Clinical Practice Guideline for Chronic Headache 2013

On Publication of Clinical Practice Guideline for Chronic Headache 2013

In 2001, the Executive Board of the Japanese Society of Neurology decided to develop clinical practice guidelines for the major neurological diseases, according to a proposal by President Nobuo Yanagisawa. In 2002, "Treatment Guidelines 2002" for six diseases comprising "chronic headache", "Parkinson disease, "epilepsy", "amyotrophic lateral sclerosis", "dementia", and "cerebrovascular disease" were published. The Japanese Headache Society developed and published the "Clinical Practice Guideline for Chronic Headache" in 2006 to improve and standardize clinical care for chronic headaches, and to disseminate this knowledge not only among specialists but also to primary care physicians.

Following the publication of "Treatment Guidelines 2002", new knowledge had accumulated markedly. The 2008 Executive Board of the Japanese Society of Neurology (President, Shigeki Kuzuhara) decided to revise the guidelines, and inaugurated the guideline development committee for "Treatment Guidelines 2010". From 2009 to 2011, guidelines on "genetic diagnosis of neurological disorders", "epilepsy", "dementia", "multiple sclerosis", and "Parkinson disease" were published. Furthermore, at the Executive Board of 2011, publication of new clinical practice guidelines for six neurological disorders (Guillain-Barré syndrome/Fisher syndrome, chronic inflammatory demyelinating polyneuropathy/multifocal motor neuropathy, amyotrophic lateral sclerosis, bacterial meningitis, Duchenne muscular dystrophy, and myasthenia gravis) in 2013 was decided. At the same time, with the accumulation of evidence for chronic headaches, mainly on pharmacotherapy, development of the "Clinical Practice Guideline for Chronic Headache 2013" was decided, to be jointly edited by the Japanese Society of Neurology and the Japanese Headache Society.

As procedures of guideline development, President/CEO of the Japanese Society of Neurology appointed the chairman for each guideline development committee, and each chairman recommended candidates as committee members, research collaborators, and evaluation/coordination members. Each candidate submitted a declaration of conflict of interest. Conforming to the review and advice of the Conflict of Interest Review Committee and upon coordinating with each chairman, appointment of the members was approved at the Executive Board. This guideline was developed with cooperation from the Japan Neurosurgical Society and the Japanese Society of Neurological Therapeutics. We would like to express our gratitude to the two societies for their gracious endorsement and support for guideline development.

As with the previous guidelines, the present guideline is developed based on the concept of evidence-based medicine (EBM), and presented in a question and answer (Q&A) format. The guideline is organized in an easy to read manner, as in the 2010 guidelines. Contents of the answers are based on careful review of the cited references, and recommendation grades based on the quality of evidence are provided. However, depending on diseases and symptoms, sufficient evidence is not available for some fields. Treatment contents vary among diseases, ranging from those with established pharmacotherapy and neurosurgical treatment to those in which pharmacotherapy has limitations and non-pharmacotherapy with long-term care are important. As a result, the grading of EBM is also diverse. Furthermore, objectives of treatment differ for diseases with freedom from symptom or symptom relief as the treatment goal and for diseases in which symptomatic relief is difficult and QOL improvement is the only goal. Even in these cases, the optimal guides available to date are provided in this guideline.

It should be noted that clinical practice guidelines do not necessarily present uniform treatment methods. Even for the same disease, the optimal treatment may vary depending on individual patients, and treatment may also vary according to the experience and the opinions of physicians. The guidelines are intended to provide physicians responsible for treatment decision a reference for selecting the best treatment method. For this purpose, the evaluations of individual medications and non-pharmacological treatments are presented based on evidence graded according to international systems.

Clinical practice for chronic headache continues to progress rapidly, and regular revisions are necessary in the future. We hope that many members of relevant societies will use this guideline actively and provide us with feedback, which will allow us to update and improve the contents of the guideline. We anticipate that this guideline will serve as an aid to physicians in their daily practice, and look forward to receiving opinions and feedback for future revisions.

