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GUIDELINES (JSH 2014)

Introduction

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The Japanese Society of Hypertension revised the Japanese Society of Hypertension Guidelines for the Management of Hypertension in 2009 (JSH 2009) and published the JSH 2014. Basically, the JSH 2014 was prepared according to strategies to prepare the JSH 2009 and the 'Guidance for the Preparation of Treatment Guidelines in 2007' established by the Medical Information Network Distribution Service. In the 'Introduction' section, methods to prepare the JSH 2014 are introduced.

1. OBJECTIVE AND SUBJECTS OF THE JSH 2014

Hypertension causes stroke (cerebral infarction, cerebral hemorrhage, subarachnoidal hemorrhage), heart disease (coronary artery disease, cardiac hypertrophy, heart failure), kidney disease (nephrosclerosis) and macrovascular disease. Therefore, the primary objective of the JSH 2014 is to present standard treatment to prevent the onset/progression of hypertensive complications of the brain/heart/kidney through the management of hypertension. The JSH 2014 does not restrict the attending physician's right to determine prescriptions. It does not present criteria for medical disputes or lawsuits. As therapeutic strategies are individually selected on the basis of the patient's background and concomitant conditions, the attending physician should sufficiently explain the contents of treatment to the patient and write the reasons for indication in the patient's chart when selecting a therapeutic strategy differing from the JSH 2014.

The management of hypertension in accordance with the JSH 2014 should be performed in hypertensive patients with a blood pressure of $\geqslant$140/90 mm Hg. In those with diabetes mellitus and chronic kidney disease complicated by proteinuria, in which the risk of stroke, heart disease and renal failure is high, hypertension treatment must be conducted if blood pressure is $\geqslant$130/80 mm Hg. On the other hand, in hypertensive patients with metabolic syndrome, lifestyle modifications are necessary even in those with a high-normal blood pressure (130–139/85–89 mm Hg). Even in normotensive patients, the prevention of hypertension through lifestyle modifications such as salt restriction, correction of obesity and exercise is an important issue as a population strategy. (see Chapter 3, Principles of treatment.)

With respect to the utilization of the JSH 2014, hypertension is the most common lifestyle-related disease and is difficult to treat by specialists in hypertension alone. Actually, hypertension is managed by many clinicians/practitioners. Considering such circumstances, the JSH 2014 was prepared for clinicians/practitioners, and it is primarily available for clinicians/practitioners and pharmacists. On the other hand, blood pressure control is also important for special health checkups/health guidance. Health promotion business by municipalities also involves blood pressure control. Therefore, the JSH 2014 should also be used by health nurses, nurses, dietitians and staff responsible for team practice for hypertension management. Therefore, in addition to specialists in hypertension, the members of The Japan Association of Medical Practitioners, The Japanese Society of Clinical Pharmacology and Therapeutics, Japan Pharmaceutical Association, Japanese Society of Clinical Nutrition, and Patient Corporation belong to the Japanese Society of Hypertension Committee for Guidelines for the Management of Hypertension. With regard to the affiliations of the committee members, their occupation, affiliated corporations and positions are described.

2. COMPOSITION OF THE JAPANESE SOCIETY OF HYPERTENSION COMMITTEE FOR GUIDELINES FOR THE MANAGEMENT OF HYPERTENSION

The Japanese Society of Hypertension Guidelines for the Management of Hypertension is official. To prepare them with all members' responsibilities, 40 writing members consisted of all officials of The Japanese Society of Hypertension and specialists in stroke, pregnancy-induced hypertension, endocrinology, dementia, dialysis and medical economics. Seventy-nine document reviewers consisted of the councilors of The Japanese Society of Hypertension and special-field members, who were recommended on a questionnaire survey. Two to five reviewers per writing item, including other writing members, were arranged. In addition, 15 liaison members were consigned based on recommendations from 14 affiliated societies. Ten assessment members, consisting of the honor members of The Japanese Society of Hypertension and persons recommended by the Patient Corporation, The Japan Association of Medical Practitioners, and Japan Pharmaceutical Association, were consigned. Three advisory members, consisting of the members of the Japan Physicians Association and Japan Primary Care Association, as well as a practitioner, were consigned, and evaluation was performed according to the Appraisal of Guidelines for Research & Evaluation II. Eight advisors were consigned. Four writing members were also selected as liaison members, and a total of 151 members comprised the committee.

