The “Guidelines for Obstetrical Practice in Japan” are the first consensus-based guidelines in the field of obstetrics and were published in 2008 owing to an obstetric medical care crisis in Japan. The Guidelines describe appropriate methods for obstetric care and were based on consensus among obstetricians in Japan. Originally, the Guidelines were not intended to be a rulebook to limit physician discretion; however, from a medical care litigation standpoint, medical practices that conform to the Guidelines are following the “medical standard”. The present study aimed to investigate obstetricians’ perceptions of the Guidelines, to assess the degree of compliance, and to consider the implication of physician discretion in medical litigation. A questionnaire exploring the perception of the Guidelines was completed by 341 obstetricians was conducted from February 2009 until May 2009; questionnaires were evaluated using simple aggregation, correlation analysis, and principal component analysis. Although more than 80% of physicians responded that content of the Guidelines was appropriate, only 34.7% complied with recommendation level A. Our findings suggest that the rate of compliance to the Guidelines should be improved, reasons for noncompliance should be clarified, and Guidelines that are easier for patients to understand should be drafted.

Key Words: Guidelines for Obstetrical Practice in Japan, practice guideline, consensus, physician discretion.

Introduction

The “Guidelines for Obstetrical Practice in Japan” (hereafter referred to simply as the Guidelines) are the first guidelines in the field of obstetrics. The Guidelines were published in 2008 owing to an obstetrics medical care crisis in Japan that resulted from reduced numbers of obstetricians due to a challenging working environment with heightened risk of litigation. ‘Medical practice guidelines’ are defined as ‘a text drafted with the aim of assisting medical professionals and patients in making the appropriate decisions, on the basis of specific clinical circumstances’1. The Guidelines are characterized by defining appropriate methods of obstetric medical care and are based on consensus among obstetricians in a field where it can be difficult to obtain ample decision-making evidence. The primary objectives of the Guidelines focus on the performance of appropriate diagnoses and treatments for which consensus has been obtained in order to [1] ensure appropriate medical care in all obstetric facilities, [2] improve obstetric safety, [3] reduce human and economic burdens, and [4] encourage mutual understanding between medical professionals and patients2. Complying with these consensus-based Guidelines is expected to reduce the high risk of litigation borne by obstetricians. On the other hand, when guideline adherence is enforced as if the Guidelines were a regulatory rulebook,
physicians’ rights of self-determination are limited. Many obstetricians were thus at a loss concerning how to use the Guidelines when they were first developed. From the patient’s perspective, it is difficult to understand a physician’s conflict whether or not compliance with medical care guidelines should be mandatory. However, there has not yet been a full discussion regarding the binding force of clinical practice guidelines or of the relationship between the Guidelines and a physician’s discretion. There is a need to discuss the problem in society as a whole. Accordingly, the aim of the present study was to investigate obstetricians’ perceptions of the Guidelines, to assess the degree of compliance, and to consider the implication of physician discretion in medical litigation.

Materials and Methods

1) Subjects
In the present study, we conducted a questionnaire-based survey to explore obstetrician perceptions of the Guidelines. The 17-question survey was conducted anonymously from February 2009 to May 2009 that passed for ten months after publication. A total of 341 obstetricians from 11 Japanese prefectures participated voluntarily in the survey, which was delivered either personally or by mail.

2) Content of the questionnaire
The 17 questionnaire items are shown in Table 1. Questions 1 to 4 asked about the profile of the obstetricians responding to the questionnaire. Questions 5, 6, and 8 asked about how the Guidelines are used (Table 2), and question 10 investigated the reasons for not implementing changes in the practice based on the Guidelines. Questions 11 to 14 addressed how the Guidelines are assessed (Table 3), and questions 15 to 17 asked about the relationship between the Guidelines and litigation (Table 4).

3) Statistical analysis
Statistical analyses were performed using SPSS16.0 for Windows (SPSS Japan Inc., Tokyo, Japan) and Excel-Statistics 2015 V1.02 (SSRI Co., Ltd. Software Group, Tokyo, Japan). The collected questionnaire results were first simply aggregated, after which Spearman’s rank correlation analysis was used to analyze whether there were statistically significant relationships between each of the questions for the 121 physicians who answered all of the questions. Principal component (PC) analysis was then carried out with the aim of classifying obstetricians on the basis of their use of the Guidelines. The variables for this PC analysis were the 142 respondents who provided valid responses to questions 5, 6, and 8 regarding their use of the Guidelines. Kruskal-Wallis and Steel-Dwass tests were used to examine the differences in each group’s responses to the questionnaire. The level of significance was set at p < 0.05 in a 2-tailed test. Results at 0.05 < p < 0.1 were also included, according to the analysis.

