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Summary of Japanese clinical practice guidelines for Bell's palsy (idiopathic facial palsy) - 2023 update edited by the Japan Society of Facial Nerve Research

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ABSTRACT

Objective: The "Summary of Japanese clinical practice guidelines for Bell's palsy (idiopathic facial palsy) - 2023 update edited by the Japan Society of Facial Nerve Research" aims to review the latest evidence regarding the treatment of Bell's palsy and to provide appropriate recommendations.
Method: Regarding the treatment of Bell's palsy, a guideline panel identified key clinical questions using an analytic PICO framework. The panel produced recommendations following the standards for trustworthy guidelines and the GRADE approach. The panel considered the balance of benefits, harm, and preferences when making recommendations.
Results: The panel identified nine key clinical questions: systemic (high/standard dose) corticosteroids, intratympanic corticosteroids, systemic antivirals, decompression surgery, acupuncture, physical therapy, botulinum toxin, and reanimation surgery.
Conclusion: These guidelines strongly recommend systemic standard-dose corticosteroids for the clinical management of Bell's palsy. Other treatments are weakly recommended due to insufficient evidence. The absolute risk reduction of each treatment differed according to the disease severity. Therefore, physicians and patients should decide on treatment based on the disease severity.

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1. Guideline objectives

The purpose of this clinical practice guideline (CPGs) [1] was to review the latest evidence regarding Bell's palsy (idiopathic facial palsy), and provide current standard treatment approaches. Bell's palsy is the most common facial palsy [2]. Epidemiological studies have reported an annual incidence of 20–30 cases per 100,000 persons [3]. Appropriate treatment leads to recovery of normal facial function [4]. However, some patients are unable to regain normal facial function and experience sequelae such as facial spasms, synkinesis, and contracture [5]. The main objectives of this study are as follows:

1. To provide proper treatment for Bell's palsy (idiopathic facial palsy)
2. To reduce the differences in treatment of the disease between facilities
3. To improve the safety and treatment outcomes of the disease

These CPGs were developed according to the GRADE (Grading of Recommendations Assessment, Development, and Evaluation) System. This document summarizes the "Clinical Practice Guidelines for Facial Nerve Paralysis 2023".

1.1. Purpose/Focus

The target patient population includes patients with Bell's palsy. We identified key clinical questions based on the PICO (Population, Intervention, Comparison, Outcome) frameworks. These questions were prioritized according to their clinical relevance and potential impact on patient outcomes. The analytical PICO framework is illustrated in Fig. 1. Approximately 70 % of patients with Bell's palsy achieve complete recovery without treatment [2]. Prognosis can be predicted using facial grading scales [5]. In Japan, the Yanagihara Facial Grading Scale is commonly used to assess the severity of Bell's palsy [6,7], and patients with Bell's palsy are treated according to the severity. This document focuses on clinical questions and recommendations for treatment, which require an evidence summary to conduct shared decision-making.

1.2. User

These CPGs are intended for healthcare professionals (e.g., physicians, physical therapists, speech therapists, acupuncturists, and nurses) involved in the diagnosis and treatment of Bell's palsy. Additionally, it is expected that patients and their families will use CPGs to deepen their understanding and decide on treatment options for these diseases.

2. Summarizing existing evidence

2.1. Systematic review and meta-analysis

A team conducted systematic reviews to gather relevant studies that addressed the identified clinical questions on CPGs' topics. The quality of evidence was assessed using the GRADE approach, considering factors such as study design, risk of bias, inconsistency, indirectness, imprecision, and publication bias. When we identified adequate existing CPGs or systematic reviews of these CPGs, we used the GRADE-ADOLOPMENT, and a team conducted a new systematic review. The details of each systematic review (e.g., eligibility criteria, list of included studies, and forest plot of outcomes) are shown in Appendix 1.