May 2013 Hidehiro Mizusawa, President/CEO, Japanese Society of Neurology Fumihiko Sakai, President, Japanese Headache Society Sadatoshi Tsuji, Chairman, Guideline Executive Committee

Preface

Introduction

With the publication of The International Classification of Headache Disorders by the International Headache Society in 1988, standardized headache diagnostic criteria began to be used worldwide, which established the foundation for headache research. As a result of this development, research on chronic headache led by the Japanese Society of Neurology and Japanese Headache Society also progressed. In 2002, the "Chronic Headache Treatment Guideline 2002" was published as one of the Japanese Society of Neurology treatment guidelines. Then in 2004, the International Headache Society published the International Classification of Headache Disorders; 2nd Edition (ICHD-II). In response to this development, the "Clinical Practice Guideline for Chronic Headache" was compiled in Japan by the Study Group for Chronic Headache Clinical Practice Guideline Development (Principal Researcher: Fumihiko Sakai) as a Mental Health Scientific Research Project funded by a Grant-in-aid from the Ministry of Health, Labour and Welfare Research. In 2006, the book entitled "The Clinical Practice Guideline for Chronic Headache (edited by Japanese Headache Society)" was published by the publisher Igakushoin. Furthermore, in 2007, the ICHD-II was translated into Japanese language and published as the "Japanese Version of the International Classification of Headache Disorders 2nd Edition (translated by International Headache Classification Promotion Committee of Japanese Headache Society)".

New approaches for "Clinical Practice Guideline for Chronic Headache" from 2010

Accompanying the popularization of triptans, clinical practice for chronic headache also changed in Japan and there was a need to revise the "Clinical Practice Guideline for Chronic Headache" (2006) developed by the Japanese Headache Society. With the objective to develop a new edition of "Clinical Practice Guideline for Chronic Headache", a guideline development committee consisting of 39 members was formed in November 2010. Then in 2011, it was decided that the revision project would be carried out mainly by the Japanese Society of Neurology and Japanese Headache Society, with collaboration from the Japanese Society of Neurological Therapeutics and the Japan Neurosurgical Society. Among 39 members on the Japanese Headache Society Guideline Committee, 12 group leaders served as guideline committee members and the other 27 members as coordinating members of the Japanese Society of Neurology. With the addition of 7 evaluation/coordination members, the guideline development committee comprised 46 members to carry out the revision tasks.

Procedures and Organization

The first task was to decide how to structure the contents, and it was decided to adopt the same format as in the second edition. Since the second edition used the format of clinical questions (CQ), this format was maintained with the contents divided into the following eight chapters, as in the second edition.

- I. Headache: General Considerations
- II. Migraine (1. Diagnosis Epidemiology Pathophysiology Precipitating factors Prognosis, 2. Acute Treatment,3. Prophylactic therapy)
- III. Tension-type headache
- IV. Trigeminal autonomic cephalalgias
- V. Other primary headache disorders
- VI. Medication-overuse headache
- VII. Headaches in Children
- VIII. Genetics

In addition to the above eight chapters, it was decided also to include the "Guideline for Self-injection of Sumatriptan at Home", "Guideline for Migraine Treatment by Valproic Acid (Provisional Edition)" and "Guideline for Migraine Treatment by Propranolol (Provisional Edition)" as Appendix.

Search for scientific evidence was conducted by a systematic approach. Using the criteria as shown in **Table 1**, the literature was searched on public databases including PubMed, Cochrane Library, and Ichushi. The results were consolidated, and recommendation grades were assigned for individual CQs (**Table 2**). During the execution of these tasks, Mr. Masahiro Yoshida, Director of Medical Information Network Distribution Service (MINDS) kindly provided valuable guidance. Taking this opportunity, we would like to express our profound gratitude for his assistance. It was also decided to construct

abstracts of important articles as far as possible and make them accessible on the website of the Society.