3. PREPARATION STRATEGIES

A basic strategy for the preparation of the JSH 2014 was to establish evidence-based consensus guidelines for clinicians/practitioners, considering the conflict of interest (COI). In addition, it was determined to announce the JSH 2014 on the homepage of The Japanese Society of Hypertension, prepare digest and English versions and newly prepare guidelines for patients. On the basis of these contents, the JSH 2014 was basically prepared according to the 'Guidance for the Preparation of Treatment Guidelines in 2007' established by the Medical Information Network Distribution Service.

4. STRATEGIES TO REACH A CONSENSUS

As a rule, previous guidelines including the JSH were prepared based on EBM. However, the new definition of EBM assessment in guidelines was presented in the treatment guidelines established by the Institute of Medicine (USA) in 2011; it was proposed that evidence-based consensus guidelines should be established, considering the quantity and quality of evidence, variations in conclusion, efficacy, clinical adaptation and evidence regarding harmful effects and costs, but not solely by mechanically evaluating the level of evidence or recommendation grade.

As a method to reach a consensus, to avoid bandwagon and halo effects, it is recommended that a final decision be made through the following process of preparation: each member's thinking, followed by group discussion and each member's thinking. In the Guidance for the Preparation of Treatment Guidelines in 2007 (Medical Information Network Distribution Service), three methods are introduced: Delphi's method (thinking by each member alone using a questionnaire sent twice or more), nominal group technique (write/share/explain/vote individuals' opinions) and consensus conference (explanation/question/discussion according to a 3-day program, preparation of the draft of a report by specialists).

In the JSH 2014, the chairperson presented counterproposals for a draft as much as possible based on clinical questions from working groups and writing members according to Delphi's method, delivered them to each member by e-mail and collected opinions from each member. Subsequently, he introduced the choices selected and opinions, and additionally collected each member's opinions by focusing on some choices. Similar procedures were repeated, and a single draft was finally selected. Finally, the members' opinions (agreement, consent, opposition and others) were summarized, and the draft of basic strategies was fixed. On decision, 97% or more of all committee members agreed/consented. In the above procedures for the preparation of the draft of basic strategies (agreement), individual members' names were closed.

Subsequently, writing members prepared the points (with the recommendation grade) and text of the Guidelines based on the basic strategies agreed, and opened them to all members on e-mail through discussion with the chairperson. In addition, the names of all members were disclosed and a final draft was prepared through open discussion among the members. On open discussion, the above draft of basic strategies delivered on e-mail was changed, suggesting the importance of repeated discussion/confirmation and adopting the majority's opinion. In the final stage, a consensus conference was held for 2 days to confirm a final draft.

5. SYSTEMATIC REVIEW

In each chapter, the post-JSH 2009 literature from January 2009 until June 2013 was investigated on PubMed using 'disease', 'target of blood pressure control' and 'selection of antihypertensive drugs' as keywords, and was adopted as the basis of systematic review. The results of the reassessment of the JSH 2009 and (ESH/ESC) European Society of Hypertension/European Society of Cardiology 2009, as well as references from the National Institute for Health and Clinical Excellence/British Hypertension Society Guidelines in 2011 and ESH/ESC 2013, were presented to each member to reinforce literature investigation. Although each member could not perform a meta-analysis from the literature, meta-analyses and other systematic reviews were quoted if possible.