2.2. Developing recommendations

Recommendations were formulated based on the quality of evidence, balance of benefits and harms, patient values and preferences, resource implications, and implementation feasibility (Table 1). A consensus was sought through a voting process without anonymity in which each panel member voted on the strength and wording of the recommendations. It was agreed that a recommendation would be accepted if at least 70 % of the voting members reached a consensus. In cases where an initial consensus was not achieved, discussions and revisions of the recommendations were conducted until a substantial majority agreement was reached. The strength of recommendations were graded as either strong or weak, reflecting the degree of confidence in the estimated effects (Table 2).

3. Guideline key action statement (recommendations)

The summary of recommendations is listed in Table 3.

Recommendation 1. *Clinicians should prescribe systemic standard-dose (e.g., 60 mg PLS) corticosteroid for Bell's palsy in acute phase (Certainty*

Table 1
Definition of levels of evidence.

Strong	⊕⊕⊕⊕	We have strong confidence that the estimated effect adequately supports the recommendation
Moderate	⊕⊕⊕◯	We have moderate confidence that the estimated effect adequately supports the recommendation
Low	⊕⊕◯◯	We have limited confidence that the estimated effect adequately supports the recommendation
Very low	⊕◯◯◯	We have very little confidence that the estimated effect adequately supports the recommendation

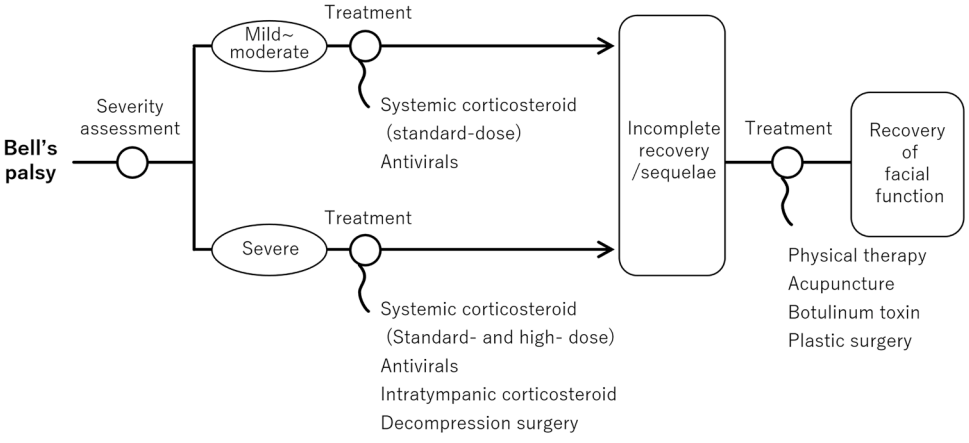

Fig. 1. Analytic PICO framework.

Table 2
Strength of recommendation.

Strong	recommended Recommended (against)	Benefits of the recommended intervention clearly outweigh / underweight the harms or burdens. Almost everyone should accept the recommended actions. It may not be necessary to facilitate formal support for supporting decision-making with patients' values and intentions.
Weakly	Recommended Recommended (against)	A conditional recommendation is made when the benefits of the intervention likely outweigh/ underweight the harms, but there may be variability in patient preferences or resource constraints that could influence the decision.

Table 3
List of CQ and Recommendations.

Treatment	Severity	Strength of recommendation	Certainty of evidence
Systemic standard-dose (e.g. 60 mg PLS) corticosteroid	All severity	Strong recommendation	⨁⨁⨁⨁
Systemic high-dose corticosteroid (e.g. 120 mg PLS)	Severe	Weak recommendation	⨁◯◯◯
	mild-to-moderate	Weak recommendation (against)	⨁◯◯◯
Intratympanic corticosteroid in addition to systemic corticosteroid	Severe	Weak recommendation	⨁◯◯◯
	mild-to-moderate	No recommendation	⨁◯◯◯
Antivirals in addition to systemic corticosteroid	All severity	Weak recommendation	⨁⨁◯◯
Decompression surgery	Severe	Weak recommendation	⨁⨁◯◯
Acupuncture	All severity	Weak recommendation	⨁⨁◯◯
Physical therapy	All severity	Weak recommendation	⨁⨁◯◯
Botulinum toxin	All severity (sequelae phase)	Weak recommendation	⨁⨁◯◯
Plastic surgery	All severity (Incomplete recovery / sequelae phase)	Weak recommendation	⨁⨁◯◯

of Evidence: Moderate, Consensus Rate: 100 %)

