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Background: Tokyo Guidelines for the management of acute cholangitis and cholecystitis

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Abstract
There are no evidence-based-criteria for the diagnosis, severity assessment, of treatment of acute cholecysitis or acute cholangitis. For example, the full complement of symptoms and signs described as Charcot's triad and as Reynolds' pentad are infrequent and as such do not really assist the clinician with planning management strategies. In view of these factors, we launched a project to prepare evidence-based guidelines for the management of acute cholangitis and cholecystitis that will be useful in the clinical setting. This research has been funded by the Japanese Ministry of Health, Labour, and Welfare, in cooperation with the Japanese Society for Abdominal Emergency Medicine, the Japan Biliary Association, and the Japanese Society of Hepato-Biliary-Pancreatic Surgery. A working group, consisting of 46 experts in gastroenterology, surgery, internal medicine, emergency medicine, intensive care, and clinical epidemiology, analyzed and examined the literature on patients with cholangitis and cholecystitis in order to produce evidence-based guidelines. During the investigations we found that there was a lack of high-level evidence, for treatments, and the working group formulated the guidelines by obtaining consensus, based on evidence categorized by level, according to the Oxford Centre for Evidence-Based Medicine Levels of Evidence of May 2001 (version 1). This work required more than 20 meetings to obtain a consensus on each item from the working group. Then four forums were held to permit examination of the Guideline details in Japan, both by an external assessment committee and by the working group participants (version 2). As we knew that the diagnosis and management of acute biliary infection may differ from country to country, we appointed a publication committee and held 12 meetings to prepare draft Guidelines in English (version 3). We then had several discussions on these draft guidelines with leading experts in the field throughout the world, via e-mail, leading to version 4. Finally, an International Consensus Meeting took place in Tokyo, on 1–2 April, 2006, to obtain international agreement on diagnostic criteria, severity assessment, and management.

Key words Cholangitis · Cholecystitis · Charcot's triad · Reynold's pentad · Biliary drainage

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Introduction

No guidelines focusing on the management of biliary infection (cholangitis and cholecystitis) have previously been published, and no worldwide criteria exist for diagnostic and severity assessment. "Charcot's triad"[1] is still used for the diagnosis of acute cholangitis. How-

ever, these criteria were first proposed in 1877 (level 4), more than 100 years ago. Here, and throughout the series, levels of evidence are stated for referenced articles in accordance with the Oxford Centre for Evidence-Based Medicine Levels of Evidence of May 2001 (see Table 1). However only 50%–70% of cholangitis patients present clinically with Charcot's triad.[2–8] In addition, Murphy's sign[9] (level 5) is useful (sensitivity of 50%–70% and specificity of 79%–96%) in diagnosing cholecystitis, and this sign is widely used in every country. Moreover, as many of the symptoms and concepts of these diseases referred to in textbooks and reference books vary from those originally stated, the issue of worldwide criteria is problematic. In view of these unfavorable situations, we considered it necessary to clarify the definitions, concepts of disease, and treatment methods for acute cholangitis and acute cholecystitis and establish universal criteria that can be widely recognized and used.

A working group to establish practical Guidelines for the Management of Cholangitis and Cholecystitis was organized in 2003 (chief researcher, Tadahiro Takada). This project was funded by a grant from the Japanese Ministry of Health, Labour, and Welfare, and was supported by the Japanese Society for Abdominal Emergency Medicine, the Japan Biliary Association, and the Japanese Society of Hepato-Biliary-Pancreatic Surgery. The working group consisted of physicians engaged in gastroenterology, internal medicine, surgery, emergency medicine, intensive care, and clinical epidemiology as the main members, and they started the work to prepare the Guidelines.

As the research progressed, the group was faced with the serious problem that high-level evidence regarding the treatment of acute biliary infection is poor. Therefore, an exective committee meeting was convened, and the committee came to the following decision: the Guidelines would be evidence-based in general, but areas without evidence or with poor evidence (such as diagnosis and severity assessment) should be completed by obtaining high-level consensus among experts worldwide.