Evidence in Europe and the United States differs in disease structure from that in Japan. Concerning some references, the recommendation grade was established, considering the present condition in Japan, where the incidence of stroke is high, without adhering to hard end points in Europe and the United States, where the incidence of myocardial infarction is high.

For literature adoption, the publication of the KYOTO Heart Study, JIKEI Heart Study and SMART were cancelled. Therefore, three articles were not adopted. The VART, and NAGOYA Heart Study, which are to be re-examined, will be determined based on the results of verification by a third organization.

6. ESTABLISHMENT OF THE EVIDENCE LEVEL AND RECOMMENDATION GRADE

The evidence level and recommendation grade are shown in Tables A, B and C. As an evidence level, epidemiological studies are high-quality ones, but the evidence level is low (IVa) in the sense of intervention/treatment for hypertension. Therefore, for quotations that are not involved in the recommendation grade, E-Ia, Ib, II and III were established, as presented in Table B. When guidelines prepared by other societies or positional statements were quoted, they were regarded as literature and expressed as GL without establishing the evidence level.

In the JSH 2014, important items were presented as POINT. Concerning items that should be recommended in clinical practice (diagnosis/treatment), the evidence level (Table A) and recommendation grade (Table C) were mentioned.

The recommendation grade in the 'POINT' was reviewed based on the evidence level and study results/significance. The rules for determining the recommendation grade are shown in Table D. However, recently, a special committees' or specialists' consensus, which is not based on high-level literature information, has also been used for recommendation grading as an individual, important material for evaluation in cases in which a randomized comparative study is difficult. The Institute of Medicine (2011) and Medical Information Network Distribution Service also recommend the consensus-based decision of the recommendation grade. As a rule, the recommendation grade of high-level research-based studies is high. However, even if such studies are absent, the recommendation grade of some matters may be established as A or B based on a consensus. The JSH 2014 also describes that a consensus can be used when determining the recommendation grade in the 'POINT'. However, in the case of low evidence, consensus-based recommendation grade was sufficiently inspected/determined at the JSH 2014 committee.

When merits may be obtained by achieving a blood pressure, although it is difficult to establish the value as a target of blood pressure control, considering the evidence level, the sentence

Table A Classification of the evidence level regarding treatment/diagnosis

Evidence level	*Classification*
I	Systematic reviews, meta-analysis of randomized comparative studies
II	Randomized comparative studies
III	Non-randomized comparative studies, subanalysis/retrospective analysis of randomized comparative studies
IVa	Epidemiological studies (cohort studies, meta-analysis of cohort studies)
IVb	Epidemiological studies (case–controlled studies, cross-sectional studies)
V	Descriptive studies (case reports, case series)
VI	Special committees' or specialists' opinions

Table B Classification of the evidence level of epidemiological studies regarding risk factors/prognosis

Evidence level	*Classification*
E-Ia	Meta-analysis of cohort studies
E-Ib	Cohort studies
E-II	Case–controlled studies, cross-sectional studies
E-III	Descriptive studies (case series)

Table C Recommendation grade described in the 'POINT'

Diagnosis/treatment items of POINT
A: strongly recommended based on strong scientific grounds
B: recommended based on scientific grounds
C1: recommended despite insufficient scientific grounds
C2: not recommended despite insufficient scientific grounds
D: not recommended based on scientific grounds

Table D Rules for determining the recommendation grade

Diagnosis/treatment items of POINT
A: there are 1 or more results at evidence level I[a]
B: there are 1 or more results at evidence level II
C1/2: based on the results at evidence level III, IV, V or VI
D: there are 1 or more results at evidence level I or II

Consensus-based recommendation grade: expressed as 'consensus'.
[a]Even if there is one Level I result, evaluation should be performed by the JSH 2014 committee when the number of patients in the randomized comparative study is not sufficient or the result is based on company-guided articles alone. (Such cases must be discussed/determined at the JSH 2014 committee.)

$<130/80$ mmHg or $<140/90$ mmHg should be targeted if possible or if the patient tolerates treatment' was expressed.

