or information is obtained before the next scheduled revision.

Chapter 3

Basic features of CNLDO

I. Clinical features

1. Pathology

CNLDO is defined as a "congenital membranous obstruction at the nasal end of the nasolacrimal duct" (Fig. 1) [1]. There is a high rate of spontaneous resolution, reaching 96% at up to 12 months of age, as reported in a large population-based study [2]. CDC, on the other hand, is characterized by the combination of CNLDO and obstruction of the common lacrimal canaliculus, resulting in a mucocele in the lacrimal sac and nasal cavity. This is a subtype of CNLDO. (refer to CQ7 for details on CDC).

2. Symptoms

Typical symptoms include persistent lacrimation and mucopurulent discharge emerging within the first month of life. While antibacterial eye drops may provide temporary relief by reducing eye discharge, the recurrence of symptoms is common upon discontinuation of the eye drops [1]. Complications such as conjunctivitis and blepharitis may arise.

II. Epidemiological features

Affecting 6–20% of newborns, this condition is the most prevalent lacrimal passage disease in infants, with no gender or laterality distinctions [1].

III. Overall flow of medical treatment

1. Diagnosis

a. medical interviews and course

CNLDO manifests with symptoms of eye discharge and lacrimation that typically begin shortly after birth. If the onset occurs after 3–4 months of age, consideration should be given to the possibility of acquired lacrimal duct obstruction. In such cases, it is advisable to interview the guardians regarding their history of conjunctivitis (e.g., epidemic keratoconjunctivitis).

b. Inspection and palpation

The eyes of patients with CNLDO often exhibit tearing and discharge, with a high tear meniscus and wet eyelashes (Fig. 2a). Patients with blepharitis are often observed. Nasolacrimal duct obstruction can be diagnosed when the mucopurulent backflow from the lacrimal punctum is observed by applying digital pressure on the lacrimal sac.

c. Inspection

It is difficult to diagnose lacrimal passage disease in infants. Initially, a hand hold slit-lamp microscopy should be considered. A fluorescent dye retention (disappearance) test is often conducted as a non-invasive test for examining tear drainage patency [1]. The fluorescent dye is instilled into the palpebral conjunctiva. If fluorescence does not disappear from the tear meniscus within 15 min, tear drainage failure (lacrimation failure) can be diagnosed (Fig. 2b).

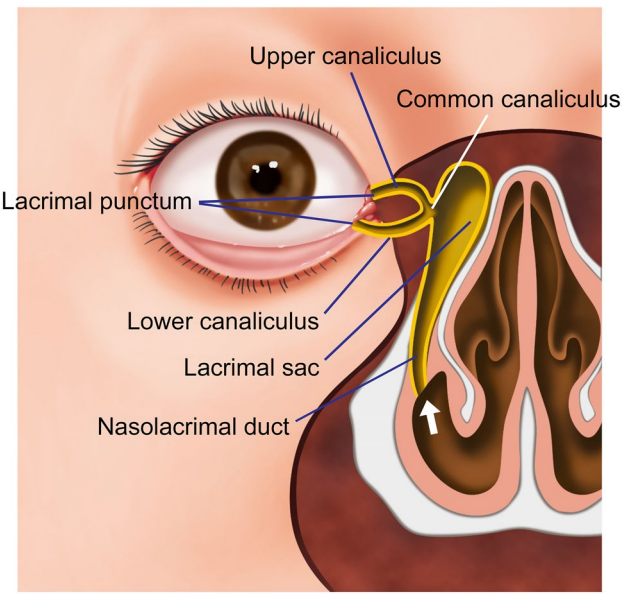


Fig. 1 Schematic representation of the right nasolacrimal duct: the site of congenital nasolacrimal duct obstruction (CNLDO) is at the lower end of the nasolacrimal duct (indicated by an arrow), with a typical example being a membranous obstruction.

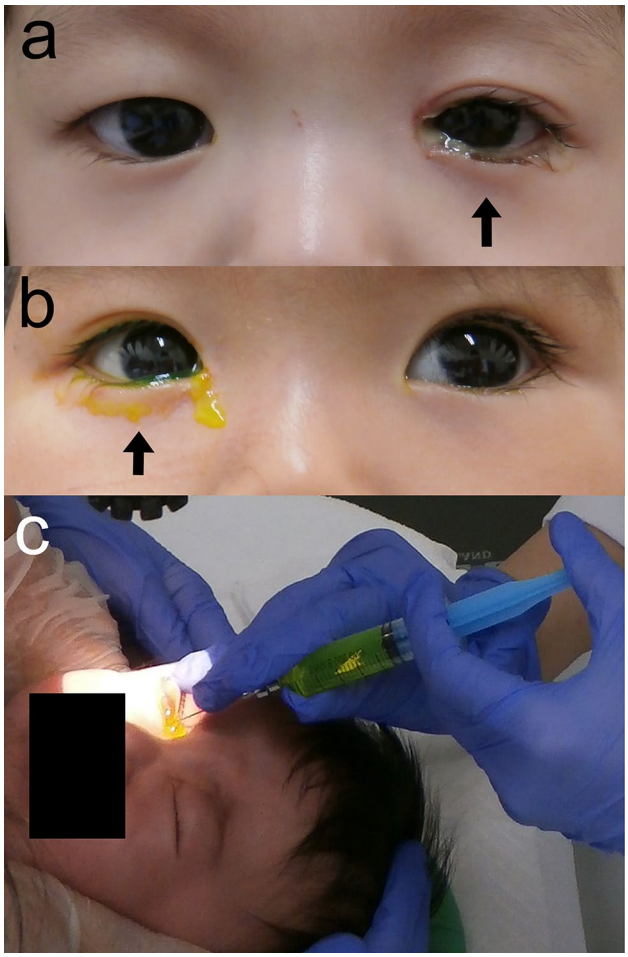


Fig. 2 Case of an infant with CNLDO. **a** Eye discharge, lacrimation, and blepharitis OS (arrow). **b** Fluorescein retention test findings for left-right CNLDO: appearance after applying fluorescein dye to both palpebral conjunctiva, letting it sit for 15 minutes. The dye has disappeared in the healthy left eye but remains in the right eye with CNLDO (arrow). **c** Lacrimal irrigation in CNLDO: the child's body is wrapped in a bath towel, and a caregiver stabilizes the child's face to prevent movement. The eye is then irrigated from the lacrimal punctum to verify if saline reaches the nasal cavity and throat. In cases of CNLDO, no fluid will pass through to the nasal cavity, and there will be a mucopurulent backflow from the lacrimal punctum.

CNLDO can be ruled out if the fluorescent dye reaches the nasal secretion owing to the patency of the lacrimal duct.

Lacrimal irrigation is a diagnostic test for lacrimal duct obstruction involving the gentle insertion of lacrimal cannula into either the upper or lower lacrimal punctum. This procedure is conducted after applying topical anesthesia eye drops and subsequently injecting saline into the lacrimal duct. In pediatric cases, this procedure is considered invasive as it involves manually securing the patient's head and immobilizing the body with a wrapped bath towel. Lacrimal duct obstruction can be diagnosed if there is no passage of saline into the nasal cavity and mucopurulent backflow (Fig. 2c).

Considering the following differential diagnoses and complications as strabismus and amblyopia, it is desirable to observe the anterior segment using a cover test, refraction test, and slit-lamp test; however, as infants often cry, tests may prove difficult.

d. Differential diagnosis

Keratoconjunctivitis (infectious or allergic), entropion of the eyelashes, and congenital glaucoma should be differentiated as representative diseases causing epiphora in children.