We established a publication committee and held 12 meetings to prepare draft Guidelines in English (version 3). Then we had several discussions on these draft Guidelines with leading experts in the field throughout the world, via e-mail, leading to version 4. Finally, an International Consensus Meeting took place in Tokyo, on 1–2 April, 2006, to obtain international agreement on diagnostic criteria, severity assessment, and management.

We now publish the "Tokyo Guidelines for the Management of Cholangitis and cholecystitis". These Guidelines consist of 13 articles, including "Discussion" sections containing comments of attendees at the consensus conference and analyses of audience voting at the meeting.

We hope that these Guidelines will help their users to give optimal treatment according to their own specialty and capability, and thus provide their patients with the best medical treatment.

Background of Tokyo Guidelines

Biliary infections (acute cholangitis and cholecystitis) require appropriate management in the acute phase. Serious acute cholangitis may be lethal unless it is appropriately managed in the acute phase. On the other hand, although various diagnostic and treatment methodologies have been developed in recent years, they have not been assessed objectively and none of them has been established as a standard method for the management of these diseases. We carried out an extensive review of the English-language literature and found that there was little high-level evidence in this field, and no systematically described practical manual for the field. Most importantly, there are no standardized diagnostic criteria and severity assessments for acute cholangitis and cholecystitis, therefore, we would like to establish standards for these items. The Tokyo Guidelines include evidence-based medicine and reflect the international consensus obtained through earnest discussions among professionals in the field on 1–2 April, 2006, at the Keio Plaza Hotel, Tokyo, Japan. Concerning the definitions in the practice guidelines, we have applied to the Japanese Institute of Medicine: Committee to Advise the Public Health Service on Clinical Practice Guidelines, to approve the systematically developed Guidelines to assist practioner and patient decisions about appropriate healthcare for specific clinical circumstances.

Notes on the use of the Guidelines

The Guidelines are evidence-based, with the grade of recommendation also based on the evidence. The Guidelines also present the diagnostic criteria for and severity assessment of acute biliary infection. As the Guidelines address so many different subjects, indices are included at the end for the convenience of readers.

The practice Guidelines promulgated in this work do not represent a standard of practice. They are suggested plans of care, based on best available evidence and the consensus of experts, but they do not exclude other approaches as being within the standard of practice. For example, they should not be used to compel adherence to a given method of medical management, which meth-

od should be finally determined after taking account of the conditions at the relevant medical institution (staff levels, experience, equipment, etc.) and the characteristics of the individual patient. However, responsibility for the results of treatment rests with those who are directly engaged therein, and not with the consensus group. The doses of medicines described in the text of the Guidelines are for adult patients.

Methods of formulating the guidelines

With evidence-based medicine (EBM) as a core concept, the Guidelines were prepared by the Research Group on the Preparation and Diffusion of Guidelines for the Management of Acute Cholangitis and Acute Cholecystitis (chief researcher, Tadahiro Takada), under the auspices of the Japanese Ministry of Health, Labour, and Welfare, and the Working Group for Guideline Preparation, whose members were selected from experts in abdominal emergency medicine and epidemiology by the Japanese Society for Abdominal Emergency Medicine, the Japan Biliary Association, and the Japanese Society of Hepato-Biliary-Pancreatic Surgery.

In principle, the preparation of the Guidelines progressed with the systematic search, collection, and assessment of references for the objective extraction of evidence. Next, the External Assessment Committee examined the Guidelines. Then we posted the draft guidelines on our website and had four open symposia, bginning in September 2004, to gain feedback for further review. Subsequently, a Publication Committee was set up, and this committee had 12 meetings to prepare draft Guidelines.

Re-examination of the draft Guidelines was then performed, via e-mail, with experts on cholangitis and cholecystitis throughout the world. After final agreement was reached at the International Consensus Meeting, held in Tokyo in April 2006, "the Tokyo Guidelines for the Management of Acute Cholangitis and Cholecystitis" were completed.