7. COURSE OF PREPARATION

The preparation of the JSH 2014 was determined at the Board of Directors, The Japanese Society of Hypertension on 15 May 2012. Dr Shimamoto was designated as a chairman. Immediately, a questionnaire survey regarding strategies to prepare the JSH 2014 and the composition of the JSH 2014 committee was conducted in the councilors of The Japanese Society of Hypertension and all specialists in hypertension. On the basis of the results of the questionnaire survey, the unresolved issues of the JSH 2009, subsequent reassessment of the ESH2009 and changes in the National Institute for Health and Clinical Excellence/British Hypertension Society Guidelines (2011) were discussed in accordance with the strategies on the preparation of the JSH 2009. In addition, changes in the ESH/ESC 2013 Guidelines, which were published in June 2013, were also discussed, and we began to prepare the JSH 2014.

Writing members' conferences were held three times (5 August 2012, 19 September 2012 and 25 May 2013). On 9 December, the JSH 2014 committee involving all members was held. During this period, opinion hearing through mail conferences was always conducted and a draft was prepared. On 14 and 15 July 2013, the second JSH 2014 committee (consensus conference) involving all members was held. All chapters were presented and discussed, and a final draft was prepared. In August 2013, public comments were recruited on The Japanese Society of Hypertension homepage. Answers were given to each question, and the Guidelines were revised/added if necessary. Simultaneously, three advisory members were requested to evaluate the contents according to the Appraisal of Guidelines for Research & Evaluation II. In addition, Professor Hasegawa, Toho University, with a career of guideline assessment, was requested to evaluate the contents according to the Appraisal of Guidelines for Research & Evaluation II. The insufficient points of the JSH 2014 were corrected. The representative of the Patient Corporation and assessment members of the Japan Pharmaceutical Association were requested to participate in the process of preparation and submit their opinions. In addition, the chairman interviewed them and inquired the representative of the Patient Corporation of wishes/opinions for the Guidelines for the Management of Hypertension from the perspective of citizens, especially matters on hypertension at telephone consultations. Hearing of opinions regarding the significance of hypertension, home blood pressure measurement, lifestyle modifications, use of antihypertensive drugs and guidelines for patients was conducted. To the representative of the Japan Pharmaceutical Association, hearing of opinions on the characteristics and adverse effects of antihypertensive drugs, drug information, cost-effectiveness, compounding agents and health insurance-matched use was performed. The JSH 2014 reflects these opinions.

Professor Oparil in the United States and Professor Lindholm in Sweden will review the english version of the JSH 2014. Their reviews will be published in the *Hypertension Research* (official journal of the Japanese Society of Hypertension).

8. INDEPENDENCE OF EDITING

All expenses for the preparation of the Guidelines were paid by The Japanese Society of Hypertension. The COI of the committee members is introduced in the next section 10.

9. CONFIRMATION AND DISCLOSURE OF COI

Concerning COI, all 151 members reported the state of COI with respect to their economic relationship with companies involved in hypertension and relevant diseases according to The Japanese Society of Hypertension Strategies to Apply COI, which were prepared based on the 'Common Guidelines regarding the Conflict of Interest (COI) in Clinical Studies' established by the Japanese Society of Internal Medicine and affiliated societies:

1) Companies/corporations from which the members or their relatives in the first degree, as a person, obtained rewards
Executive rewards (1 000 000 yen or more), shares (1 000 000 yen or more, or 5% or more of the stock), patent fee (1 000 000 yen or more), lecture/manuscript fee (1 000 000 yen or more), research funds/grants (2 000 000 yen or more), travel expenses/gifts (50 000 yen or more).

2) Companies/corporations responsible for cooperative industrial-academic activities with departments to which the members belong
Scholarship funds (2 000 000 yen or more), belonging to contribution lectures sponsored by companies.