2. Treatment

According to a large population-based study the spontaneous resolution rate of CNLDO was 96% up to 12 months of age [2]. Unless the symptoms of severe blepharitis or acute dacryocystitis are observed, observations are often conducted for a certain period. Gently wiping off eye discharge with wet soft tissue is recommended during the observation period. Antibacterial eye drops are administered when eye discharge is severe and constant. Moreover, lacrimal sac massage is reported to increase the rate of resolution. These cases are summarized in CQ1 and CQ2.

Surgical treatment is conducted when the above-mentioned measures fail to resolve within an established period. The first-line surgical treatment is nasolacrimal duct probing, with a probe carefully inserted into the lacrimal duct through the punctum to rupture the membranous obstruction (Fig. 3a). This treatment is often effective; however, there is some controversy about its timing and method [3, 4]. The use of general anesthesia is often necessary for treatment after the age of one, significantly influencing both the timing and method of treatment. Factors such as the presence of a lacrimal disease specialist and pediatric anesthesiologist, along with access to a dacryoendoscope, play a crucial role in determining when treatment can be administered, considering both human and non-human resources. Dacryoendoscopy, which enables probing under visual guidance, has been used in Japan in recent years, and good outcomes are reported [5, 6] (Fig. 3b). Indications, techniques, and timing of surgical treatment are summarized in CQ3, CQ4, and CQ5.

IV. Items related to contents covered by the clinical guideline

1. Ttile

CNLDO: clinical guidelines

2. Purpose

To improve the following:

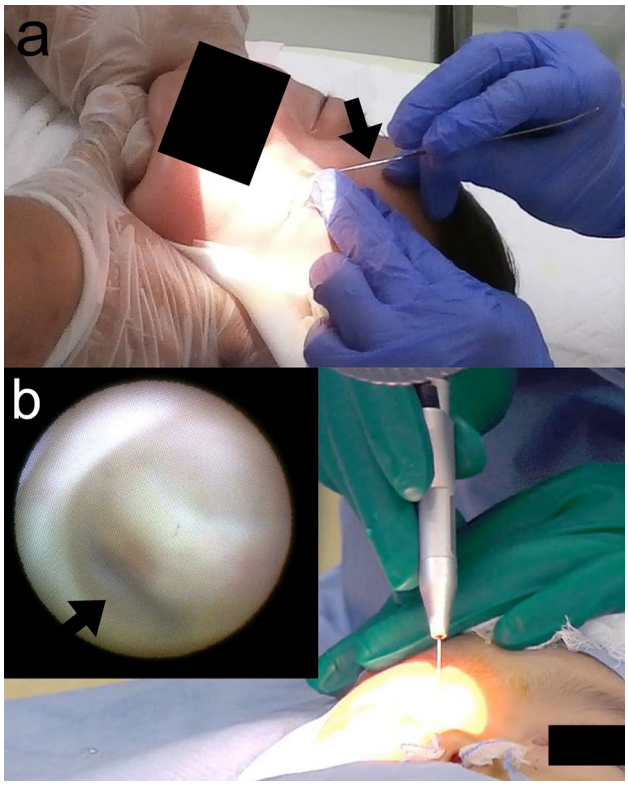


Fig. 3 Surgical treatment of CNLDO. **a** Nasolacrimal duct probing with a bougie (probe): insertion of a wire-like device called a bougie (arrow) through the lacrimal punctum to blindly locate and puncture the obstruction site. **b** Visual probing using dacryoendoscope: observation and probing of the site of CNLDO using a dacryoendoscope. The image in the upper left black circle is the dacryoendoscope view. The area resembling a dark streak represents the obstruction site (arrow). The membranous obstruction in this area is punctured and opened for treatment.

- Diagnosis of CNLDO
- Conservative treatment
- Timing of probing
- Method of surgical treatment and the need for repeated surgery
- Relationship between CNLDO and visual function
- Diagnosis and treatment of CDC

3. Topics

Diagnosis and management of CNLDO and CDC

4. Anticipated users, facilities, and medical sites where indications are anticipated

Obstetricians, pediatricians, otolaryngologists, plastic surgeons, public health nurses, midwives, general ophthalmologists, ophthalmologists in regional core hospitals or university hospitals, parents or guardians of patients

5. Important clinical issues

a. Interventional treatment options

There is controversy on whether antibiotic eye drops should be used in follow-up observations of CNLDO, and if so, for how long they should be used. Lacrimal sac massage toward the lower end of the nasolacrimal duct (Crigler method) reportedly promotes healing. However, there is controversy regarding its efficacy, safety, and duration.

b. Spontaneous resolution rate and timing of surgical treatment

Considering the high spontaneous resolution rate, the common worldwide policy for CNLDO in children less than six months old is conservative treatment. The timing of surgical treatment (mainly probing), whether it is better to conduct the procedure under local anesthesia when the patient is aged around 6–12 months or to wait until the patient is one year old and to conduct the procedure under general anesthesia are issues that have been investigated in terms of treatment outcomes and cost-effectiveness; however, no definitive results have been established.

c. Indications for dacryoendoscope as a surgical instrument

A dacryoendoscope enables visualized probing, and good consequent treatment outcomes are reported i both in Japan and overseas. Surgery using dacryoendoscope is a relatively new treatment that has been covered by the national health insurance since 2012, and has become popular mainly in Japan. There are no established methods and indications for children, and the number of surgeons and facilities is, at the moment limited.

d. Treatment options for unsuccessful initial blind probing

Probing usually is successful. However, occasionally probing is unsuccessful. In such cases, treatment options include blind re-probing, insertion of a lacrimal tube, and probing using a dacryoendoscope. Deciding which of these treatment is appropriate is, as yet undetermined.

e. Amblyopia risk of CNLDO

It is unclear whether CNLDO affects visual function in children. Some reports indicate that it does, whereas some indicate no connection between CNLDO and amblyopia. However, the evaluation of visual function in infants is difficult, and there are growth related changes; thus, the effect on visual function development is undetermined.

f. CDC diagnosis and treatment

CDC is seen in newborns, and in some cases prenatal ultrasonography established CDC. The disease is often diagnosed by obstetrics, neonatology, and pediatric

departments; however, since it is a relatively rare disease diagnosis and treatment can be difficult. Various names are used for the disease, including CDC, congenital lacrimal hernia, nasolacrimal cyst, and neonatal dacryocystitis. Therefore, the terminology, pathophysiology and treatment of CDC should be established; and not only ophthalmologists, but also obstetricians, pediatricians, otolaryngologists, and midwives should be informed.

6. cope of the guideline

Pediatric patients diagnosed with CNLDO or CDC without facial anomalies.

7. List of CQs

CQ1: Is lacrimal sac massage recommended?
CQ2: Is topical antibiotic administration recommended in conservative treatment?
CQ3: Is surgical intervention recommended for patients with CNLDO aged 6–15 months?
CQ4: Is a dacryoendoscope recommended for the treatment of CNLDO?
CQ5: Is additional blind probing (regardless of anesthetic method) recommended for patients with an unsuccessful initial blind probing?
CQ6: Should consideration be given to the risk of amblyopia in patients with CNLDO?
CQ7: Is surgical treatment indicated for CDC?

Chapter 4

Recommendations

CQ1: Is lacrimal sac massage recommended?

Recommendation

Lacrimal sac massage may promote resolution as the pressure pushes the lacrimal sac contents toward the lower end of the nasolacrimal duct (Crigler method). There is no sufficient proof of its effectiveness, but it can be done at home; thus, there are no costs involved. Moreover, there are no reports of clear negative effects; Its implementation is suggested, whenever possible.