The process of extending the literature search

The literature was selected as follows: Using "cholangitis" and "cholecystitis" as the medical subject heading (MeSH; explode) or the key search words, approximately 17200 items were selected from Medline (Ovid; 1966 to June 2003). These articles were subjected to a further screening with "human" as the "limiting word". This screening provided 9618 items in English and in Japanese. A further 7093 literature publications were obtained from the Japana Centra Revuo Medicina (internet version), using "cholangitis", "cholecystitis", and "biliary infection" as the key words, with further screening with "human" as the "limiting word". This process provided 6141 items. After the titles and abstracts of a total of 15759 works were examined by two committee members, 2494 were selected for a careful examination of their full texts.

Other literature quoted in these selected works, together with works suggested by the specialist committee members, were included in the examination.

To evaluate each article, a STARD (standards for reporting of diagnostic accuracy) checklist (Table 1)[12] was considered important. The purpose of this checklist is to evaluate the format and study process, in order to improve the accuracy and completeness of the reporting of studies of diagnostic accuracy.

However, the STARD checklist is not suitable for classifying various categories (e.g., therapy, prevention, etiology, harm, prognosis, diagnosis, differential diagnosis, economic and decision analysis) and levels of evidence. Therefore, in the Guidelines, the science-based classification used by the Cochrane Library (Table 2) was adopted.

The evidence obtained from each item of reference was evaluated in accordance with the science-based classification used by the Cochrane Library (Table 2), and the quality of evidence for each parameter associated with the diagnosis and treatment of acute biliary infection was determined. As stated above, the level of evidence presented by each article was determined in accordance with the Oxford Centre for Evidence-Based Medicine Levels of Evidence (May 2001), prepared by Phillips et al.[13] (Table 2). The terms used in the categories are explained in the footnote to Table 2.

Categories of evidence and grading of recommendations

Based on the results obtained from these procedures, grades of recommendation were determined, according to the system for ranking recommendations in clinical guidelines[14–16] shown in Table 3, and mentioned, as required, in the text of the Guidelines. The grades of recommendation in the Guidelines are based on the Kish[14] method of classification and others.[15,16] Recommendations graded "A" (that is, "do it") and "B" (that is, "probably do it"), are based on a high level of evidence, whereas those graded "D" (that is, "probably don't do it") or "E" (that is, "don't do it") reflect a low level of evidence.

Acknowledgments. We would like to express our deep gratitude to the Japanese Society for Abdominal Emergency Medicine, the Japan Biliary Association, and the Japanese Society of Hepato-Biliary-Pancreatic Surgery, who provided us with great support and guidance in the preparation of the Guidelines. This process was conducted as part of the project for the Preparation and

Table 1. STARD checklist for the reporting of studies of diagnostic accuracy

Section and topic	Item no.		On page no.
Title/Abstract/ Key words	1	Identify the article as a study of diagnostic accuracy (recommend MeSH heading "sensitivity and specificity")	
Introduction	2	State the research questions or study aims, such as estimating diagnostic accuracy or comparing accuracy between tests or across participant groups	
Methods		Describe	
Participants	3	The study population: the inclusion and exclusion criteria, setting and locations where the data were collected	
	4	Participant recruitment: was recruitment based on presenting symptoms, results from previous tests, or the fact that the participants had received the index tests or the reference standard?	
	5	Participant sampling: was the study population a consecutive series of participants defined by the selection criteria in items 3 and 4? If not, specify how participants were further selected	
	6	Data collection: was data collection planned before the index test and reference standard were performed (prospective study) or after (retrospective study)?	
Test methods	7	The reference standard and its rationale	
	8	Technical specifications of material and methods involved, including how and when measurements were taken, and/or cite references for index tests and reference standard	
	9	Definition of and rationale for the units, cutoffs, and/or categories of the results of the index tests and the reference standard	
	10	The number, training, and expertise of the persons executing and reading the index tests and the reference standard	
	11	Whether or not the readers of the index tests and reference standard were blind (masked) to the results of the other test, and describe any other clinical information available to the readers	
Statistical methods	12	Methods for calculating or comparing measures of diagnostic accuracy, and the statistical methods used to quantify uncertainty (e.g., 95% confidence intervals)	
	13	Methods for calculating test reproducibility, if done	
Results		Report	
Participants	14	When study was done, including beginning and ending dates of recruitment	
	15	Clinical and demographic characteristics of the study population (e.g., age, sex spectrum of presenting symptoms, comorbidity, current treatments, recruitment centers)	
	16	The number of participants satisfying the criteria for inclusion that did or did not undergo the index tests and/or the reference standard; describe why participants failed to receive either test (a flow diagram is strongly recommended)	
Test results	17	Time interval from the index tests to the reference standard, and any treatment administered between	
	18	Distribution of severity of disease (define criteria) in those with the target condition; other diagnoses in participants without the target condition	
	19	A cross-tabulation of the results of the index tests (including indeterminate and missing results) by the results of the reference standard; for continuous results, the distribution of the test results by the results of the reference standard	
	20	Any adverse events from performing the index tests or the reference standard	
Estimates	21	Estimates of diagnostic accuracy and measures of statistical uncertainty (e.g., 95% confidence intervals)	
	22	How indeterminate results, missing responses, and outliers of the index tests were handled	
	23	Estimates of variability of diagnostic accuracy between subgroups of participants, readers, or centers, if done	
	24	Estimates of test reproducibility, if done	
Discussion	25	Discuss the clinical applicability of the study findings	