The contents of all members' reports were inspected at the COI Committee of The Japanese Society of Hypertension (10 January 2013). Initially, the absence of COI to be applied to the chairman was confirmed. Subsequently, individual members were examined. In members responsible for preparation, it was confirmed that the contents of COI application were not involved in the contents of writing. In liaison members and document reviewers, the association with items for which they were responsible was individually

inspected, and it was confirmed that there were no problems regarding the preparation of the guidelines. (The contents of the COI Committee are published on The Japanese Society of Hypertension homepage.)

As a method to open COI in the guidelines, the names of companies reported by members responsible for preparation are presented below in reference to the guidelines prepared by other societies.

The names of companies reported are as follows (inspection period: from 6 August 2011 to 5 August 2012). Their names are expressed as those as of April 2013 (syllabary order). However, neither publishing companies nor corporations taking a neutral stand are included.

DESCRIPTION

1) Companies/corporations from which the members or their relatives in the first degree, as a person, obtained rewards

Actelion Pharmaceuticals Japan Co., Ltd., Astellas Pharma Inc., AnGes MG Inc., Eisai Co., Ltd., MSD Co., Ltd., Otsuka Pharmaceutical Co., Ltd., Omron Healthcare Co., Ltd., Kyowa Hakko Kirin Co., Ltd, Glaxo Smith Kline K.K., Sanofi K.K., Sunstar Inc., Shionogi & CO., Ltd., 3-D Matrix Inc., Daiichi Sankyo Company, Limited, Dainippon Sumitomo Pharma Co., Ltd., Takeda Pharmaceutical Company Limited, Mitsubishi Tanabe Pharma Corporation, Central Miso Research Institute, Chugai Pharmaceutical Co., Ltd., Teijin Pharma Limited, Torii Pharmaceutical Co., Ltd., Nippon Shinyaku Co., Ltd., Boehringer Ingelheim, Novartis Pharma K.K., Bayer Pharmaceutical Co., Ltd., Pfizer Japan Inc., Mochida Pharmaceutical Co., Ltd.

2) Companies/corporations responsible for cooperative industrial-academic activities with departments to which the members belong

Actelion Pharmaceuticals Japan Co., Ltd., Asahi Kasei Medical Co., Ltd., Astellas Pharma Inc., AstraZeneca K.K., AnGes MG Inc., A&D Company, Limited, Eisai Co., Ltd., MSD Co., Ltd., Entatsu Corporation Co., Ltd., Otsuka Pharmaceutical Co., Ltd., Ohno Co., Ltd., Omron Healthcare Co., Ltd., Kyowa Hakko Kirin Co., Ltd., Glaxo Smith Kline K.K., Kowa Pharmaceutical Company Ltd., Sanofi K.K., Sunstar Inc., Sanwa Kagaku Kenkyusho Co., Ltd., Shionogi & Co., Ltd., JMS Co., Ltd., Secom Co., Ltd., Daiichi Sankyo Company, Limited, Dainippon Sumitomo Pharma Co., Ltd., Takeda Pharmaceutical Company Limited, Mitsubishi Tanabe Pharma Corporation, Chugai Pharmaceutical Co., Ltd., Teijin Limited, Teijin Pharma Limited, Terumo Corporation, Toray Medical Co., Ltd., Eli Lilly Japan K.K., Nihon Kojin Kenkyukai, Servier Inc., Boehringer Ingelheim, Nihon Medi-Physics Co., Ltd., Medtronic Inc., Novartis Pharma K.K., Novo Nordisk Pharma Ltd., Baxter Limited, Pfizer Japan Inc., Philips Respironics, Boston Scientific Corporation, Mushroomsoft Co., Ltd., Mochida Pharmaceutical Co., Ltd., Roche Diagnostics Japan.

Citation Information

We recommend that any citations to information in the Guidelines are presented in the following format:

The Japanese Society of Hypertension Guidelines for the Management of Hypertension (JSH 2014). *Hypertens Res* 2014; **37**: 253–392.

Please refer to the title page for the full list of authors.