Strength of recommendation Implementation suggested.

Strength of evidence for CQ C

1. Incidental items to recommendation

Lacrimal sac massage refers to pressure massage that pushes the lacrimal sac contents toward the lower end of the nasolacrimal duct (Crigler method) (Fig. 4) [9]. In the Crigler method a finger is placed on the lacrimal sac, and pressure is applied toward the lower end of the nasolacrimal duct so that the lacrimal sac contents do not come out of the punctum (Fig. 4). This is done 2–4 sets per day to 5–10 times per set (10–40 times per day, number of times varies depending on the report). There are reports that this pressure massage promotes resolution; however, two RCTs report that simple massage by pressing the lacrimal sac with a finger does not improve the resolution rate [10, 11]. Instructions on the correct technique (Crigler method) are necessary when proposing the massage to parents.

2. Background/purpose

CNLDO is characterized by a high spontaneous resolution rate; therefore, initial follow-up observations are conducted, except in some severe cases. To date, the lacrimal sac massage has been widely recommended

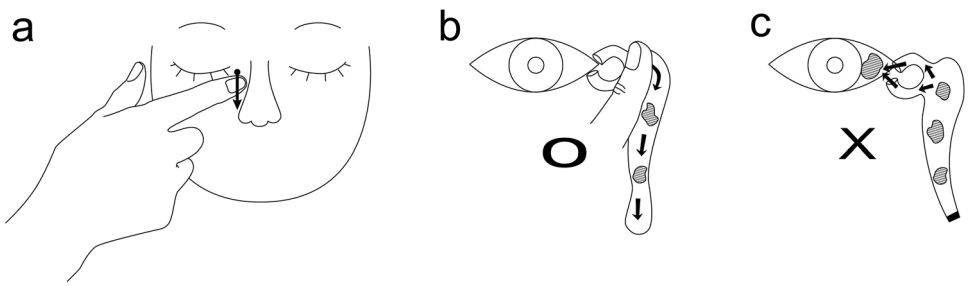


Fig. 4 Lacrimal sac massage technique (Crigler method). **a** Massage technique: Begin by washing your hands and placing a clean finger slightly inside the medial corner of the eye, over the lacrimal sac. Gently massage the contents of the lacrimal sac in a manner that pushes them towards the nose (foot side, indicated by the arrow). Perform 5–10 massage strokes, constituting one set. If the skin reddens or discomfort is manifest, discontinue and consult an ophthalmologist. **b** Correct massage: Ensure the contents of the lacrimal sac are pushed toward the feet without pushing them toward the eyeball. **c** Incorrect massage: When the contents of the lacrimal sac flow back toward the eyeball, gentle inward pressure near the lacrimal sac is considered ineffective

for parents in settings such as obstetric, pediatric, and ophthalmology departments and public health centers to promote resolution during follow-up observations. However, the correct massage method (Crigler method) has not always been consistently taught, and the efficacy of the massage remains unclear. Considering this background, when recommending the massage, guidance on the correct method and demonstration of its effectiveness should be applied.

3. Explanation

Two intervention studies as the main studies, and five additional observational studies were studied to consider whether lacrimal sac massage increases the resolution rate. The age of the target patients in each report varied. The spontaneous resolution rate of CNLDO decreases with age; hence, it was difficult to compare studies with patients of different ages. All these reports applied the Crigler method; however, the number of implementation times as instructed varied, ranging from 2–4 sets per day to 5–10 times per set (10–40 times per day) [9–16]. None of the reports evaluated the actual number and duration of the massage, and what these numbers and durations should be is still unclear. In two RCTs, the control group was a simple massage group in which the lacrimal sac area was lightly pressed, and both reported that the resolution rate was significantly higher in the Crigler method group than in the simple massage group [10, 11]. An RCT conducted by Kushner et al. [10] involved dividing 175 patients (mean age of seven months) into three groups, with resolution rates of 30.5% in the Crigler method group, 8.6% in the simple massage group, and 6.9% in the non-massage group, with only the Crigler method group showing significantly higher resolution rates. An RCT conducted by Shivpuri et al. [11] divided 66 patients (mean age of two months) into the Crigler method and simple massage groups, with 33 patients each, and reports that the resolution rates were 91% for the Crigler method group and 21% for the simple massage group, with the Crigler method group showing a significantly high-resolution rate. There were only two interventional studies, both of which were published over 25 years ago with high risks of bias, such as no mention of randomization or concealment. Thus, the effect of lacrimal sac massage (Crigler method) could not be sufficiently confirmed based on these two studies. However, the results of both studies agreed that the Crigler method increased the resolution rate compared to simple massage, hence there was no problem with consistency.

The ages in months of the patients studied for differences in responses depending on age, greatly varied, and many reports did not record the number of patients by age in months. The results of lower ages in months resulting in higher resolution rates are consistent [9–16]; however, these results are similar to the report of MacEwen et al. [2], in which the natural course of the disease was prospectively observed without applying massage. Therefore, it cannot be said that the effectiveness of the massage was demonstrated.

The actual rate of massage implementation and its feasibility was also examined. The number of massages reported in each study varied. All the reports state that "massage was applied until either resolution was accomplished or surgical intervention was performed," and there was a large variation in the implementation period and frequency, with no examination of the implementation status. Thus, evaluation was difficult.

The two intervention studies [10, 11] and five observation studies [12–16] did not report any negative effects or complications resulting from lacrimal sac massage. In the meantime, cases have been reported of acute dacryocystitis and blepharitis developing concurrently during follow-up observations while lacrimal sac massage was being performed, and surgical treatment was not pursued [14]. This, however, is considered to be a complication arising from follow-up observations without surgical intervention, and cannot be regarded as a direct negative effect of the massage itself. In terms of cost-effectiveness, lacrimal sac massage is easily implementable as it does not necessitate special equipment or incur additional costs, making it feasible for home use. In summary, lacrimal sac massage using the Crigler method may promote resolution, but the evidence supporting its effectiveness is insufficient. Differences in effect depending on age in months, as well as frequency and duration of its implementation. However, given the absence of special costs and the lack of reported significant negative effects, the perceived benefits outweigh potential harm. Therefore, we recommend considering implementation whenever feasible.

In this SR, there were only two interventional studies on the efficacy of lacrimal sac massage published over 25 years ago which have high risks of bias. Thus, future research based on the state of modern intervention research with Japanese participants must be conducted. Moreover, future studies must investigate the follow-up observation period, massage method, implementation status and frequency, differences in effect depending on age in months, and parents' values and wishes.

4. Recommendation decision process

The pre-determined adoption criteria were satisfied in the first round of voting; however, votes were held on whether or not to recommend revisions based on the supplementary literature outlined below.

5. Literature research

A literature search was conducted using the PubMed database (https://www.ncbi.nlm.nih.gov/pubmed/) (Last search date: December 28, 2022).

6. Explanation on the supplementary literature accompanying the search period lag in the Japanese version

In the supplementary literature search, two SRs (Mohney et al. [17] and Bansal et al. [18]) that met the adoption criteria were added. Both are indirect, have selection bias, detection, and execution bias; they were consistent in their conclusions that lacrimal sac massage using the Crigler method may be effective. Thus, there was no problem with consistency. Considering these, the level of evidence for the effectiveness of the massage was determined to be C.

CQ2: Is topical antibiotic administration recommended in conservative treatment?

Recommendation

The topical administration of antibiotics does not promote resolution; it alleviates ocular discharge and mucopurulent secretion. However, there is a potential for the emergence of resistant bacteria; thus, whereas long-term use should be avoided, its administration should be recommended only when necessary.