Table 1. Oxford Center for Evidence-Based Medicine Levels of Evidence (2001)

Level	Descriptions
1a	Systemic review (with homogeneity) of RCTs
1b	Individual RCT with narrow confidence interval
Ic	All or none
IIa	Systemic review (with homogeneity) of cohort studies
IIb	Individual cohort study (including low quality RCT; e.g.,<80% follow-up)
IIc	Outcomes research
III	Systemic review (with homogeneity) of case-control studies, or individual case-control study
IV	Case series (and poor quality cohort and case-control studies)
V	Expert opinion without explicit critical appraisal, or based on physiology, bench research or first principles

Table 2. Grades (Strength) of Recommendation

Grade A	Use strongly recommended
Grade B	Use recommended
Grade C	No clear evidence to support recommendation for use

After each committee member wrote the part that he or she was responsible, the contents were discussed within each group. The results was opened to all committee members on the internet, and the contents were brushed up. On June 3, 2012, all committee members met to brush up all the items. Then on November 17, 2012, a symposium on the guideline was held during the Congress of Japanese Headache Society to invite opinions from a wide audience. In addition, the opinions from the evaluation/coordination members were collected, and public comments were invited from all society members. Final compilation of the guideline took place on March 20, 2013, and the guideline was published in May.

Contents of guideline

As was also stated in the 2006 version, this guideline is intended to support clinical practice, and not to restrict clinical practice. In the clinical setting, in addition to the guideline, physician's' experience is important. We hope that this guideline will facilitate better clinical decision-making, and will improve patients' quality of life.

The new guideline adopted the Clinical Questions (CQ) used in the 2006 version, and added 19 new CQs. All the previous CQs were reviewed and rewritten.

Closing remark

Essentially based on the 2006 version of the Clinical Practice Guideline for Chronic Headache, the new guideline has added the latest information and presented the concept of international standards of chronic headache care. If the guideline of 2002 is considered the first edition of clinical practice guideline for chronic headache in Japan, then the 2006 guideline is the second edition, and the present guideline is the third edition. We hope that this guideline will become an indispensable document for physicians to provide effective and standardized treatments in their clinical care for chronic headache. We have also planned to produce an English version of the guideline to disseminate information to the world on the clinical practice guideline for chronic headache in Japan.

Last but not the least, we would like to convey our gratitude to all the committee members for their tremendous efforts and dedication that have led to the publication of this guideline.

May 2013

Nobuo Araki

Takao Takeshima

Representing the Chronic Headache Clinical Practice Guideline Development Committee

On publication of the English edition of the guideline

While we were drawing up a plan to compile the English Edition of the Clinical Practice Guideline for Chronic Headache 2013 which was originally written in Japanese language, we were confronted with a dilemma: one month after we published the original guideline in Japanese, the International Classification of Headache Disorders 3rd Edition beta version (ICHD-3beta) was published. Since the diagnoses of headache disorders worldwide would be made according to the ICHD-3beta, we felt that a new guideline based on the diagnostic criteria of the 2nd edition (ICHD-II) would be less valuable. The Chronic Headache Clinical Practice Guideline Development Committee discussed over this issue, and confirmed that there would be no problem to update the guideline based on the diagnostic criteria of ICHD-3beta. This guideline is the final product of the Committee's efforts with editorial input from Teresa Nakatani. During the compilation of this guideline, we were greatly saddened by the sudden demise of Professor Junichi Hamada who had contributed enormously to the development of the guideline. We would like to convey our sincere condolences. We hope that this book will help many people around the world to understand the clinical practice for headache disorders in Japan.

February 24, 2015 Nobuo Araki Takao Takeshima Hisaka Igarashi Toshihiko Shimizu Representing the Chronic Headache Clinical Practice Guideline Development Committee

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