Systemic corticosteroids are the standard treatment, and several CPGs worldwide recommend this treatment [8,9]. Six randomized controlled trials (RCTs) were included in the meta-analysis (Appendix 1, SR1) [10-15]. Systematic review revealed that systemic corticosteroid (standard dose, e.g., 60 mg prednisolone [PLS]) reduced the non-recovery rate at 6 months after disease onset (risk ratio [RR] 0.60 [95 %CI 0.43 to 0.83]), and as well as the sequelae (RR 0.53 [95 %CI 0.42 to 0.68]). No critical adverse event was observed.

Of the studies included in the meta-analysis, most started systemic corticosteroids within 72 h of symptom onset. The effectiveness of systemic corticosteroids 72 h after symptom onset remains unclear.

Recommendation 2–1. *Clinicians may prescribe systemic high-dose (e.g., 120 mg PLS) corticosteroid instead of standard-dose for severe Bell's palsy in acute phase (Certainty of Evidence: very low, Consensus Rate: 100 %)*

Recommendation 2–2. *Clinicians may not prescribe systemic high-dose corticosteroid instead of standard-dose for mild-to-moderate Bell's palsy in acute phase (Certainty of Evidence: very low, Consensus Rate: 100 %)*

Eight cohort studies were included in the meta-analysis (Appendix 1, SR2) [16-23]. Compared with standard-dose corticosteroid, high-dose corticosteroid reduces the non-recovery rate at the last of follow-up (odds ratio [OR] 0.37 [95 %CI 0.18 to 0.79]) in severe Bell's palsy. The efficacy of high-dose corticosteroids was unclear in mild-to-moderate cases (OR, 0.89 [95 %CI 0.30 2.59]). As the adverse effects of corticosteroids increased in a dose-dependent manner, patients treated with high-dose corticosteroids had a higher incidence of adverse events (OR, 1.56 [95 %CI 0.58, 4.02]).

In patients with severe Bell's palsy treated with standard-dose corticosteroids, the non-recovery rate is 290 per 1000 persons [1]. High-dose corticosteroids can reduce this rate to 183 per 1000. The guidelines panel weakly recommends high-dose corticosteroids. However, in mild to moderate Bell's palsy, the non-recovery rate is 44 per 1000 when treated with standard doses [1]. The absolute reduction in non-recovery was small, and adverse events were clear. Therefore, the guideline panel does not weakly recommend high-dose corticosteroids.

Recommendation 3–1. *Clinicians may prescribe intratympanic corticosteroid in addition to systemic standard-dose corticosteroid for severe Bell's palsy in acute phase (Certainty of Evidence: very low, Consensus Rate: 100 %)*

Recommendation 3–2. *No recommendation can be made regarding intratympanic corticosteroid for mild-to-moderate Bell's palsy in acute phase (Certainty of Evidence: none, Consensus Rate: 100 %)*

Three RCTs and one cohort study were included in the meta-analysis (Appendix 1, SR3) [24-27]. The systematic team published the results of the SR and meta-analysis [28]. Compared with systemic standard-dose corticosteroids, intratympanic corticosteroids, in addition to systemic standard-dose corticosteroids, reduced non-recovery (OR 0.23 [95 %CI 0.08 0.69]). In mild-to-moderate cases, the OR is 0.37 (95 %CI 0.03 to 5.00), but the confidence interval is wide. Intratympanic corticosteroids can also cause permanent tympanic perforations (approximately 10 per 1000 persons) [29].

In patients with severe Bell's palsy treated with standard-dose corticosteroids, the non-recovery rate is 290 per 1000 persons [1]. Intratympanic corticosteroid in addition to systemic corticosteroid can reduce this rate to 223 per 1000. Subsequently, the guideline panel weakly recommends high-dose corticosteroids. There were only two small studies on mild-to-moderate Bell's palsy, and the guideline panel does not make any recommendations.