Strength of recommendation Implementation is suggested.

Strength of evidence for CQ C

1. Background/purpose

CNLDO typically manifests with ocular discharge and epiphora. The administration of antibacterial eye drops mitigates eye discharge, but symptoms often relapse upon discontinuation of treatment [1]. At the same time, long-term use of antibacterial eye drops may lead to the development of resistant bacteria. In this CQ, SRs were conducted on the following three points: does topical antibiotic administration (1) increase the CNLDO resolution rate, (2) decrease eye discharge and mucopurulent secretion from the lacrimal sac, and (3) result in the emergence of resistant bacteria. The purpose was to show the best form of application of antibacterial eye drops for CNLDO.

2. Explanation

No intervention studies addressing the effect of the administration of antimicrobial eye drops on the resolution rate that could be evaluated were found. Additionally, there was no evidence that antibacterial eye drops were the factor that increased the resolution rate, regardless of the difference in usage, such as administration only when needed or constant administration.

There were three papers on the bacterial isolation rate in the culture of lacrimal sac secretions from CNLDO. The bacterial isolation rate is reported to be 72–97% [19–21], and the bacterial isolation rate from secretions was high in all the reports. It is reported that 68% of cases with CNLDO had mucopurulent secretions [21]. The differences in the properties of secretions are reported as follows: mucous, 67%; mucopurulent, 21%; serous, 10%; purulent, 0.5%; and no secretion, 1.3%. Mucous secretions decreased with the use of ofloxacin eye drops [19]. There are no reports on the preventive effect of antibacterial eye drops on acute dacryocystitis.

Regarding the emergence of resistant bacteria associated with the administration of antibacterial eye drops. There are no direct reports of resistant bacteria in the lacrimal sac secretions in CNLDO. One RCT investigated changes in conjunctival flora following the use of antibacterial eye drops (levofloxacin hydrate eye drops) post-cataract surgery in adults [22]. The study reveals a significantly higher minimum inhibitory concentration of levofloxacin hydrate against Staphylococcus epidermidis three months after surgery in the one-month postoperative group compared to the one-week postoperative group. While this outcome suggests that prolonged use of antibacterial eye drops may contribute to the emergence of resistant bacteria, the overall certainty of the evidence was assessed as C due to low directness.

After considering the above benefits and harms, it is suggested that antibacterial eye drops reduce ocular discharge and mucopurulent secretions, although there is no evidence that they increase the CNLDO resolution rate. Long-term use should be avoided in consideration of the emergence of harmful resistant bacteria, and they should be used only when necessary, after considering the intensity of inflammation and the results of bacterial tests.

In this analysis, there were no RCTs or intervention studies on the use of antimicrobial eye drops for CNLDO; thus, the certainty of the body of evidence for this recommendation was judged to be C. Future research should include surveys on differences in the CNLDO resolution rate with and without antimicrobial eye drops and intervention studies that evaluate changes in symptoms and bacterial flora, as well as the presence or absence of resistant bacteria and parents' values and wishes.

3. Recommendation decision process

The pre-determined adoption criteria were satisfied in the first round of voting; however, votes were held on the

supplementary literature on whether or not to recommend revisions, and the pre-determined adoption criteria were satisfied.

4. Literature research

A literature search was conducted using PubMed (https://www.ncbi.nlm.nih.gov/pubmed/)
database (Last search date: December 28, 2022).

CQ3: Is surgical intervention recommended for patients with CNLDO aged 6–15 months?

Recommendation

Probing under local anesthesia of patients aged around 6–9 months rather than waiting until after 1 year of age and then probing under general anesthesia is proposed for surgical intervention for unilateral CNLDO. It was impossible to determine which timing was better for bilateral cases.

Strength of recommendation Implementation is suggested.

Strength of evidence for CQ C

1. Incidental items incidental items to recommendation

The surgical intervention in this CQ refers to probing. A certain amount of training is required, irrespective of the chosen anesthesia method.

2. Background/purpose

CNLDO tends to exhibit a strong inclination for spontaneous resolution, with 80–96% of patients resolving with conservative treatment at 12 months of age [23–25]. There is controversy over the optimal timing of surgical interventions such as probing in the absence of spontaneous resolution. The advantage of early probing is that it can be conducted with local anesthesia and the disease stage can be shortened, although the body movement of the patient needs to be controlled. A disadvantage is that surgical intervention is conducted even in cases where spontaneous resolution may occur, and it may not have been necessary. On the other hand, waiting until the age of 1 year for probing presents the advantage of expecting spontaneous resolution during that period, potentially reducing the need for surgical intervention. However, a disadvantage of delayed probing is the necessity of general anesthesia due to difficulty in controlling body movements in children over 1 year of age. Furthermore, there are associated burdens with general anesthesia, and only a limited number of surgeons and facilities can conduct lacrimal duct surgery under anesthesia for young children.

This CQ aims to provide a guideline for the optimal timing of probing and the judgment criteria, considering these various factors.

3. Explanation

Papers on the efficacy of probing for CNLDO, differences in the course depending on unilateral and bilateral cases, and timing of surgery included one Cochrane SR [4] and five multicenter RCTs [1, 3, 25–27].

Results of a study that observed 133 sides of 107 cases of CNLDO with no history of intervention at 6–9 months of age with only the conservative treatment of lacrimal sac massage and topical administration of antibiotics for six months [1] shows resolution in 66% of unilateral cases and 56% of bilateral cases. However, there were only 26 bilateral cases, and the sample size was small; thus, it was judged as having insufficient evidence.

An RCT with unilateral CNLDO cases aged 6–9 months without prior surgical intervention [3] conducted a comparative study between 82 patients who underwent outpatient probing under local anesthesia immediately after diagnosis (immediate probing group) and 81 patients who underwent conservative follow-up observations for six months and who underwent probing under general anesthesia if no resolution was observed (delayed probing group). For the immediate probing group, 69 out of 75 (92%) patients showed resolution at 18 months of age. In the delayed probing group, 58 out of 71 (82%) patients showed resolution at 18 months of age. Resolution during the six-month waiting period was observed in 44 out of 67 patients (66%), and 22 out of 81 patients (27%) subsequently underwent probing under general anesthesia. Comparison of both groups showed that the success rate at 18 months of age was 10 points higher in the immediate probing group than in the delayed probing group, but there were no significant differences.

There is a multicenter joint RCT in which 54 patients aged 6–9 months with bilateral CNLDO who had no history of surgical intervention were divided into immediate and delayed probing groups [26]. For the immediate probing group, out of 29 patients, 19 (66%) recovered bilaterally, while three (10%) recovered unilaterally. In the delayed probing group, out of 25 cases, 14 (56%) recovered bilaterally after only a six-month wait, five (20%) recovered unilaterally, and six (24%) did not recover on either side. Among the eight patients who did not recover during the waiting period and underwent probing, six (75%) recovered bilaterally, one (12.5%) recovered only unilaterally, and one (12.5%) did not recover on either side. A comparison of the rate of bilateral resolution showed that the delayed probing

group had a value that was 10 points higher, but there was no significant difference. This report has a small number of cases and high attrition bias; hence, it was judged as having insufficient evidence.

Another multicenter RCT [25] conducted a comparative analysis between a group for which probing was conducted under general anesthesia at 12–14 months of age (immediate general anesthesia probing group) and a group in which follow-up observations were conducted until 24 months of age (follow-up observation group). It resolution was observed in 29 out of 39 patients (74%) for the immediate general anesthesia probing group and 30 out of 50 patients (60%) for the follow-up observation group, and the immediate general anesthesia probing group had a higher recovery rate than the follow-up observation group. However, the certainty of the body of evidence was judged to be C because only some cases were selectively randomized, and the risk of bias was high.