4) Ethical considerations
Potential participants received information explaining the study objectives, including that participation was voluntary and nonparticipation would in no way engender any disadvantage. Responses were assumed to be returned with consent. The aggregated responses to the survey were processed anonymously, without identification of the respondents. Although the present study involved humans, it began before the “Ethical Guidelines for Clinical Studies” (1 April 2009) were published and thus was not subject to the ethical considerations of the guidelines. There were no conflicts of interest between the participants of the present study and the surveyed medical institutions or the Japan Society of Obstetrics and Gynecology, which developed the guidelines.

Results

1) Simple aggregation
Valid responses to the questionnaire were received from 150 of 341 individuals, a response rate of 44%. Table 1 shows questions on the present questionnaire survey. The years of experience of the 150 obstetricians who responded to this survey were distributed from under 5 years to more than 20 years. About 73% of the physicians who responded worked in a medical institution that performs deliveries. Physicians working in medical institutions with 500 or more deliveries annually accounted for 66% of respondents.

Table 2, 3, and 4 show the results of simple aggregation. Regarding question 5, nearly 90% of all physicians had seen the Guidelines, and 48% of all respondents answered that they had carefully read items of interest. Regarding question 6, 66% of the physicians who responded worked in a medical institution that performs deliveries. Physicians working in medical institutions with 500 or more deliveries annually accounted for 66% of respondents.
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all recommended levels (A to C). 34.7% of physicians responded that they complied only with A, and 28% responded that they complied with up to levels A and B (Table 2).

Question 9 asked about the introduction of thromboprophylaxis (recommendation level B), and 20.7% physicians responded that they do not implement this.

Regarding question 11, more than 80% of physicians answered that they considered the contents of the Guidelines to be appropriate and standard. Question 12 asked, using a 5-step scale, whether the Guidelines have useful content for patients. Answers were divided.
with 30% of physicians answering that the Guidelines are only partially useful for patients.

Regarding question 13, 56.7% of physicians answered that the physician’s right of discretion is limited by the Guidelines, and regarding question 14, 87.3% of physicians answered that the Guidelines contribute to standardizing obstetric medical care (Table 3).

Regarding question 15, 76.7% of physicians answered that having the Guidelines would not lead to a decrease in medical litigation, and more than 80% of physicians responded to question 16 by saying that the Guidelines would be frequently used in judicial processes. Regarding question 17, more than 60% of physicians had positive thoughts toward the concept that the Guidelines would be used for judicial decisions (Table 4).

2) Correlation analysis

Table 5 shows the results of Spearman’s rank correlation analysis. The answers to question 6 and 11 were positively correlated with the answer to question 5 (r = 0.267, p < 0.01; r = 0.240, p < 0.01; shown in red in Table 5). This reveals a positive correlation between the extent to which the Guidelines are carefully read and the extent to which changes in the practice are made based on the Guidelines, as well as the tendency to believe that the content of the Guidelines is appropriate. A weak negative correlation was observed between the answer to question 13 and the answers to questions 15 and 17 (r = -0.196, p < 0.05; r = -0.191, p < 0.05; shown in blue in Table 5). This shows that physicians who believe that the Guidelines limit physician discretion in medical care also tend to believe that compliance to the Guidelines will not lead to a reduction in medical litigation and have negative thoughts regarding judicial use of the Guidelines. There was no significant correlation between question 8, which asked to what extent physicians complied with the recommended levels, and question 1 (years of experience) or question.

### Table 5: Results of Spearman’s rank correlation analysis

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<tr>
<th>Q1</th>
<th>Q2</th>
<th>Q3</th>
<th>Q5</th>
<th>Q6</th>
<th>Q7</th>
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<th>Q12</th>
<th>Q13</th>
<th>Q14</th>
<th>Q15</th>
<th>Q16</th>
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<td>.035</td>
<td>-0.006</td>
<td>.041</td>
<td>.209*</td>
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<td>-0.095</td>
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<td>.101</td>
<td>.084</td>
<td>.025</td>
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<td>.944</td>
<td>.658</td>
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<td>.442</td>
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</table>

Spearman’s rank correlation analysis was used to analyze whether there were statistically significant relationships between each of the questions for the 121 physicians who answered all of the questions. The red and blue parts are described in the text.

upper: correlation’s coefficient  lower: p value  n=121  * p value< 0.01%(bilateral)  ** < 0.05%(bilateral)
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3 (number of deliveries). There was also no significant correlation between question 9, which asked about the introduction of thromboprophylaxis, and question 1 or question 3. This demonstrated that differences in the rate of compliance to the Guidelines are caused by factors other than the years of experience or number of deliveries.