Recommendation 4. *Clinicians may prescribe systemic antivirals in addition to systemic corticosteroid for Bell's palsy in acute phase (Certainty of Evidence: moderate, Consensus Rate: 100 %)*

Nine RCTs were included in the meta-analysis (Appendix 1, SR4) [11,13,30-36]. Systematic review revealed that systemic antivirals reduced the non-recovery rate at 6 months after disease onset (RR 0.60 [95 %CI 0.40 to 0.90]), and as well as the sequelae (RR 0.56 [95 %CI 0.36 to 0.87]). Antivirals did not increase the incidence of adverse events (RR: 1.02 [95 %CI 0.66 1.57].

In severe cases, antivirals, in addition to systemic corticosteroids, can reduce non-recovery (116 per 1000) [1], and the guideline panel weakly recommends the treatment. In mild-to-moderate cases, the benefit was small, and there were no adverse events. Therefore, the guideline panel also weakly recommends the treatment for mild-to-moderate cases.

Recommendation 5. *Clinicians may conduct decompression surgery for severe Bell's palsy in acute phase (Certainty of Evidence: very low, Consensus Rate: 100 %)*

One RCT and five cohort studies were included in the meta-analysis (Appendix 1, SR5) [37-42]. A systematic review revealed that decompression surgery was likely to reduce non-recovery (OR 0.63 [95 %CI

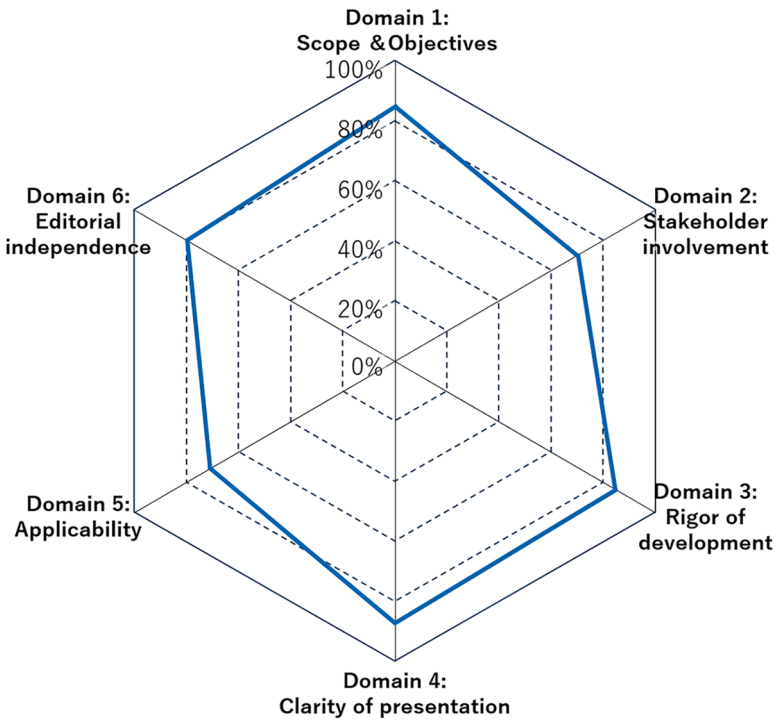

Fig. 2. Minds assessment using AGREE II tool.
Minds evaluated this CPGs in six domains using AGREE II tool.

0.35 1.14]). Decompression surgery can cause an elevation in pure-tone audiometry at high frequencies. The included studies enrolled severe cases, and the guideline panel weakly recommends decompression surgery for severe Bell's palsy.

Recommendation 6. *Clinicians may prescribe acupuncture for Bell's palsy (Certainty of Evidence: very low, Consensus Rate: 100 %)*

A total of 14 RCTs were included in this meta-analysis (Appendix 1, SR6) [43-56]. Two RCTs assessed acupuncture in patients with sequelae and found that acupuncture was likely to reduce non-recovery at the final follow-up (RR 0.63 [95 %CI 0.32 1.22]). Three RCTs assessed acupuncture in patients during the acute phase. Acupuncture in acute phase was not associated with non-recovery at final follow-up (RR 0.93 [95 %CI 0.80 to 1.08]), and was associated with reduction of no response (RR 0.52 [95 %CI 0.42 to 0.64]). The guideline panel weakly recommends acupuncture for peripheral facial palsy in the acute and late (sequelae) phases.