A comparison of the treatment outcomes of the immediate probing of unilateral and bilateral cases from two RCTs [3, 26] showed that the bilateral cases (66%) had a lower resolution rate than the unilateral cases (92%). The reason for this was the patients' resistance for treatment to the second eye due to the long operation time and possibility of a tight procedure time. Consequently, the treatment outcomes may be better under general anesthesia in bilateral cases.

Only observational studies have been reported on waiting periods and probing treatment outcomes, but it is reported that treatment outcomes declined with age (1 year: 80–90%, 2 years: 73–84%, 3 years: 65–75%, 4–5 years: 63%) [28, 29]. Therefore, probing, which is a surgical intervention is thought to be a more rational treatment option than continuing conservative treatment.

In summary, a comparison of immediate probing and waiting for probing for cases of unilateral CNLDO at 6–15 months of age showed that the resolution rate at 18 months of age tended to be higher for the immediate probing cases. However, further research is needed for definitively determining which is better. There are few reports and small number of sample sizes for bilateral cases. Thus, it is difficult to make a judgment.

For comparisons of cost-effectiveness between the immediate and delayed probing groups, there is only one report regarding unilateral probing [3]. It is reported that the mean treatment cost in the immediate probing group was lower than in the delayed probing group, but it is unclear whether there was a meaningful difference. It is also unclear whether these results can be directly applied to treatment in Japan due to the different health insurance systems between the United States and Japan.

A satisfaction survey of 81 parents was published [30]. Among the participants, 92% of 50 participants who recovered, and 65% of the 17 participants who did not recover were satisfied with immediate probing; and 88% of the participants who recovered and 53% of the participants who did not recover responded that they preferred outpatient probing under local anesthesia rather than general anesthesia. Participants who were satisfied accounted for 90% of 47 unilateral cases and 64% of nine bilateral cases. Based on the above, there was a tendency for the satisfaction level to be higher for the outpatient immediate probing in recovered and unilateral cases.

Additionally, regarding the shortening of the disease period, the disease period in the immediate probing group was approximately three months shorter than that in the delayed probing group in unilateral cases [3].

Studies on complications due to probing, included five RCTs [1, 3, 25–27], one Cochrane SR [4], and two case series [14, 31]. None of the studies report on systemic complications. On the local complications of probing, 12 out of 60 sides (20%) reported backflow of blood from the lacrimal punctum during probing [25]. In addition, although rare, there are reports of cellulitis as a complication during the waiting period in three cases [14, 31], and caution is required.

When considering the above balance of benefits and harms, for the surgical treatment of unilateral CNLDO at 6–9 months of age, outpatients' immediate probing is recommended rather than probing under general anesthesia after 1 year of age. However, it was difficult to judge which is better for bilateral cases. The certainty of the body of evidence for this recommendation was judged to be C. Additionally, during the waiting period, there is the possibility of the occurrence of eye discharge/epiphora and cellulitis complications, and considerations of both patient and parent must be given.

Future tasks involve implementing RCTs on this theme that targets Japanese children or registration-based all-case surveys, which include surveys of parents' values and wishes, and dissemination of facilities where lacrimal duct surgery can be conducted under general anesthesia for children.

4. Are interventions evaluated differently by patients, families, and physicians?

A U.S. report on parent satisfaction shows that satisfaction was high in unilateral cases that underwent outpatient immediate probing and cases recovered [30].

5. Recommendation decision process

The pre-determined adoption criteria were satisfied in the first round of voting.

6. Literature research

A literature search was conducted using the PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) database (Last search date: December 28, 2022).

7. Explanation of the supplementary literature accompanying the search period lag in the Japanese version

In the supplementary literature search, there was no literature that satisfied the adoption criteria; it was decided that there was no need to change the recommendation text.

CQ4: Is a dacryoendoscope recommended for the treatment of CNLDO?

Recommendation

The use of a dacryoendoscope is proposed for the probing of CNLDO. However, considering the high spontaneous resolution rate of CNLDO and the extremely limited number of facilities where dacryoendoscopy can be conducted on children, its use is proposed depending on the situation.

Strength of recommendation Implementation is suggested.

Strength of evidence for CQ C

1. Incidental items to recommendation

A dacryoendoscope allows visualization of the inside of the lacrimal duct. Anatomically, the lacrimal duct is curved, and the dacryoendoscope can visualize the curved portion. A certain amount of training is required.

2. Background/purpose

CNLDO is a disease with a high spontaneous resolution rate, and treatments require high response rates and involve few complications. This CQ aimed to provide a guideline on whether a dacryoendoscope would prove useful for probing.

3. Explanation

In total, 11 studies [5, 6, 32–40] were adopted for this CQ. There were no RCTs or SRs on probing that directly compared the presence or absence of the use of a dacryoendoscope. Only case reports and case series were available.

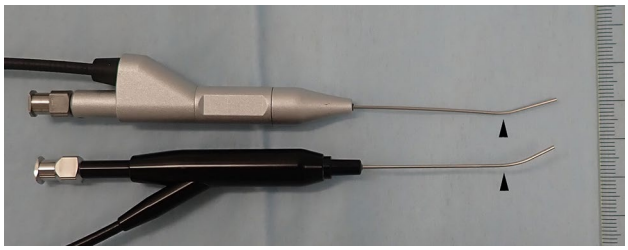


Fig. 5 Handpieces of two kinds of dacryoendoscopes (curved type), authorized in Japan. The ruler is graduated in millimeters. Top: made by Machida Endoscope, bottom: made by Fiber tech. The tip is bent to facilitate insertion and manipulation without damaging the lacrimal mucosa (arrowheads).

Handpiece held dacryoendoscopes include curved and straight types (Fig. 5), and their ease of use differs greatly. The curved and straight types were evaluated separately.

Among the 11 studies [5, 6, 32–40], eight [5, 6, 32–34, 36, 39, 40] involved the use of a curved dacryoendoscope, and the reported success rates were almost consistent across the studies (92.3–100%). Additionally, among eight of these studies, four [5, 6, 36, 39] originally excluded facial congenital abnormalities and bony obstructions, remaining four studies [32–34, 40] demonstrated no bony obstructions in totally 109 cases. And three [35, 37, 38] used a straight dacryoendoscope, and the success rates varied from 53.8% to 94.4%. Additionally, cases of bony obstruction diagnosed with a straight dacryoendoscope and treated with dacryocystorhinostomy included four out of 13 sides in a report by Gupta et al. [35], one out of 26 sides in a separate report by Gupta et al. [37], and one out of 18 sides in a report by Heichel [38] (six out of 57 sides, 11%). The rate of diagnosis of bony obstruction was higher in examinations with straight dacryoendoscope was that it is difficult to observe and open the strongly curved lacrimal duct using straight dacryoendoscopes. There are no RCTs that differentiated cases by the presence or absence of the use of a dacryoendoscope or handpiece shape, and resolution rates are difficult to compare; however, there was a tendency for the success rate to be high when a curved dacryoendoscope was used. Since only case reports and case series were present, the certainty of the body of evidence was judged to be C.