3) Principal component analysis

Figure 1 shows the results of PC loadings, PC scores, and the scatter diagram. The results of the PC analysis, which focused on utilization of the Guidelines, enabled division of participating obstetricians into four groups according to two new scales (Figure 1). According to PC loadings, the first PC was delineated “degree of obstetric guideline utilization”, and the second PC was delineated “degree of compliance with recommended levels”. Cluster analysis made it possible to divide the obstetricians into four groups. The first group had 63 members with a low “degree of obstetric guideline utilization” but proactive “compliance with recommended levels”. The second group had 51 members with a high “degree of obstetric guideline utilization” as well as proactive “compliance with recommended levels”. The third group had 11 members with a high “degree of obstetric guideline utilization” but low “compliance with recommended levels”, and the fourth group had 17 members with a low “degree of obstetric guideline utilization” as well as low “compliance with recommended levels”.

Responses to question 11 through question 17 from the physicians of these four groups were analyzed using the Kruskal-Wallis test and Steel-Dwass test. The Kruskal-Wallis test showed that question 12 was significantly different (P < 0.1; Table 6), and the Steel-Dwass test...
showed that there was a significant difference between the first and second groups (Table 7).

4) Reasons for not implementing changes in the practice based on the Guidelines

In response to question 6, the 49 physicians (32.7%) who answered that they had made no modifications in their practice after the Guidelines were published were asked in question 10 about their reasons for not consulting the Guidelines. The response "Because the content of the Guidelines is identical to the way we practice", was selected by 28 physicians, while "Because there is nothing wrong with how things have been done so far" was selected by four physicians. “Because I have not read it yet” was selected by four physicians, "Because I do not handle delivery" was selected by 10 physicians, and no answer was selected by three physicians.

Discussion

In this survey, more than 80% of physicians found the content of the Guidelines appropriate, but the number of physicians who answered that they actually implemented the recommended levels A and B was 62.7% (Table 2). While many physicians regarded the content of the Guidelines as appropriate, nevertheless they did not comply with the Guidelines completely.

In the present study, we found that thromboprophylaxis, a level B recommendation, was not being implemented by 20.7% of physicians. A study conducted in Tochigi Prefecture also found multiple items where the implementation rate was about 10% to 50%4. In a 2013 study conducted by Nagata and other members of the Japan Society of Obstetrics and Gynecology’s Perinatal Committee, it was reported that the implementation rate of recommended levels A and B was 75.7 ± 15.7%5. The reasons for the differences in the rates of implementation of the Guidelines seem to vary. In the report by Nagata et al., factors affecting the implementation rate included the number of years of experience, whether or not the physician was a perinatal specialist, the type of facility, the number of obstetricians at the facility, and the number of deliveries per year. It was also observed that clinics with few physicians and few beds and physicians with more years of experience tended to have lower implementation rates5. The correlation analysis in the present study, however, did not reveal a significant correlation between the extent to which physicians complied with the recommended levels (question 8) and the years of experience or number of
deliveries in the institution at which they were employed. Similarly, there was no significant correlation between the introduction of thromboprophylaxis (question 9) and the years of experience or number of deliveries (Table 5). This result suggests that one reason for the difference in rates of compliance to the Guidelines may be that obstetricians have a variety of opinions regarding the Guidelines, irrespective of their years of experience and number of deliveries.

In the present study, PC analysis and cluster analysis were used in an attempt to categorize the obstetricians with respect to their individual utilization of the Guidelines. Two new scales, "degree of obstetric guideline utilization" and "compliance with recommended levels", were used to successfully classify the participating obstetricians into four groups (Figure 1).