Recommendation 7. *Clinicians may prescribe physical therapy for Bell's palsy (Certainty of Evidence: very low, Consensus Rate: 100 %)*

Seven RCTs were included in the meta-analysis (Appendix 1, SR7) [57-62]. The systematic team published the results of the SR and meta-analysis [63]. Systematic review revealed that physical therapy reduced non-recovery at final follow-up (RR 0.51 [95 %CI 0.31 to 0.83]), and improved Sunnybrook score (12.7 point [95 %CI 3.11 to 21.02]. Two studies assessed the efficacy of physical therapy for sequelae, but have shown no reduction in sequelae (RR 0.64 [95 %CI 0.07 to 5.95]). The guideline panel weakly recommended physical therapy for patients with peripheral facial palsy.

Recommendation 8. *Clinicians may prescribe botulinum toxin treatment for sequelae (Certainty of Evidence: very low, Consensus Rate: 100 %)*

We identified a systematic review on this topic [64] and used it as an adaptation method. We searched RCTs comparing botulinum toxin versus placebo/no treatment. Two RCTs were included, and these studies used different outcomes for assessing the efficacy (facial grading score and synkinesis physician grading scale) [65,66]. Therefore, we did not conduct a meta-analysis. Both studies reported the efficacy of botulinum toxin; therefore, the guideline panel weakly recommends botulinum toxin treatment for peripheral facial palsy.

Recommendation 9. *Clinicians may conduct facial reanimation surgery for non-recovery/sequelae in Bell's palsy (Certainty of Evidence: very low, Consensus Rate: 100 %)*

We identified a systematic review of this topic [67] and employed it as an adaptation method. Facial reanimation surgery is a treatment for non-recovery and sequelae of facial paralysis. However, the number of cases treated with facial reanimation surgery remains low. Consequently, we included studies that compared facial functions before and after facial reanimation surgery. Six cohort studies assessed facial reanimation surgery in non-recovery patients (incomplete facial function) [68-73], and six studies evaluated treatment efficacy in patients with sequelae [74-79]. The included studies used various outcomes for assessing the efficacy. All the included studies reported the efficacy of facial reanimation surgery. The guideline panel weakly recommends facial reanimation surgery for non-recovery/sequelae in Bell's palsy.

4. Limitations and out of scope of this document

This document summarizes the "Clinical Practice Guidelines for Facial Nerve Paralysis 2023". This document does not contain some CQ (e.g., CQ for Ramsay Hunt syndrome, CQ for traumatic facial paralysis, and stellate ganglion block for peripheral facial palsy).

5. External reviews and further challenges

Before publication, the Japanese Society of Otolaryngology Head and Neck Surgery and Japan Society of Facial Nerve Research reviewed the guidelines. After publication, the Medical Information Distribution Service (Minds) evaluated the guidelines using the AGREE II tool [80]. The results are shown in Fig. 2. Overall, these guidelines are well-established. However, in this guideline, efforts regarding "patients'

involvement (domain 2)" and "application and monitoring (domain 5)" are insufficient. This CPG is an update of the 2011-edition CPG [81]. As the evidence in this area has not been revised quickly, we are considering revising it within approximately 10 years. We will also discuss further changes to improve "application and monitoring (domain 5)" (Appendix 2).

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Authors contribution

N.H., T.K., D.K., K.S., M.T., H.N., S.H., M.H., A.H., Y.F., K.M., N.M., T.Y., and T.N. concepted this study. T.F., T.K., H.N., A.H., K.M., and N. M. conducted data curation and analysis in systematic review. All authors voted for developing recommendations. T.F. drafted the manuscript and all others reviewed. All authors approved the final manuscript.

Declaration of competing interest

No financial conflict of interest.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.anl.2024.07.003.

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