Subsequently, complications were examined. There were no reports of complications among the 11 studies [5, 6, 32–40]. Systemic complications are rare even with blind probing [41], and whether probing using a dacryoendoscope significantly decreased or increased complications cannot be evaluated. Local complications during probing, such as backflow of blood from the lacrimal duct punctum, are reported [25]; this is believed to have been caused by injury to the lacrimal mucosa by the bougie. A dacryoendoscope allows for visual probing; hence, this may lead to a reduction

in complications. However, surgery using a dacryoendoscope in children requires a certain level of training and ability to conduct general anesthesia.

In summary, the benefits are thought to outweigh the harms if the operators familiarize themselves with dacryoendoscope surgery and pay attention to complications, and the use of a dacryoendoscope is indicated. Particularly for patients in which blind probing was unsuccessful, a dacryoendoscope can visualize the obstruction morphology and site, which may facilitate the opening of the obstruction. The certainty of the body of evidence for this recommendation was rated to be C.

Future tasks include conducting a registration-based all-case survey, comparison of treatment outcomes using a dacryoendoscope and surgery, such as blind probing, and evaluation of adverse events and parents' values and wishes.

4. Recommendation decision process

The pre-determined adoption criteria were satisfied in the first round of voting.

5. Literature research

A literature search was conducted using the PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Ichushi Web (https://search.jamas.or.jp/) databases (Last search date: December 28, 2022).

6. Explanation of the supplementary literature accompanying the search period lag in the Japanese version

In the supplementary literature search, there was no literature that satisfied the adoption criteria, and it was judged that there was no need to change the recommendation text.

CQ5: Is additional blind probing (regardless of anesthesia method) recommended for patients with an unsuccessful initial blind probing?

Recommendation

It is suggested that additional blind probing (regardless of anesthesia method) should not be conducted in patients with an unsuccessful initial blind probing.

Strength of recommendation Non-implementation is suggested.

Strength of evidence for CQ C

1. Incidental items to recommendation

Treatment outcomes among cases wherein initial blind probing was unsuccessful may improve because of probing using a dacryoendoscope or combination of supplementary measures, such as lacrimal tube insertion. However, complications related to the lacrimal tube should be considered.

2. Background/purpose

Surgical interventions for CNLDO include options such as blind probing (bougie treatment), probing using a dacryoendoscope (Fig. 5), lacrimal tube insertion, and dacryocystorhinostomy. Blind probing is often conducted for the initial treatment. Success rates for initial blind probing are generally high, but no treatment policy has been established for unsuccessful cases, with repeated blind probing, probing using a dacryoendoscope, and lacrimal tube insertion (blind insertion, insertion using a dacryoendoscope) as possible options. The purpose of this CQ is to present a policy for when the initial blind probing was unsuccessful.

3. Explanation

In this CQ, whether repeated blind probing is recommended in cases where the initial blind probing was unsuccessful was determined by comparing the procedure with (1) follow-up observations, (2) probing using a dacryoendoscope, and (3) lacrimal tube insertion; SR was conducted for the success rate and complications.

Other reports related to this CQ include using nasal endoscopy, balloon catheters, and dacryocystorhinostomy. However, given that, in Japan, physicians who use nasal endoscopy will also use a dacryoendoscope, balloon catheters are not reimbursed under national health insurance, and few physicians would choose dacryocystorhinostomy as the next option in cases where initial probing was unsuccessful, these were omitted.

Evaluating the success rates, there were six reports of repeat blind probing after an unsuccessful initial blind probing. Succesful treatment outcomes for repeat blind probing were 53% and 25% in the two prospective cohort studies, respectively [42, 43]; and 61–85.7% for the four retrospective studies [28, 44–46]. One prospective cohort study that described the treatment outcomes for both initial and repeat blind probing [43] showed success rates of 73.3% and 25.0%, respectively. For the treatment outcomes in the four retrospective studies, Hung et al. [28] report values of 81.0% and 64.2%, respectively; Cha et al. [44] report values of 80% and 61%, respectively; Valcheva et al. [45] report values of 90% and 76%, respectively; and Beato et al. [46] report values of 77.3% and 85.7%, respectively. The success

rates of initial blind probing and repeat blind probing tended to decrease with repeat procedures, but Beato et al. [46] showed an increase, and it was judged that there was an inconsistency. CNLDO has a high spontaneous resolution rate; therefore, the success rate may have been overestimated particularly in retrospective studies due to the inclusion of spontaneous resolution, which makes evaluation difficult. The adopted studies were observational studies, and only one report prospectively evaluated both the initial and repeat procedures [43]; hence, the certainty of the body of evidence was judged to be C.

There are no reports directly comparing the success rates of follow-up observations and repeat blind probing. There are two reports on follow-up observations after the initial blind probing was unsuccessful [25, 39], both of which conclude that the spontaneous resolution rate was not related to the probing history. Even if follow-up observations were conducted after the initial blind probing was unsuccessful, it was thought that some degree of spontaneous resolution could be expected depending on the patient's age.

There are no reports that directly compared the success rates of probing with a dacryoendoscope and repeat blind probing. Two retrospective studies reporte on probing using a dacryoendoscope after the initial probing was unsuccessful [5, 35]. The success rates for repeat blind probing were 25.0–85.7%, as mentioned above, whereas the success rates for probing using a dacryoendoscope were 97.1% for a handpiece with a curved tip (curved type) as reported by Fujimoto et al. [5], and 53.8% for a handpiece with a straight tip (straight type) as reported by Gupta et al. [35]. It was thought that there were differences in treatment outcomes for probing using a dacryoendoscope depending on whether the shape of the tip of the handpiece is curved [5] or straight [35], and there are many reports showing favorable treatment outcomes for the curved type, which is mainly used in Japan. Please refer to CQ4 for this aspect. It is difficult to analyze the reports of repeat blind probing, and probing with a dacryoendoscope is difficult; however, it is possible that a curved dacryoendoscope may be better than repeat blind probing. There was a limited number of reports, all of which were retrospective studies; thus, the certainty of the body of evidence was judged to be C.

One report compares lacrimal tube insertion and repeat blind probing [47]. This was a retrospective study, it reports that the success rate of the repeat blind probing group was 67%, and that of the lacrimal tube insertion group was 92%, with a significant difference. There are seven reports that summarize the results of lacrimal tube insertion in cases where initial blind probing was unsuccessful [48–54], and the success rate of lacrimal tube insertion was almost consistently high at 75–100%, whereas the success rate of repeat blind probing was inconsistently low, at 25.0–85.7%; it is speculated that there was a factor that worsened the treatment outcomes for repeat blind probing. A common type of lacrimal tube used internationally is the Crawford tube, which needs manipulation in the nasal cavity; this tube is different from the Nunchaku-type that is used in most facilities in Japan. Hence, the possibility that the outcomes may be different due to differences in the tube should be considered.

Summarizing the success rate for repeat blind probing, a comparison with follow-up observations was difficult. For comparisons with probing using a dacryoendoscope, it was thought that the use of a dacryoendoscope should be considered; however, the certainty of the body of evidence was weak. Additionally, lacrimal tube insertion may increase the success rate.

Subsequently, regarding a comparison of complications in each treatment group, there was only one paper regarding complications from repeat blind probing, which reports no complications [42]. There were no reports regarding complications in follow-up observations. Regarding complications due to probing using a dacryoendoscope, one study reports no complications [5], and a separate study does not mention any complications either [35]. With lacrimal tube insertion, it is reported that complications occurred at a frequency of 0–31% [48, 50, 53, 54], with tube dislodgment and self-removal being the most common (19 out of 39 sides). Additionally, complications such as damage to the punctum and canaliculus, foreign body sensation, hyperemia, granulomas in the punctum, intranasal granulomas, infections, and corneal disorders are reported, albeit in small numbers.