Adapted from reference 12
MeSH, medical subject heading; STARD, standards for reporting of diagnostic accuracy

Table 2. Categories of evidence (refer to levels of evidence and grades of recommendations on the homepage of the Centre for Evidence-Based Medicine)

The science-based classification used by the Cochrane Library: Oxford Centre for Evidence-based Medicine Levels of Evidence (May 2001) (http://www.cebm.net/levels_of_evidence.asp#levels)[13] was used as a basis to evaluate evidence presented in each article; the quality of evidence for each parameter associated with the diagnosis and treatment of acute cholangitis and acute cholecystitis was determined

Level	Therapy/prevention, aetiology/harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity[a]) of RCTs	SR (with homogeneity[a]) of inception cohort studies; CDR[b] validated in different populations	SR (with homogeneity[a]) of level 1 diagnostic studies; CDR[b] with 1b studies from different clinical centers	SR (with homogeneity[a]) of prospective cohort studies	SR (with homogeneity[a]) of level 1 economic studies
1b	Individual RCT (with narrow confidence interval[c])	Individual inception cohort study with >80% follow-up; CDR[b] validated in a single population	Validating[d] cohort study with good[e] reference standards; or CDR[b] tested within one clinical center	Prospective cohort study with good follow-up[f]	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none[g]	All or none case-series	Absolute SpPins and SnNouts[h]	All or none case-series	Absolute better-value or worse-value analyses[i]
2a	SR (with homogeneity[a]) of cohort studies	SR (with homogeneity[a]) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity[a]) of level >2 diagnostic studies	SR (with homogeneity[a]) of 2b and better studies	SR (with homogeneity[a]) of level >2 economic studies
2b	Individual cohort study (including low-quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR[b] or validated on split-sample[j] only	Exploratory[d] cohort study with good[e] reference standards; CDR[b] after derivation, or validated only on split-sample[j] or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	"Outcomes" research; ecological studies	"Outcomes" research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity[a]) of case-control studies		SR (with homogeneity[a]) of 3b and better studies	SR (with homogeneity[a]) of 3b and better studies	SR (with homogeneity[a]) of 3b and better studies
3b	Individual case-control study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor-quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations

Table 2. *Continued*

Level	Therapy/prevention, aetiology/harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
4	Case-series (and poor-quality cohort and case-control studies[k])	Case-series (and poor-quality prognostic cohort studies[l])	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opi\nion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research, or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Users can add a minus-sign "–" to denote the level that fails to provide a conclusive answer because of: EITHER a single result with a wide confidence interval (such that, for example, an ARR in an RCT is not statistically significant but whose confidence intervals fail to exclude clinically important benefit or harm) (Note #1), OR a systematic review with troublesome (and statistically significant) heterogeneity (Note #2). Such evidence is inconclusive, and therefore can only generate grade D recommendations (Note #3)
SR, Systematic review; RCT, Randomized controlled trial; ARR, absolute risk reduction
[a] By homogeneity, we mean a systematic review that is free of worrisome variations (heterogeneity) in the directions and degrees of results between individual studies. Not all systematic reviews with statistically significant heterogeneity need be worrisome, and not all worrisome heterogeneity need be statistically significant. As noted above, studies displaying worrisome heterogeneity should be tagged with a "–" at the end of their designated level
[b] Clinical decision rule. These are algorithms or scoring systems which lead to a prognostic estimation or a diagnostic category
[c] See note #2 for advice on how to understand, rate, and use trials or other studies with wide confidence intervals
[d] Validating studies test the quality of a specific diagnostic test, based on prior evidence. An exploratory study collects information and trawls the data (e.g., using a regression analysis) to find which factors are "significant"
[e] Good reference standards are independent of the test, and are applied blindly or objectively to all patients. Poor reference standards are haphazardly applied, but still independent of the test. Use of a nonindependent reference standard (where the "test" is included in the "reference", or where the "testing" affects the "reference") implies a level 4 study
[f] Good follow-up in a differential diagnosis study is >80%, with adequate time for alternative diagnoses to emerge (e.g., 1–6 months, acute; 1–5, years, chronic)
[g] Met when all patients died before the Rx became available, but some now survive on it; or when some patients died before the Rx became available, but none now die on it
[h] An "absolute SpPin" is a diagnostic finding whose specificity is so high that a positive result rules-in the diagnosis. An "absolute SnNout" is a diagnostic finding whose sensitivity is so high that a negative result rules-out the diagnosis
[i] Better-value treatments are clearly as good but cheaper, or better at the same or reduced cost. Worse-value treatments are as good and more expensive, or worse and equally or more expensive
[j] Split-sample validation is achieved by collecting all the information in a single tranche, then artificially dividing this into "derivation" and "validation" samples
[k] By poor-quality cohort study, we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both exposed and nonexposed individuals, and/or failed to identify or appropriately control known confounders, and/or failed to carry out a sufficiently long and complete follow-up of patients. By poor-quality case-control study, we mean one that failed to clearly define comparison groups and/or failed to measure exposures and outcomes in the same (preferably blinded), objective way in both cases and controls and/or failed to identify or appropriately control known confounders
[l] By poor-quality prognostic cohort study, we mean one in which sampling was biased in favor of patients who already had the target outcome, or the measurement of outcomes was accomplished in <80% of study patients, or outcomes were determined in an unblinded, nonobjective way, or there was no correction for confounding factors
Good, better, bad, and worse refer to the comparisons between treatments in terms of their clinical risks and benefits

Table 3. Grading system for ranking recommendations in clinical guidelines[14–16]

Grade of recommendation	
A	Good evidence to support a recommendation for use
B	Moderate evidence to support a recommendation for use
C	Poor evidence to support a recommendation, or the effect may not exceed the adverse effects and/or inconvenience (toxicity, interaction between drugs and cost)
D	Moderate evidence to support a recommendation against use
E	Good evidence to support a recommendation against use

Diffusion of Guidelines for the Management of Acute Cholangitis (H-15-Medicine-30), with a research subsidy for fiscal 2003 and 2004 (Integrated Research Project for Assessing Medical Technology) sponsored by the Japanese Ministry of Health, Labour, and Welfare.

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Discussion at the Tokyo International Consensus Meeting

Tadahiro Takada (Japan): "Dr. Strasberg, please explain the difference between a 'Guidelines' and 'Standards' in your mind?"

Steven Strasberg (USA): "To me, 'guidelines' represent a suggested course of action based on available evidence. They do not imply that other courses of action are below an acceptable level of care. Practice 'standards' are different, in that they imply that actions other than those listed as acceptable practice standards are below the level of acceptable care. It is particularly true that, in an area in which high levels of evidence are not available, that guidelines are not construed to be standards. Reliance on expert opinion to form guidelines may be useful, but even a consensus of experts may not be correct. For this reason a statement of the following type should be inserted in the introduction. 'The practice guidelines promulgated in this work do not represent a standard of practice. They are a suggested plan of care based on best available evidence and a consensus of experts, but they do not exclude other approaches as being within the standard of practice'."

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