The characteristics of the physicians in these four groups were also investigated. The findings showed that there was a difference between the first group and second groups in their beliefs regarding the value of the Guidelines for patients (Tables 6, 7). The results suggest that physicians’ viewpoints whether the Guidelines are useful for patients may be important for future investigations concerning compliance to the Guidelines. It is true that the content of the Guidelines was not intended for patients. However, clinical practice guidelines that incorporate patient perspective reportedly enhance informed consent, improve the quality of medical care and safety, and even increase patient satisfaction6. Therefore, drafting obstetric practice guidelines that are easier for the patient to understand should be a future task to help deepen the mutual understanding between medical professionals and patients.

The first reason why so many obstetricians have been confused about the extent to which they were obliged to comply with the Guidelines is that, unlike previous sets of guidelines, the Guidelines emphasize the idea of consensus. According to Eddy, a guideline is distinct from a standard or option7. Namely, the author states that a standard applies to at least 95% of cases, and deviating from a standard would be inappropriate, whereas a guideline applies to 60% to 95% of cases, but whether it is applied is adjusted based on individual circumstances. Moreover, an option is only indicated in about 50% of cases and is open to interpretation. The implementation rate of clinical practice guidelines has generally been reported to be between 50–60%8. One of the causes of confusion among the physicians regarding compliance to the Guidelines may have been that it is unclear whether the conventional definition of guidelines that prioritize evidence-based medicine should be applied to the Guidelines, which are based on consensus among obstetricians. The foreword to the 2014 revised Guidelines states that the content of the Guidelines is the best currently available9. Such consensus-based Guidelines may be considered to demand a high level of compliance, unlike conventional evidence-based guidelines. It will thus be necessary to improve the rate of compliance with the Guidelines in the future.

The second reason why obstetricians may have felt confused regarding compliances to the Guidelines is their sense of unease regarding treatment of the Guidelines in medical malpractice suits. In table 4, question 17 showed that more than 60% of physicians agreed the use of the Guidelines in the judicial process. The results suggest that the Guidelines cannot be a factor of excessively defensive medicine.

The Guidelines were not originally intended to limit a physician’s discretion. Rather, the Guidelines were developed to aid in the decision-making process and not to function as a regulatory rulebook of medical practice and decision-making in the field. When a medical treatment is not strictly consistent with recommendations of the Guidelines, there is little possibility that problems will arise provided that there is agreement between the health-care provider and the patient10; however, if a given treatment that differs from that recommended in the Guidelines reaches litigation, it is possible that the recommendations in the Guidelines would be considered to prevail over a physician’s discretion11. In medical litigation, the term “medical standards” is used to define the standards by which physicians and medical institutions determine their legal duty concerning the diagnosis and treatment for each individual patient for which they are responsible12; however, clinical practice guidelines could potentially affect the legal interpretation of medical standards in medical malpractice lawsuits. In fact, drug package inserts and guidelines have come to be frequently used in litigation13. Hurwits argues against making clinical practice guidelines an absolute legal standard14, but there are many medical professionals who are concerned that the content of clinical practice guidelines could potentially impact trends in trials and litigation. There have already been judicial decisions declaring “even if clinical practice guidelines have not been followed, it is impossible to assess immediately that it falls under tort or defaults on a medical contract; however, medical procedures need to be carried out on the basis of the content of guidelines, and physicians have a duty to do so”15. Interventions performed in accordance with guidelines have a high likelihood of
being acknowledged as meeting the defined medical standard, and they might play a role where guidelines indicate the medical validity of civil litigation. Clinical practice not per the guidelines is, of course, also acceptable if the physician has a valid reason for not adapting the guidelines for an individual patient, but the patient’s situation would need to be explained clearly from a medical perspective.

Ideally, the Guidelines should not be treated as a regulatory rulebook, because this limits physicians’ rights of self-determination when adherence to the Guidelines is enforced in this manner. However, the Guidelines are based on consensus and may be more likely than other guidelines to be recognized as the legal medical standard. Therefore, the goal compliance rate of the Guidelines should be higher than that of other evidence-based guidelines.

A limitation of our study was that the investigation was conducted only once when the first edition of the Guidelines was published. The continuity of research on physicians’ perceptions of the Guidelines is necessary after the revised version is published.

In conclusion, this study suggests that many obstetricians regarded the contents of the Guidelines as appropriate, but that the implementation rates were low. The consensus-based guidelines demand a high level of compliance, and the rate of compliance with the Guidelines should be improved. The reasons for noncompliance should be clarified from the viewpoint of medical litigation, and Guidelines that are easier for patients to understand should be drafted.

References