Summarizing the above, repeat blind probing tends to result in a lower success rate, and this should be considered. Even cases in which the initial blind probing is unsuccessful may experience spontaneous resolution depending on age. The use of a curved dacryoendoscope is more likely to increase the success rate than repeat blind probing. Although the success rates are thought to be high in cases using lacrimal tube insertion, tube-related complications may occur although no serious complications are reported for these cases.

When considering the balance between these benefits and harms, it is thought that the addition of supplementary treatment such as a dacryoendoscope and lacrimal tube insertion when possible, may improve the treatment outcomes rather than repeat blind probing. The certainty of the body of evidence for this recommendation was judged to be C.

Future tasks include conducting a prospective study on the spontaneous resolution rates of cases in which initial blind probing was unsuccessful, as well as treatments that used a dacryoendoscope or lacrimal tubes, and surveys that included parents' values and wishes. Moreover, a treatment

policy for when the initial blind probing is unsuccessful must be considered.

4. Recommendation decision process

The pre-determined adoption criteria were satisfied in the first round of voting; votes were cast on the supplementary literature and whether or not to recommend revisions, and the pre-determined adoption criteria were satisfied.

5. Literature research

A literature search was conducted using the PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) database (Last search date: December 28, 2022).

6. Explanation on the supplementary literature accompanying the search period lag in the Japanese version

In the supplementary literature search, one study by Eshraghi et al. [55] satisfied the criteria as a case series study. It reports the success rate in 34 of 40 cases of lacrimal tube (monocanalicular tube) insertion that underwent a second procedure (85%), with no descriptions of complications. It was an indirect study, and the level of evidence of this study was C. It was judged that no changes in the recommendations were necessary.

CQ6: Should consideration be given to the risk of amblyopia in patients with CNLDO?

Recommendation

It was not possible to judge whether CNLDO was a factor in amblyopia. hence, it is uncertain whether special attention should be given to amblyopia; however, it is recommended that comprehensive ophthalmic examinations be conducted to the extent possible, keeping in mind the possibility of amblyopia.

Strength of recommendation Implementation is recommended.

Strength of evidence D

1. Incidental Items to recommendation

All reports used the American Association for Pediatric Ophthalmology & Strabismus (AAPOS) criteria [57]. Here, refractive error among the risks of amblyopia was verified.

2. Background/purpose

Compared with healthy children with CNLDO are reportedly more likely to have refractive error, a risk of amblyopia, [57]. In such cases, early detection and treatment may be important for the development of good visual function. Based on the above, we investigated the relationship between CNLDO and refractive error.

3. Explanation

Three observational studies [58–60] satisfied the criteria after conducting a systematic literature search on whether CNLDO was involved in the presence or absence of refractive error.

There were two retrospective case-control studies [58, 59]: a report comparing 446 cases of previously treated CNLDO aged 4 years or younger in South Korea with 446 age-matched controls [58] and a report comparing 151 cases of CNLDO aged 30–60 days in Italy with 218 age-matched controls [59]. One prospective observational study [60] reports 94 cases of unilateral CNLDO aged 6–30 months at the Kanagawa Children's Medical Center in Japan. The unilateral CNLDO rates in each report were 78.5%, 80.8%, and 100%, respectively. The Korean report [58] found no significant difference in the prevalence of refractive error between patients with CNLDO and the control group (5.4% vs. 6.5%), but children who had ophthalmology visits at the same institution were used as the control group, and the group with refractive error was not excluded; hence, the bias risk was judged to be serious. The Italian report [59] did not exhibit significant differences in the prevalence of refractive error between patients with CNLDO and the control group (11.9% vs. 8.7%); however, the participants were mainly Italians, and there was a high level of indirectness. The Japanese report [60] reports that 13% of patients with unilateral CNLDO had refractive errors that corresponded to the risk of amblyopia. In this study, there was non-continuous case selection and attribution bias; hence, the bias risk as an observational study was judged to be serious.

The reasons for low levels of evidence common in the three papers were that the diagnostic criteria for CNLDO differed among the reports, and the presence or absence of treatment interventions was unclear. AAPOS [56] judged the risk of amblyopia in those aged 12 months or older but including children younger than this reference age was a common factor across all the reports, and the detection bias was high. Additionally, the conclusions differed for each report, and the consistency was judged to be low. Therefore, the certainty of the body of evidence in this CQ was judged as D.

Based on the above, a certain number of cases of CNLDO may have refractive errors that are a risk of amblyopia, but

whether CNLDO is a factor for amblyopia cannot be judged, and it is uncertain whether special precautions are needed with regard to amblyopia. There was no evidence regarding the need for refraction tests under cycloplegia, which is a burdensome condition; but given that there is a possible risk for amblyopia, it is recommended that comprehensive ophthalmic examinations be conducted to the extent possible. Future tasks that are called for include large-scale, long-term, multicenter, registration-based all-case surveys of CNLDO cases that also includes parents' values and wishes.

4. Recommendation decision process

The pre-determined adoption criteria were satisfied in the first round of voting. All seven members of the clinical guideline creation group agreed the risk of amblyopia due to CNLDO could not be judged. and that it was uncertain whether special attention should be given to amblyopia.

5. Literature research

A literature search was conducted using PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Ichushi Web (https://search.jamas.or.jp/) databases (Last search date: December 28, 2022).

6. Explanation on the supplementary literature accompanying the search period lag in the Japanese version

In the supplementary literature search, no literature satisfied the adoption criteria. Thus, there was no need to change the recommendation text.

CQ7: Is surgical treatment indicated for CDC?

Recommendation

Congenital dacryocystoceles (CDC) should be carefully monitored in the early postnatal period because although most cases can spontaneously resolve, serious complications such as acute dacryocystitis, cellulitis, and respiratory and breastfeeding problems are possibilities. Early surgical treatment should be considered if serious complications are observed; this treatment may involve transnasal marsupialization, probing, or a combination of the two.

Strength of recommendation Implementation is suggested.

Strength of evidence for CQ C

1. Background/purpose

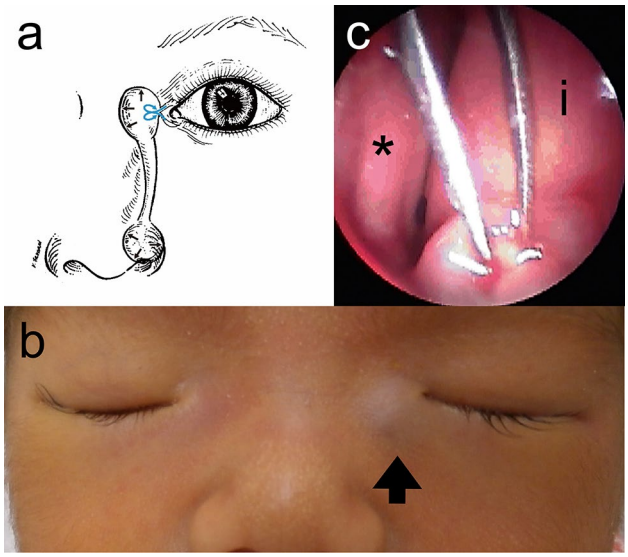


Fig. 6 Left congenital dacryocystocele (CDC). **a** Conceptual diagram of CDC: combined CNLDO with functional obstruction (check valve mechanism, indicated by the blue arrow) or organic obstruction of the common canaliculus, resulting in the dilation of the lacrimal sac, accumulation, and cyst formation at the nasolacrimal duct opening (black arrow). **b** Dark blue mass in the left medial canthus (arrow). **c** Nasal endoscopy findings in left CDC: holding the cyst protruding into the inferior nasal meatus with forceps (*: nasal septum, i: inferior nasal turbinate).

CDC is characterized by the blockage of the common canaliculus and nasolacrimal duct, which may result in the accumulation of fluid in the lacrimal sac and cause the nasolacrimal duct to be dilated (Fig. 6a). These guidelines provide an overview of CDC, its treatment options, and the intervention period.

2. Explanation

There were no RCTs explicitly addressing CDC; therefore, an SR was conducted using literature consisting of four prospective studies and 19 case series with a minimum of 20 cases.

a. CDC pathology

CDC is a combination of congenital obstruction of the nasolacrimal duct and common canaliculus. Mucus or amniotic fluid accumulation in the nasolacrimal duct causes the lacrimal sac to dilate, resulting in the appearance of a dark blue mass in the medial canthus (Fig. 6ab). In addition, the dilation of the nasolacrimal duct may expand to form an enlarged cyst in the nasal cavity (Fig. 6ac).

b. Epidemiological features

CDC can be diagnosed prenatally using ultrasound or magnetic resonance imaging (MRI), with reported prevalence rates of 0.004–0.2% in the United States and United Kingdom [Q7-1,-3] and 0.016–0.43% in East

Asia [64, 65]. Retrospective studies utilizing MRI report higher prevalence rates of 0.7–2.76%, although this may be influenced by a selection bias. [62, 63]. Prenatal diagnosis is often made during the third trimester [61–65], and there is evidence suggesting spontaneous resolution of CDC can occur the on the 32–38 weeks of gestation [64].

Postnatal prevalence rates range from 0.005–0.1%. Variability in prevalence may be attributed to differences in age at diagnosis (0–60 days after birth) and racial differences [64, 66, 67].

c. Diagnosis

CDC is typically detected soon after birth as a dark blue mass in the medial canthus and is diagnosed earlier than CNLDO (Fig. 6b). The average age at first visit [66, 68–74] was 10.7 days (range: 0–23.7 days). Diagnostic methods include interviews, observation of the mass and color tone, nasal endoscopy, and ultrasonography to confirm the presence of dilated lacrimal sacs and cysts in the inferior nasal meatus. CT and MRI may be necessary but should be used judiciously owing to the associated risks.

d. Clinical Course (Spontaneous recovery and possibility of serious complications)

Spontaneous resolution rates for prenatally diagnosed CDC cases are 76–90.6% [64, 65]. In postnatally diagnosed cases, conservative treatment resulted in resolution rates of 84% for uninfected CDC and 68.2% for CDC complicated with dacryocystitis. [66, 68]. These results suggest that conservative treatment is an option for CDC, as is the case with CNLDO. Nevertheless, cystic dilation of the nasolacrimal duct mucosa into the nasal cavity can manifest in 51.6% (with a range of 11.1–100%) of cases of congenital dacryocystocele (CDC). This dilation can lead to dyspnea during breastfeeding, observed in 17–22% of cases, an occurrence uncommon in CNLDO [66, 74–77]. In bilateral cases with an obstructed airway, severe dyspnea may necessitate emergency airway management, including measures such as continuous positive airway pressure [77] or transnasal airways [78]. In contrast to CNLDO, CDC is more prone to being comorbid with acute dacryocystitis and cellulitis, with infections typically emerging within the first month after birth. Although reported complication rates vary, it is suggested that at least 10% of CDC cases may progress to severe infections.

Compared to CNLDO, CDC may be associated with a higher incidence of complications such as acute dacryocystitis and cellulitis.

On average, infection became established at 27 days (9–50 days) when follow-up observations were conducted with the use of antibacterial eye drops [68]. A case series wherein infection had been established at the initial visit showed that 62.5% were infected within two weeks and 31.3% were infected within two to four weeks [75]. Particular attention should be given to infections around the first month after birth. Following an SR of the 19 adopted studies, the reported complication rates vary, with an incidence of acute dacryocystitis and cellulitis of 15.2–75% and 10–31%, respectively. However, it is important to note that the rates of acute dacryocystitis and cellulitis are at least 10% in CDC cases.

e. Treatment

Surgical treatment for CDC includes probing, transnasal marsupialization, and drainage with skin incisions. Probing is the most reported procedure, with success rates ranging from 53% to 100% [68, 72–76, 79, 80]. Transnasal marsupialization showed a good success rate, with successful outcomes in 12 out of 12 sides (100%) [60] and 10 out of 10 sides (100%) [81]. There are also many case reports of its subtype, which is the combination of the opening of the common lacrimal canaliculus and transnasal marsupialization [66, 67, 69–71, 73–76, 80–82], and their success rates were high, with successful outcomes of 10 out of 10 sides (100%) [74] and four out of four sides (100%) [82]. Some reports indicate that transnasal marsupialization, especially in cases where cysts are sufficiently large to cause respiratory failure, is notably effective [83]. Importantly, there are no reports of serious complications associated with this procedure. Despite these positive findings, it is crucial to note that CDC is a rare disease, and the results, while consistently favorable may be inaccurate. Consequently, the level of evidence has been classified as C, reflecting limited confidence in the overall effectiveness.

A retrospective case series of 29 cases reports that the success rates of probing may decrease from 100% to 53%, after infection [73].

This was a retrospective case series study [73], and the certainty of the body of evidence was judged to be C.

A few infected CDC cases that underwent drainage were resolved without probing in an average of 18 days [68]; however, this procedure is not common and involves palliative treatment that is not recommended here.

Summarizing the above, many CDC cases spontaneously resolved; however, severe complicated cases such as the development of cellulitis, acute dacryocystitis, and respiratory distress, especially in the early postnatal period around 1 month, can be anticipated. Thus, careful follow-up observations are necessary., Early surgical treatment is indicated when complicated severe infection or nasal cysts cause respiratory and feeding difficulties. Surgical intervention includes probing, nasal marsupialization, or a combination of the two, and they consistently showed good success rates. All reports were case series; thus, the certainty of evidence for these recommendations is considered to be Level C.

Future tasks include conducting RCTs or registry studies that include the perspectives of Japanese pediatric patients

and their caregivers, as well as their values and preferences (a nationwide registration-based survey) on this topic.

3. Recommendation decision process

The pre-determined adoption criteria were satisfied in the first round of voting.

4. Literature research

A literature search was conducted using the PubMed (https://www.ncbi.nlm.nih.gov/pubmed/) and Ichushi Web (https://search.jamas.or.jp/) databases (Last search date: December 28, 2022).

5. Explanation on the supplementary literature accompanying the search period lag in the Japanese version

In the supplementary literature search, no literature satisfied the adoption criteria. Thus, there was no need to change the recommendation text.

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Declarations

Conflicts of interest T. Sasaki, Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events (Senju, Alcon, Santen, Kaneka Medix, Novartis, HOYA, Nitto Medic), FiberTech and the author own the patent for medical endoscope ; N. Matsumura, Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events (FiberTech, Machida Endoscope, Senju, Santen); C. Miyazaki, None; T. Kamao, Payment or honoraria for lectures, presentations, speakers bureaus, manuscript writing or educational events (Santen, Senju, Fiber Tech, Machida Endoscope, Logic & Design, Taiho, Rohto Nitten, Johnson & Johnson, Nipro); N. Yokoi, None; M. Fujimoto, None; M. Hayami, None; A. Iwasaki, None; M. Mimura, None; A. Murata, None; T. Nakayama, None; K. Shinomiya, None; H. Tanaka, None; Y. Ueta, None.

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